

(19) World Intellectual Property Organization
International Bureau



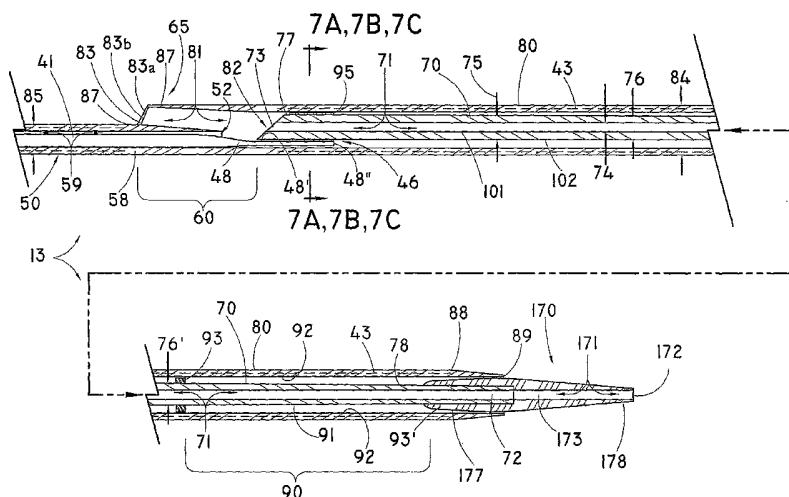
(43) International Publication Date
26 October 2006 (26.10.2006)

PCT

(10) International Publication Number
WO 2006/113868 A2

- (51) International Patent Classification: Not classified
- (21) International Application Number:
PCT/US2006/014874
- (22) International Filing Date: 20 April 2006 (20.04.2006)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/673,199 20 April 2005 (20.04.2005) US
60/761,676 23 January 2006 (23.01.2006) US
- (71) Applicant (for all designated States except US): **COOK INCORPORATED** [US/US]; 750 Daniels Way, P.o. Box 489, Bloomington, Indiana 47402 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **PAL, Dharmendra** [US/US]; 7101 Pouliot Place, Wilmington, Massachusetts 01887 (US).
- (74) Agent: **LEFFEL, Kevin, L.**; P.o. Box 2269, Bloomington, Indiana 47402-2269 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— without international search report and to be republished upon receipt of that report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MEDICAL DELIVERY APPARATUS HAVING TAPERED COMPONENTS



(57) Abstract: Medical devices for delivering stents, prosthetic valve devices, and other implantable articles inside a patient's body are provided. The devices have an elongate inner compression member having a proximal end and a distal mating end with a tapered portion and outer engaging surface, a first portion proximal to the distal mating end, and the tapered portion having a smaller cross sectional area than the first portion and being more flexible than the first portion. The devices further have an inner guide channel member with a first end and a second end defining a channel of substantially uniform inner diameter, the second end having an outer diameter, and the first end having a taper extending from the second end outer diameter to a smaller second outer diameter. A joint is configured for melt bonding or implanting the inner compression member distal mating end and the inner guide channel member second end.

MEDICAL DELIVERY APPARATUS HAVING TAPERED COMPONENTS

DescriptionTechnical Field

The present invention relates to an inner compression member and an inner guide channel member for use with medical device delivery systems that deploy an implantable prosthesis such as self-expanding, balloon expandable, or non-expanding stents, prosthetic valve devices, and other implantable articles (individually and collectively, "stent," "stents," "implantable prosthesis," and "implantable prostheses") at a selected location inside a patient's body.

Background of the Invention

This invention relates generally to an inner compression member and an inner guide channel member for medical device delivery systems and, in particular, to a tapered inner compression member and a tapered inner guide channel member for medical device delivery systems that employ a catheter. These medical device delivery systems have a host of uses, including, for example, the deployment of a self-expanding implantable prosthesis at selected locations inside a patient's body. The invention may also be used, however, with a balloon expandable and non-expanding implantable prosthesis. In addition to being used with a rapid insertion delivery system, the invention may be used in an "over-the-wire" delivery system, so both systems will be described below.

By way of background, stents are configured to be implanted into body vessels having a passageway in order to reinforce, support, repair, or otherwise enhance the performance of the passageway. The term "passageway" is understood to be any lumen, channel, flow passage, duct, chamber, opening, bore, orifice, or cavity for the conveyance, regulation, flow, or movement of bodily fluids and/or gases of an animal. As an example, stents have been used in the passageways of an aorta, artery, bile duct, blood vessel, bronchiole, capillary, esophagus, fallopian tube, heart, intestine, trachea, ureter, urethra, vein, and other locations in a body (collectively, "vessel") to name a few.

- 2 -

One type of stent is self-expanding. For a self-expanding stent, the stent is resiliently compressed into a collapsed first, smaller diameter, carried by the delivery system, and due to its construction and material properties, the stent expands to its second, larger diameter upon deployment. In its expanded configuration, the stent exhibits sufficient stiffness so that it will remain substantially expanded and exert a radially outward force in the vessel passageway on an interior surface of the vessel. One particularly useful self-expanding stent is the Z-stent, introduced by Cook Incorporated, due to its ease of manufacturing, high radial force, and self-expanding properties. Examples of the Z-stent are found in United States Patent Nos. 4,580,568; 5,035,706; 5,282,824; 5,507,771; and 5,720,776, the disclosures of which are incorporated in their entirety. The Zilver stent, introduced by Cook Incorporated, is another particularly useful self-expanding stent due to its nitinol platform and use of the Z-stent design properties. Examples of the Zilver stent are found in United States Patent Nos. 6,743,252 and 6,299,635, the disclosures of which are incorporated in their entirety.

Many delivery systems employ a tubular catheter, sheath, or other introducer (individually and collectively, "catheter") having first and second ends and comprising a lumen for receiving the wire guide. Optionally, these delivery systems may fit through a working channel within an endoscope or an external accessory channel device used with an endoscope.

Generally stated, these delivery systems may fall within two categories. The first category of delivery systems to have been used, and consequently the first to be discussed below, is commonly referred to as an "over-the-wire" catheter system. The other category of delivery systems is sometimes referred to as a "rapid exchange" catheter system. In either system, a wire guide is used to position the delivery system within a vessel passageway. The typical wire guide has proximal and distal ends. A physician inserts the distal end into the vessel passageway, advances, and maneuvers the wire guide until the distal end reaches its desired position within the vessel passageway.

In the "over-the-wire" catheter delivery system, a physician places the catheter over the wire guide, with the wire guide being received into a lumen that

- 3 -

extends substantially through the entire length of the catheter. In this over-the-wire type of delivery system, the wire guide may be back-loaded or front-loaded into the catheter. In front-loading an over-the-wire catheter delivery system, the physician inserts the distal end of the wire guide into the catheter's lumen at or near the catheter's proximal end. In back-loading an over-the-wire catheter delivery system, the physician inserts a distal portion of the catheter over the proximal end of the wire guide. The back-loading technique is more common when the physician has already placed the wire guide into the patient, which is typically the case today. In either case of back-loading or front-loading an over-the-wire catheter delivery system, the proximal and distal portions of the catheter will generally envelop the length of the wire guide that lies between the catheter first and second ends. While the wire guide is held stationary, the physician may maneuver the catheter through the vessel passageway to a target site at which the physician is performing or intends to perform a treatment, diagnostic, or other medical procedure.

Unlike the over-the-wire system where the wire guide lies within the catheter lumen and extends substantially the entire length of the catheter, in a novel "rapid insertion" catheter delivery system described in application serial number 60/673,199, the wire guide occupies a catheter lumen extending only through a distal segment of the catheter. The so-called rapid insertion system comprises a system proximal end, an elongate flexible middle section and a system distal end that is generally tubular.

The system distal end, in general, comprises an inner guide channel member sized to fit within an outer guide channel member that is substantially axially slideable relative to the inner guide channel member. The outer guide channel member and inner guide channel member further have entry and exit ports defining channels configured to receive a wire guide. A port includes any structure that functions as an entry or exit aperture, cutout, gap, hole, opening, orifice, passage, passageway, port, or portal, while a guide channel is understood to be any aperture, bore, cavity, chamber, channel, duct, flow passage, lumen, opening, orifice, or passageway that facilitates the conveyance, evacuation, flow, movement, passage,

- 4 -

regulation, or ventilation of fluids, gases, or a diagnostic, monitoring, scope, other instrument, or more particularly a catheter or wire guide.

A wire guide may extend from the outer and inner member entry ports, through the outer and inner member guide channels, and exit the distal end at or near a breach position opening located at or near a transition region where the guide channels and exit ports are approximately aligned relatively coaxially to facilitate a smooth transition of the wire guide. Furthermore, the outer guide channel member has a slightly stepped profile, whereby the outer guide channel member comprises a first outer diameter and a second smaller outer diameter proximal to the first outer diameter and located at or near the transition region.

The system distal end also has a self-expanding deployment device mounting region (e.g., a stent mounting region) positioned intermediate the inner guide channel member entry and exit ports for releasably securing a stent. At the stent mounting region, a stent is releasably positioned axially intermediate distal and proximal restraint markers and sandwiched transversely (i.e., compressed) between the outside surface of the inner guide channel member and the inside surface of an outer guide channel member.

Turning to the system proximal end of the rapid insertion delivery system, the proximal end, in general, comprises a handle portion. The handle portion has a handle that the physician grips and a pusher stylet that passes through the handle. The pusher stylet is in communication with—directly or indirectly through intervening parts—the inner guide channel member at the distal end. Meanwhile, the handle is in communication with—directly or indirectly through intervening parts—the outer guide channel member at the distal end. Holding the pusher stylet relatively stationary (while, for example, actuating the handle) keeps the stent mounting region of the inner guide channel member properly positioned at the desired deployment site. At the same time, proximally retracting the handle results in a corresponding proximal movement of the outer guide channel member relative to the inner guide channel member to thereby expose and, ultimately, deploy the self-expanding stent from the stent mounting region. At times, a physician may need to deploy a second self-expanding stent by withdrawing the system from the proximal end of the wire

- 5 -

guide. The physician may then reload the catheter with additional stents, and if that is not an option the physician may load another stent delivery system with an additional stent, onto the wire guide. Also, the physician may withdraw the stent delivery system altogether and replace the delivery system with a catheter or different medical device intended to be loaded onto the wire guide.

The delivery system in the rapid insertion delivery system further comprises an elongate flexible middle section delivery device extending intermediate the system proximal end and the system distal end. The middle section delivery device comprises an outer sheath and an inner compression member having first and second ends associated with the system distal end and system proximal end, respectively.

More particularly, the outer sheath first end may be coterminous with or, if separate from, may be associated with (e.g., joined or connected directly or indirectly) the distal end outer guide channel member at or near the transition region, while the outer sheath second end is associated with the handle at the system proximal end. The inner compression member first end is associated with the distal end inner guide channel member at or near the transition region, while the inner compression member second end is associated with the pusher stylet at the proximal end. Therefore, the outer guide channel member of the distal end may move axially (as described above) and independently relative to an approximately stationary inner guide channel member of the system distal end and, thereby, deploy the stent.

Before the novel "rapid exchange" catheter delivery system described in application serial number 60/673,199 and the present invention, the ways of associating the inner compression member first end to the inner guide channel member has typically been to use a mechanical lap joint. A lap joint, however, may increase the manufacturing time because it introduces a third part for joining the inner compression member and inner member. Also, the small physical dimensions of the lap joint, inner guide channel member, and inner compression member first end all are factors that increase the difficulty in manufacturability and, therefore, the assembly time. Another drawback to a mechanical lap joint connection is the propensity to lose the friction fit between the components. Accordingly, a glued

- 6 -

joint is often employed as an alternative to a mechanical lap joint. While glue, adhesives, and the like (collectively, "glue"), offer advantages over a mechanical lap joint, one must choose the right glue to join dissimilar materials. Also, glue must cure, thereby increasing the total processing (fixture) time in the application and assembly of the joint. In any event, lap joints and glued joints may vary in strength and integrity depending on the type of materials being joined, and whether the materials have incongruous mating surfaces. In addition, the point attachments that are typically formed by these joints could cause joint failure due to inadequate stress distribution. Moreover, lap joints and glued joints tend to have point attachments that have non-uniform or irregular flexibility relative to the remainder of the joint or the region of the inner compression member or inner guide channel member held by the joint. As the device negotiates a tortuous path within a vessel passageway and "pushes" the inner guide channel member during stent deployment, the forces encountered by the distal end of the device may result in prolapse, buckling, kinking, or an irregular bend at or near the joint.

It would be desirable to have relatively uniform flexibility through the joint. Therefore, the present invention solves these and other problems by providing an inner compression member having a tapered portion. In another aspect of the invention, the inner compression member distal mating end comprises a second portion with an even smaller cross sectional area. In yet another aspect of the invention, a joint operatively couples the tapered portion and/or the second portion of the distal mating end of the inner compression member to the inner guide channel member.

Before the novel "rapid exchange" catheter delivery system described in application serial number 60/673,199, another problem often encountered with conventional inner guide channel members is that the wall has uniform thickness and/or sudden changes in dimensions. The uniform dimension is less compliant (e.g., less flexible) compared to walls that get progressively thinner and, therefore, more compliant (e.g., more flexible). Also, sudden changes in a wall dimension could result in kinking or buckling of the wall at the point where the wall suddenly changes its dimension from, for example, thicker walls to thinner walls. Moreover, an inner

- 7 -

guide channel member that has a uniform thickness will effectively require more space within the device, because the stent still needs to dispose about an outer diameter of the inner member.

Therefore, it would be desirable to have tapered inner compression member and a tapered inner guide channel member for a medical device delivery system such as, for example, a delivery system for self-expanding devices such as stents, prosthetic valve devices, and other implantable articles inside a patient's body as taught herein.

Summary of the Invention

The present invention provides a medical delivery device. In one embodiment, an inner compression member includes a distal inner guide channel member distal mating end having a tapered portion. An inner guide channel member has a distal first end and a proximal second end. A joint is configured for operatively coupling the inner compression member distal mating end and the inner guide channel member second end.

In another embodiment of a stent delivery device, an inner guide channel member includes first and second ends, an outer diameter at or near the second end, and a taper intermediate the first and second ends. According to this embodiment, an elongate inner compression member has a proximal end and a distal mating end and an outer engaging surface. A joint is configured for operatively coupling the inner compression member distal mating end outer engaging surface and the inner guide channel member second end.

In yet another embodiment, the present invention provides a delivery system configured for rapid insertion delivery of self-expanding devices such as stents, prosthetic valve devices, and other implantable articles inside a patient's body. The delivery apparatus includes a proximal end, an inner compression member having a distal mating end with a tapered portion, and a distal end having inner and outer guide channel members, the inner guide channel member having a first end and a second end and a taper intermediate the first and second ends. A joint is configured for operatively coupling the inner compression member distal mating end and the inner guide channel member second end.

Brief Description of the Drawing

Figure 1 is a schematic view, broken away, of a medical device system according to one embodiment of the invention.

Figure 2 is an exploded side view, broken away, of a proximal end of a medical device according to one embodiment of the invention.

Figure 2A shows longitudinally sectioned exploded side views of a handle first connector and a handle second connector according to one embodiment of the invention.

Figure 2B shows a longitudinally sectioned side view of operatively coupled first and second connectors according to Figures 2A.

Figure 2C shows a longitudinally sectioned side view of a handle first connector and a handle second connector according to Figure 2B operatively coupling a strain relief member and/or an outer sheath according to one embodiment of the invention.

Figure 3 is a longitudinally sectioned view along a partial length of an embodiment of an outer sheath of a middle section and/or for an outer guide channel member of a distal end of a medical device according to the invention.

Figure 4 is a longitudinally sectioned view, broken away, of a distal end of medical device delivery system according to one embodiment of the invention.

Figures 4A and 4B schematically represent cross sectional views of melt bonding of components according to one embodiment of the invention; Figure 4A before melt bonding and Figure 4B after melt bonding.

Figure 5 is a longitudinally sectioned view, broken away, of an alternative embodiment of a distal end of a medical device delivery system according to one embodiment of the invention.

Figure 6 is a longitudinally sectioned view of an embodiment of a distal end according to the invention, shown having a portion of a wire guide.

Figure 7 is a longitudinally sectioned view, broken away, of another embodiment of a distal end of a medical device delivery system according to one embodiment of the invention.

- 9 -

Figures 7A, 7B, and 7C show cross sectional views of Figure 7 taken along the lines 7A-7A, 7B-7B, and 7C-7C, respectively.

Figure 8 shows a perspective view, broken away, of an embodiment of an inner compression member according to one embodiment of the invention.

Figures 8A, 8B, 8C, 8D, 8E, and 8F show cross sectional views of Figure 8 taken along the lines 8A-8A, 8B-8B, 8C-8C, 8D-8D, 8E-8E, and 8F-8F, respectively.

Figures 9A, 9B, 9C, 9D, 9E, 9F, 9G, and 9H are schematic perspective views, broken away, of an inner compression member distal mating end according to embodiments of the invention.

Figure 10 is a sectional view, broken away, showing a distal end of a stent delivery device according to one embodiment of the invention.

Figure 10A is a sectional view, broken away, showing a distal end having an alternative embodiment of an inner compression member according to the invention.

Figures 11A, 11B, 11C, 11D, and 11E are schematic diagrams illustrating a method of making an internal joint for joining an inner compression member to an inner guide channel member according to the invention.

Detailed Description

The present invention relates to medical devices, and in particular to a tapered inner compression member, a tapered inner guide channel member, and an internal joint for use in a delivery system configured for deploying expandable metallic, polymeric, and plastic devices or non-expanding metallic, polymeric, and plastic devices, which devices may include, by way of example and not by way of limitation, stents, prosthetic valve devices, and other implantable articles at selected locations inside a patient's body. For conciseness and ease of description of the embodiments of the invention, the term "stent" and its variations shall refer individually and collectively (without limiting the invention) to all self-expanding, balloon-expandable, or non-expanding devices used with the invention, such as stents, prosthetic valve devices, and other implantable articles inside a patient's body.

For the purposes of promoting an understanding of the principles of the invention, the following provides a detailed description of embodiments of the invention as illustrated by the drawings as well as the language used herein to describe the aspects of the invention. The description is not intended to limit the invention in any manner, but rather serves to enable those skilled in the art to make and use the invention. As used herein the terms comprise(s), include(s), having, has, with, contain(s) and the variants thereof are intended to be open ended transitional phrases, terms, or words that do not preclude the possibility of additional steps or structure.

In Figure 1, an illustrative embodiment of a delivery system 10 having a host of uses, including for the rapid insertion of self-expanding stents, is provided. The delivery system 10 comprises a system proximal end 12, a middle section delivery device 14, and a system distal end 13 shown in a partially deploying position.

SYSTEM PROXIMAL END 12

In the embodiments shown in Figure 1, the proximal end 12 remains outside

- 11 -

of the patient's body. The proximal end 12 comprises a handle 30 and an optional pusher stylet 20.

Figure 1 depicts a schematic representation of the handle 30 and the optional pusher stylet 20 shown more particularly in Figure 2. In general, a handle 30 retracts an outer guide channel member (discussed below) of the distal end 13 of the delivery system 10 to deploy a stent, as will be explained later. The handle 30 may comprise any mechanical, electromechanical, pneumatic, or hydraulic handle configured in communication with—directly or indirectly through intervening parts—the distal end's outer guide channel member. Communication would include, by way of illustration and not by way of limitation, a handle 30 that uses or is otherwise associated with, directly or indirectly, an elongated mechanical wire, rod, shaft, cable, sheath, pneumatic tube, or hydraulic pistons, cylinders and/or flow paths configured for moving the outer guide channel member proximally in order to deploy a stent.

Figure 2 provides a schematic view, broken away, of a delivery system 10 for rapid insertion of self-expanding stents, but could be used with other implantable prostheses described above. The delivery system 10 shown in Figure 2 is one embodiment of the proximal end 12, middle section delivery device 14, and distal end 13 shown in a partially deploying position. The middle section delivery device 14 extends distally from the proximal end 12, and a distal end 13 extends to a position that is distal the middle section delivery device 14. More particularly, Figure 2 shows an exploded view of the proximal end 12 of the delivery system 10 according to one embodiment of the invention, with an emphasis on the handle 30 and the optional stylet 20. Features of one embodiment of a handle 30 and pusher stylet 20 are discussed below.

The handle 30 comprises any tubular structure having a distal aperture 30" and a proximal aperture 30', the apertures defining a chamber 31 therebetween. In general, the handle 30 is a component, instrument, mechanism, tool, device, apparatus, or machine configured for directly or indirectly retracting an outer guide channel member (discussed below) of the distal end 13 of the device to expose and, ultimately, to deploy a stent self-expanding implantable prostheses such as stents,

- 12 -

prosthetic valve devices, and other implantable articles (hereafter, "stent" or "stents") at a selected location inside a patient's body.

The handle 30 is axially slideable relative to an elongate (long) inner compression member 41 that comprises a proximal end 40 and a middle section 40'. As discussed more fully below, the inner compression member 41 helps to keep the stent from moving proximally with proximal movement of the handle 30, which handle movement causes the outer guide channel member to withdraw proximally over the stent in order to expose and thereby to deploy the stent. Thus, the inner compression member helps to "push" the stent or stent carrying inner guide channel member in order to counter the urge for the stent or stent carrying member to prolapse proximally with the withdrawing of the outer guide channel member. As will be understood, "pushing" on the inner compression member will keep the stent carrying inner guide channel member (and therefore the stent) from translating as a result of an outer sheath or outer guide channel member being pulled over the stent; thereby "pushing" holds the stent in place at the desired deployment site within the patient's body. In one embodiment, the handle 30 is a unidirectional handle that is axially slideable relative to the inner compression member 41 and/or the optional pusher stylet 20 in order to deploy a stent. In one embodiment, the inner compression member 41 is secured to a pusher stylet 20.

As shown in Figure 2, one embodiment of a pusher stylet 20 comprises a proximal end 20', a distal end 20", and a cannula 23 intermediate the proximal and distal ends 20', 20", respectively, and a receptacle 22. The cannula 23, as should be understood, comprises any suitable hollow plastic or metal tube. As a hollow tube, the cannula 23 optionally allows the inner compression member 41 to pass proximally through the cannula 23 and to the proximal end 20' so that the inner compression member proximal end 40 (such as a proximal end that is flared) may secure to a plug 21 that fits within the receptacle 22, wherein Figure 2 shows the proximal end 20', plug 21, and an optional securing material 28 are shown in an exploded view relative to the receptacle 22 into which they may be secured. Furthermore, the cannula 23 assists with keeping that portion of the inner compression member substantially straight.

- 13 -

The stylet 20 is optional, because in an alternative embodiment the physician may hold the inner compression member proximal end 40' directly in order to "push" (e.g., hold substantially stationary) the stent carrying inner guide channel member (and therefore the stent). This controls the stent carrying inner guide channel member and stent from translating as a result of an outer sheath or outer guide channel member being pulled over the stent, so that the stent remains at the desired deployment site within the patient's body. Alternatively, the stylet 20 is any stationary handle secured to the inner compression member 41 for achieving the "pushing" (e.g., hold substantially stationary) of the stent or stent carrying inner guide channel member while the outer sheath or outer guide channel member are moved proximally.

The stylet distal end 20" is housed within the handle chamber 31 and is flared or otherwise flanged sufficiently to be larger than the handle proximal aperture 30' so as not to pull out of the chamber 31. In one embodiment, the stylet distal end 20" is secured to the distal portion of the stylet cannula 23, while in another embodiment the stylet distal end 20" is formed integral with the distal portion of the stylet cannula 23. Consequently, the stylet distal end 20" functions as a proximal stop that prevents the stylet cannula 23 from backing all the way out the handle while being axially slideable within the handle chamber 31. Thus, the stylet 20 will not slide off the handle 30, if so desired. The stylet distal end 20" may also, in one embodiment, function as a distal stop against a restraint 33 formed in the handle chamber 31 intermediate the handle proximal and distal apertures 30', 30", respectively, where intermediate should be understood to be any position between, and not necessarily equidistant to, the handle apertures 30', 30". As a result of the stylet distal end 20", the handle 30 may slide axially the distance separating the handle restraint 33 and the stylet distal end 20", which has a maximum distance of when the stylet distal end 20" is abutting the handle proximal aperture 30'.

A threaded tapered plug 21 and threaded tapered receptacle 22 optionally secure the inner compression member proximal end 40. In one embodiment, the inner compression member proximal end 40 is flared. Securing material 28, such as glue, adhesives, resins, welding, soldering, brazing, chemical bonding materials or

- 14 -

combinations thereof and the like (collectively and individually, "glue") may be used to keep the threaded tapered plug 21 from backing out of the threaded tapered receptacle 22. A portion of the cannula 23 and stylet distal end 20" are received within the handle chamber 31 distal to the handle proximal aperture 30' as previously explained.

By optionally placing the inner compression member proximal end 40 in mechanical communication with the plug 21 and receptacle 22, the gripping and "pushing" (e.g., hold substantially stationary) on the stylet 20 (e.g., the receptacle 22) thereby helps to keep the inner compression member 41 from moving away from the distal end 13 and, accordingly, counters the tendency for a stent or stent carrying member to move proximally during withdrawal of the outer guide channel member as will be explained below. Of course, the inner compression member may be secured elsewhere by the stylet 20, such as at or near the stylet distal end 20" or intermediate the stylet proximal and distal ends 20', 20", respectively, and the stylet distal end 20" may extend to a position at or near the distal end aperture 30" of the handle 30.

Figure 2 shows a middle section 40' that extends distally from the proximal end 40 of the inner compression member 41. In one embodiment, the middle section 40' passes through the handle 30 (and may pass through the cannula 23 and/or bushings housed within the handle chamber 31 or other portions of the proximal end 12). In one embodiment, the middle section 40' is elongate (at least 50.0 cm or longer as described below) and extends to a distance distally of the handle 30 and to a position at or near the medical system delivery device distal end 13. It should be understood that, by describing the middle section 40' as passing through the handle 30, the middle section 40' does not necessarily need to pass proximally through the entire length of the handle 30, such as in an embodiment (by way of example and not by way of limitation) where the proximal end 40' of the inner compression member 41 is secured to a distal portion of the cannula 23 and/or the stylet distal end 20" extending within the handle chamber 31 to a position at or near the handle restraint 33.

- 15 -

In addition to holding a threaded tapered plug 21 and optionally the proximal end 40 of the inner compression member 41, the threaded tapered receptacle 22 may secure the proximal portion of the optional cannula 23. Glue 28' may be used at or near an interface of the cannula 23 and distal aperture of the threaded tapered receptacle 22. The glue 28' serves many functions, such as to keep dust from settling within the threaded tapered receptacle 22, to make the cannula 23 easier to clean, and to give aesthetics and a smooth feel to the device.

The handle 30 slidably receives the distal portion of the cannula 23 within the handle aperture 30' and handle chamber 31. As a result, the handle 30 is slidable relative to the stylet 20 (e.g., slidable relative to the threaded tapered plug 21, threaded tapered receptacle 22, and the cannula 23). In use, the physician grips the handle 30 in one hand and grips the stylet 20 (e.g., the receptacle 22) in the other hand. The physician holds the stylet 20 relatively stationary, which prevents the inner compression member and inner guide channel member and its stent carrying portion from moving proximally, and then withdraws the handle 30 proximally relative to the stationary stylet 20 and inner compression member 41. As a result, the physician is thereby retracting an outer guide channel member (discussed below) of the distal end 13 of the delivery system 10 to expose and, ultimately, to deploy a stent locatable at the distal end 13 of the delivery system 10. The handle 30 is in communication with—directly or indirectly through intervening parts—the outer guide channel member at the distal end 13.

As shown in Figure 2, some of those optional parts may include the following: a first bushing 36 having an optional first bushing flange 35; a second bushing 36' having an optional second bushing flange 35'; an intermediate seal 37 intermediate the first and second bushing flanges 35, 35', respectively; a second seal 37' intermediate the second bushing flange 35' and a check flow body 38; and a detachable cap 39, such a Luer cap by way of example but not by way of limitation. In one embodiment, one or both of the intermediate seal 37 and the second seal 37' is from a class such as an O-ring. In another embodiment, one or both of the intermediate seal 37 and the second seal 37' is a cylinder or disk with a center aperture, and may be made from material that comprises an O-ring. The

- 16 -

bushings 36, 36' are hollow plastic or metal tubes that take up space within the handle 30 so that the inner compression member has less room to buckle. Fully assembled in one embodiment, the first bushing 36 is inserted within the cannula 23 and the first bushing flange 35 is distal to and abutting the handle restraint 33, which is sized to interfere with the bushing flange 35 to prevent the bushing flange 35 from moving proximal to the handle restraint 33. The second bushing flange 35' is distal to and optionally abutting the bushing flange 35 so to prevent it from moving proximal the first bushing flange 35, and the second bushing 36' is inserted within an opening 139 of the check flow body 38. The intermediate seal 37 and the second seal 37' help to prevent fluids that could be used with the device (discussed below) from entering the handle chamber 31, which directs fluids distally, which fluids may be conveyed through an outer sheath 50 of the middle section delivery device 14 and distal end 13. In one embodiment, the handle restraint 33 is from a class such as a counterbore wherein the restraint 33 comprises, by way of example only and not by way of limitation, a flat-bottomed cylindrical enlargement of the handle chamber 31 sized for receiving a first bushing flange 35, an intermediate seal 37, a second bushing flange 35', and/or a check flow body proximal mating end 38" intermediate the restraint 33 and the handle distal aperture 30".

The handle 30 and check flow body 38 operatively couple with the handle distal aperture 30" receiving a check flow body proximal mating end 38" and being secured together by any suitable means, including but not limited to a crimp, friction fit, press fit, wedge, threading engagement, glue, adhesives, resins, welding (laser, spot, etc.), soldering, brazing, adhesives, chemical bonding materials, or combinations thereof. In one embodiment, the handle 30 comprises a coupling member 32 and the check flow body proximal mating end 38" comprises a coupling member 32', the coupling members 32, 32' being complementary to hold the handle 30 and check flow body proximal mating end 38" together. In one embodiment, the coupling members 32, 32' may form complementary threads. If it is desired to achieve quicker assembly for manufacturing purposes, then the coupling members 32, 32' may be an array of circumferential ridges that form an interference fit when pressed together. If a one-time snap fit is desired, then the coupling members 32,

- 17 -

32' may be circumferential ridges in the form of barbs. In another embodiment, the handle 30 and check flow body proximal mating end 38" may be put together and taken apart for servicing, in which case the coupling members 32, 32' may be circumferential ridges in the form of knuckle threads (e.g., circumferential ridges forming complementary undulating waves). The operatively coupled handle 30 and check flow body proximal mating end 38" according to these embodiments may be fixed such that they do not rotate relative to each other, or may rotate while preventing undesired axial separation.

During use, the detachable cap 39 may be detached or opened and the device flushed with saline to remove air in order to help keep air out of the patient. The intermediate seal 37 and the second seal 37' ensure that any flushed fluid moves distally in the device and does not back up into the handle 30, such as between the handle restraint 33 and the first bushing 36, into the handle chamber 31, or out the handle proximal aperture 30'. The detachable cap 39 (such as a Luer cap) keeps saline from backing out of the check flow body 38, air from flowing into the check flow body 38, and blood from rushing out during periods of high blood pressure inside the patient.

The medical device delivery systems 10 may be used to deploy an implantable prosthesis that is a balloon expandable or self-expanding stent, prosthetic valve device, or other implantable articles provided on the distal end of a delivery system. In operation, a physician inserts the distal end and at least a portion of the middle section delivery device into a vessel passageway, and advances them through the vessel passageway to the desired location adjacent the target site within the vessel passageway of a patient. In a subsequent step, the physician moves the handle proximally, which withdraws the outer sheath and/or the outer guide channel member and releasably exposes the stent for deployment. In another step, the physician inflates the expandable member, such as a balloon, positioned under the stent inner surface to plastically deform the stent into a substantially permanent expanded condition. The physician may inflate the expandable member by injecting fluid such as saline from a syringe into the inner compression member 41, via pusher stylet 20, through a Luer fitting at the proximal end 20'. Therefore, the fluid is

- 18 -

directed distally to the expandable member, filling the expandable member chamber and expanding the stent. The physician then deflates the balloon and removes the catheter or delivery device from the patient's body.

In one embodiment as shown in Figure 2, the handle 30 further comprises a check flow body distal mating end 38' and a connector cap 39' (optionally detachable) secured to the check flow body distal mating end 38', and a strain relief 29. In one embodiment, the connector cap 39' is from a class of fasteners such as nuts, and in one embodiment is a flare nut. The connector cap 39' functions to hold (or assist in holding in combination with the check flow body distal mating end 38') a flared proximal portion of an outer sheath 50 and/or a flared strain relief 29 disposed about (and optionally extending proximally from) that held portion of the outer sheath 50. The strain relief member 29 provides a kink resistant point where the outer sheath 50 connects to the connector cap 39' and/or the check flow body distal mating end 38'.

The check flow body distal mating end 38' and connector cap 39' may be operatively coupled mechanically, chemically, and/or chemical-mechanically. In one embodiment, the connector cap 39' is crimped, friction fitted, press fitted, and/or wedged into engagement onto the check flow body distal mating end 38'. In another embodiment for example, the check flow body distal mating end 38' and connector cap 39' are operatively coupled by glue, adhesives, resins, welding (laser, spot, etc.), soldering, brazing, adhesives, chemical bonding materials, or combinations thereof.

According to Figure 2A, yet another embodiment of the connector cap 39' comprises a handle first connector 130 and the check flow body distal mating end 38' comprises a handle second connector 132. According to Figure 2A, the handle first and second connectors 130, 132, respectively, function to operatively couple a strain relief member 29 operatively coupled to the proximal end of the outer sheath 50 (discussed below). In one embodiment, the handle first connector 130 is from a class of fasteners such as nuts, and in one embodiment is a flare nut. Optionally, the distal portion of the second bushing 36' is sized (but for the second bushing flange 35') to be received within a check flow body proximal opening 139 in communication with the second connector 132.

- 19 -

Figure 2A shows an exploded longitudinally sectioned side view of one embodiment of a portion of the handle comprising a first connector 130 and a second connector 132. The handle first connector 130 further comprises a proximal end 134 and a distal end 136. An opening 138 at the proximal end 134 and an opening 140 at the distal end 136 and define a lumen 133 therebetween. There is an engaging surface 142 at or near the distal end 136. A threaded first piece 146 is disposed within the lumen 133 and intermediate the handle first connector distal end opening 140 and proximal end opening 138. The handle second connector 132 further comprises a proximal end 135 and a distal end 137. An opening 141 at the distal end 137 and check flow body proximal opening 139 (e.g., Fig. 2) at the proximal end 135 define a lumen 131 therebetween. There is an engaging surface 143 at or near the distal end 137. A threaded second piece 145 is disposed on the outside surface and intermediate the handle second connector distal end opening 141 and the check flow body proximal opening 139.

According to one embodiment shown in Figures 2A and 2B, the second connector distal end 137 is received within the first connector proximal end opening 138. The first connector 130 and second connector 132 are operatively coupled by a threading engagement between the first connector threaded first piece 146 and the second connector threaded second piece 145. Alternatively, the first connector 130 and second connector 132 are operatively coupled mechanically, chemically, and/or chemical-mechanically. In one embodiment for example, the first connector 130 and second connector 132 are crimped, friction fit, press fit, and/or wedged into engagement. In another embodiment for example, the first connector 130 and second connector 132 are operatively coupled by glue, adhesives, resins, welding (laser, spot, etc.), soldering, brazing, adhesives, chemical bonding materials, or combinations thereof.

Figure 2B shows the second connector threaded second piece 145 operatively coupled to the first connector threaded first piece 146 such that the second connector proximal end 135 is proximal to the first connector proximal end 134 and the second connector distal end 137 is located at or near the first connector distal end 136. As shown in Figure 2B, the second connector engaging surface 143

- 20 -

is spaced proximal to the first connector engaging surface 142 for receiving and compressing a strain relief member second end portion therebetween.

Figure 2C shows one embodiment of an optional strain relief member 29 comprising a tubular first end portion 118 and a flared second end portion 117. According to Figure 2C, the medical device delivery system includes an elongate outer sheath 50 (Figs. 3, 4, 5, 6, 7). Like elements from the previous drawings, embodiments, and description from above are labeled the same. The term elongate is used, not lexicographically but instead, to describe embodiments according to the embodiment that measures at least about 50.0 cm or measures within one of the ranges of lengths exceeding 50.0 cm and as more fully discussed above.

More particularly, Figure 2C shows that the outer sheath 50 comprises a proximal end 57 and a distal end 58. The distal end 58 comprises an opening 52 and the proximal end 57 comprises an opening 53; the openings define a passageway 59 therebetween. In one exemplary embodiment according to Figure 2C, the strain relief member tubular first and second end portions 118, 117, respectively, are disposed about and operatively coupled to the outer sheath proximal end 157. In another embodiment, the tubular first end portion 118 disposes about the outer sheath proximal end 157 while the flared second end portion 117 extends proximally from outer sheath proximal end 157. In addition, the strain relief member second end portion 117 and/or outer sheath proximal end 57 comprise an opening 123 in fluid communication with the outer sheath passageway 59.

By way of example only and not by way of limitation, the terms "operatively coupling," "operatively coupled," "coupling," "coupled," and variants thereof are not used lexicographically but instead are used to describe embodiments of the invention having a point, position, region, section, area, volume, or configuration at which two or more things are mechanically, chemically, and/or chemical-mechanically bonded, joined, adjoined, connected, associated, united, mated, interlocked, conjoined, fastened, held together, clamped, crimped, friction fit, pinched, press fit tight, nested, wedged, and/or otherwise associated by a joint, a junction, a juncture, a seam, a union, a socket, a melt bond, glue, adhesives, resins,

- 21 -

welding(laser, spot, etc.), soldering,brazing,adhesives,chemical bondingmaterials, implanted arrangement, or combinations thereof.

Figure 2C shows the strain relief member second end portion 117 and/or outer sheath proximal end 57 being operatively coupled between the first connector 130 and the second connector 132, and the second connector lumen 131 being in fluid communication with the outer sheath passageway 59. In one embodiment, the strain relief member second end portion 117 and/or outer sheath proximal end 57 comprises a first opposing surface 124 and a second opposing surface 125. The first connector engaging surface 142 is disposed against the first opposing surface 124 and the second connector engaging surface 143 is disposed against the second opposing surface 125, whereby the strain relief member second end portion 117 and/or outer sheath proximal end 57 becomes operatively coupled between the first and second connector engaging surfaces 142, 143, respectively. In one embodiment, the operatively coupled strain relief member second end portion 117 and/or outer sheath proximal end 57 is compressed (e.g., sandwiched) between the first and second connector engaging surfaces 142, 143.

Thus, the check flow body 38 provides an optional three way connector. The check flow body proximal mating end 38" and handle coupling member 32 are operatively coupled. The side port is controlled by the detachable connector cap 39. The body distal mating end 38' is operatively coupled to a second connector cap 39', or optionally the handle second connector 132 is received within and operatively coupled to a handle second connector cap 130.

The foregoing description of a proximal end 12 of a medical device delivery system 10 according to one embodiment of the invention may be one assembly during shipping, or may include a two-part assembly or more. Otherwise stated, the stylet 20 and handle 30 may be sold already combined or may be combined after purchase by inserting the stylet cannula 23 into the handle at the hospital via the threaded tapered plug 21 and threaded tapered receptacle 22. An optional safety lock 34 helps to ensure against unintentional actuation by preventing distal movement of the stylet distal end 20" by extending inwardly within the handle chamber 30 through a slot in the handle outer wall distal to the handle proximal

- 22 -

aperture 30'. Consequently, the optional safety lock 34 thereby maintains the handle 30 in an undeployed position until the physician is ready to deploy an implantable prosthesis (e.g., a self-expanding, balloon expandable, or non-expanding stent; prosthetic valve devices, and other implantable articles) at a selected location inside a patient's body.

MIDDLE SECTION DELIVERY DEVICE 14

A delivery system 10 as shown in Figures 1 and 2 comprises a middle section delivery device 14. According to the invention, the middle section delivery device 14 is intermediate the proximal end 12 (Figs. 1, 2) and the distal end 13 (Figs. 1, 2) of the delivery system 10. The term "intermediate" is intended to describe embodiments of the invention whereby the middle section delivery device 14 is intermediary, intervening, lying or occurring between two extremes, or spatially in a middle position, state, or nature—though not necessarily equidistant—between the distal tip of the distal end 13 and the proximal tip of the proximal end 12. Furthermore, the middle section delivery device 14 may overlap or be partially inserted into a portion of the distal end 13 and/or the proximal end 12. In another embodiment, a portion of the middle section delivery device 14 (such as the sheath 50 explained below) and the distal end outer guide channel member 80 (discussed below; see Figs. 4, 5, 6, 7) may be an elongate tubular catheter or Flexor® sheath of integral construction.

According to the invention, a middle section delivery device 14 is a flexible, elongate (long, at least about 50.0 centimeters ("cm")) tubular assembly. In one embodiment, the middle section delivery device 14 is from approximately 100.0 centimeters ("cm") to approximately 125.0 cm for use when placing a distal end 13 of the invention within a patient's body, although it may be sized longer or shorter as needed depending on the depth of the target site within the patient's body for delivering the stent. The term "tubular" in describing this embodiment includes any tube-like, cylindrical, elongated, shaft-like, rounded, oblong, or other elongated longitudinal shaft extending between the proximal end 12 and the distal end 13 and defining a longitudinal axis. As used herein and throughout to describe embodiments of the invention, the term "longitudinal axis" should be considered to be an

- 23 -

approximate lengthwise axis, which may be straight or may at times even be curved because the middle section delivery device 14, for instance, is flexible and the distal end 13 also may be substantially or partially flexible.

A middle section delivery device 14 comprises an outer sheath 50 (e.g., Figs. 2, 2C, 5, 6, 7). Figure 2C shows that the outer sheath 50 is generally tubular and comprises a proximal end 57 and a distal end 58 and defining a passageway 59 therebetween (e.g., Fig. 2C). In one embodiment, the distal end 58 comprises an opening 52 and the proximal end 57 comprises an opening 53, which openings define the passageway 59. The middle section delivery device 14 further comprises an elongate inner compression member 41 (e.g., Figs. 2, 2C, 5, 6, 7). The outer sheath passageway 59 is configured for slideably receiving the inner compression member 41, a catheter, or other medical device.

Figure 3 depicts an enlarged, longitudinally sectioned view along a partial length of one embodiment of an outer sheath 50 for use as the middle section delivery device 14, with the delivery system's proximal and distal 12, 13 ends, respectively, of the device being removed for clarity. In one embodiment, the outer sheath 50 comprises three layers: an inner layer 44 comprising Teflon material; a middle layer comprising a stainless steel circumferential spiral coil 43; and an outer layer 42 comprising a nylon, a polyether block amide ("PEBA"), and/or other melt bonding material discussed below. The outer layer 42 and inner layer 44 optionally may comprise a lubricious material, one example of which includes a fluorocarbon such as polytetrafluoroethylene (PTFE), to present a slideable surface to allow easier inserting and retracting the middle section delivery device 14 for deploying a self-expanding stent, as will be explained later.

The wall of the inner layer 44 of the outer sheath 50 has sufficient radial rigidity to decrease any tendency of bulging, kinking, and the like under an internal radial expansile force. In other words, the inner layer 44 resists an inner object from protruding or becoming embedded into the inner layer 44, which is beneficial to the slideability of an outer sheath 50. The coil 43 may be compression fitted or wound around the inner layer 44. The coil 43 includes a plurality of turns, and preferably includes uniform spacings 43' between the turns of the coil 43. The coil 43 may be

- 24 -

formed of any suitable material that will provide appropriate structural reinforcement, such as stainless steel flat wire or biologically compatible metals, polymers, plastics, alloys (including super-elastic alloys), or composite materials that are either biocompatible or capable of being made biocompatible.

Although the embodiment in Figure 3 shows a flat ribbon shaped wire coil 43, coils of other cross-sectional dimensions, such as round wire, may also be used. When flat wire stainless steel is used, the coil 43 is optionally formed from wire that is about 0.003 inches thick by about 0.012 inches wide. In one embodiment, the turns of coil 43 are uniformly spaced 43' apart by approximately 0.0118 inches. While Figure 3 shows an embodiment that uses coils 43 having uniformly spaced turns and a constant pitch, this is not required and coils 43 may be spaced 43' by non-uniform distances or at varying distances. In one embodiment, the ends of coil 43 are positioned approximately 0.197 inches proximal to the distal end 13 and approximately 0.591 inches distal to the proximal end 12.

The outer sheath 50 for use with the middle section delivery device 14, and the outer guide channel member 80 (Figs. 4, 5, 6, 7) and/or the inner guide channel member 70 (Figs. 4, 5, 6, 7) for use with the distal end 13, are available for purchase from Cook Incorporated, of Bloomington, Indiana under the trade name of "Flexor®." Examples of the Flexor® sheath devices, materials, and methods of manufacturing them are found in United States Patent Nos. 5,700,253 and 5,380,304, the contents of which are incorporated herein by reference. The Flexor® sheath is particularly suited for the outer sheath 50 of the middle section delivery device 14 and/or the outer guide channel member 80 of the distal second end 13 due to its thin PTFE liner on the inside wall of the inner layer 44, thin flat wire coil 43, and Nylon, PEBA, and/or PEBAX overcoat 42 that captures the coil 43 and PTFE liner 44 and binds the structure together. The PTFE inner layer 44 of the Flexor® sheath resists an expansile inner object from protruding or becoming embedded into the inner layer 44 and, thereby, provides a slick, smooth surface that slides (e.g., across the surface of a stent if the Flexor® sheath is used with the distal end 13 or across the surface of an inner compression member 41 if the Flexor® sheath is used with the middle section 14) relatively easily when retracted to expose, release, and deploy

- 25 -

the stent or allow the outer sheath 50 to move relative to the inner compression member 41, and the outer guide channel member 80 to move relative to the inner guide channel member 70, during deployment of the stent.

As an alternative to purchasing the outer sheath 50 for use with the middle section 14 and the outer guide channel member 80 for use with the distal end 13 from Cook Incorporated, one may manufacture the outer sheath and outer guide channel member from various component parts. For instance, one may purchase a tubular inner layer 44 comprising a lubricious material comprising a fluorocarbon such as polytetrafluoroethylene (PTFE or Teflon) from Zeus, Inc. in Orangeburg, South Carolina, and dispose that inner layer 44 over a mandrel. Alternatively, a sheet of material comprising Teflon may be positioned on a mandrel and formed into a tubular body for the inner layer 44 by any suitable means known to one skilled in the art.

The tubular inner layer 44 (whether formed from a sheet on a mandrel or purchased as a tube and slid onto a mandrel) may be slightly longer than the desired length described above for the outer sheath 50 and/or outer guide channel member 80, and slightly longer than the mandrel. In one embodiment, the tubular inner layer 44 may extend about 5.0 cm from each mandrel end. As explained below, the "loose" ends of the tubular inner layer 44 help during manufacturing of the device.

The mandrel-tubular inner layer 44 assembly is prepared for a middle layer comprising a stainless steel circumferential spiral coil 43 as described above and available for purchase from Cook Incorporated or Sabin Corporation in Bloomington, Indiana. As purchased, the coil 43 comes in a long, pre-coiled configuration and will be cut by hand or machine to the desired length either before or after winding the coil about the inner layer 44 to the desired length. As an alternative, one may manufacture the coil from raw material available from Fort Wayne Medical in Fort Wayne, Indiana, and process it into a spiral coil 43 shape.

The operator may apply the spiral coil 43 about the mandrel-tubular inner layer 44 assembly by hand or machine. If by hand, then an end of the spiral coil 43 may be started onto the tubular inner layer 44 by any suitable means, for example, such as hooking and winding (e.g., wrapping) the coil 43 around the tubular inner layer 44 in a pigtailed manner at an initial position a desired distance (e.g., 5.0 cm

- 26 -

or more) from a first end of the tubular inner layer 44 and to a terminating position that is a desired distance (e.g., 5.0 cm or more) from a second end of the tubular inner layer 44, and then cutting the coil 43 at the terminating position before or after hooking the coil 43 onto the inner layer 44. If by machine, then chucks, for instance, may hold the opposing ends of the mandrel-tubular inner layer 44 assembly while the spiral coil 43 is threaded through an arm on a machine and started onto the tubular inner layer 44 at the initial position as described above. As the chucks rotate, the inner layer 44 rotates, and the arm moves axially down the length of the inner layer 44, thereby applying the coil 43 in a spiral configuration about the inner layer 44. The machine arm moves to a terminating position where the machine or operator cuts the coil before or after hooking the coil 43 onto the inner layer 44.

An operator then applies an outer layer 42 about the coil-inner layer-mandrel assembly. The outer layer 42 may comprise a polyether block amide, nylon, and/or a nylon natural tubing (individually and collectively, "PEBA," "PEBAX," and/or "nylon"). The outer layer 42 preferably has a tubular configuration that disposes about (e.g., enveloping surrounding, wrapping around, covering, overlaying, superposed over, encasing, ensheathing, and the like) a length of the coil-inner layer-mandrel assembly.

Heat shrink tubing, available from many suppliers, including Zeus, Inc. in Orangeburg, South Carolina for instance and also Cobalt Polymers in Cloverdale, California, may be disposed about the outer layer-coil-inner layer-mandrel assembly. Heating the assembly causes the outer layer 42 to melt. The inner surface of the outer layer 42 thereby seeps through spaces 43' in or between middle layer coils 43 and bonds to both the outer surface of the inner layer 44 and the coils 43. In one embodiment, the inner surface of the outer layer 42 forms a melt bond 47 (explained below) to the outer surface of the inner layer 44. Upon cooling, a solid-state bond results such that the assembly comprises the three layers discussed above. The operator removes the shrink wrap (e.g., by cutting) and withdraws the mandrel. The operator may cut the Flexor® sheath to a desired length for an outer sheath 50 and/or outer guide channel member 80.

- 27 -

The temperature, total rise time, and dwell time for the heat shrink-outer layer-coil-inner layer-mandrel assembly will vary depending on many factors including, for instance, the actual melt bonding material that the outer layer 42 comprises, and also the diameter of the desired Flexor® sheath. For example, the baking parameters for a 2.5 French Flexor® sheath may be approximately 380 degrees Fahrenheit for about five minutes, while the baking parameters for a 4 French Flexor® sheath may be approximately 380 degrees Fahrenheit for about six minutes.

As an alternative to a Flexor® sheath, the outer sheath 50 may comprise a construction of multifilar material. Such multifilar material or tubing may be obtained, for example, from Asahi-Intec USA, Inc. (Newport Beach, California). Materials and methods of manufacturing a suitable multifilar tubing are described in Published United States Patent Application 2004/0116833 (Koto et al.) having an Application Serial No. 10/611,664 and entitled, "Wire-Stranded Hollow Coil Body, A Medical Equipment Made Therefrom and a Method of Making the Same," the contents of which are incorporated herein by reference. Use of multifilar tubing in a vascular catheter device, for instance, is described in United States Patent No. 6,589,227 (Sonderskov Klint, et al.; Assigned to Cook Incorporated of Bloomington, Indiana and William Cook Europe of Bjaeverskov, Denmark), which is also incorporated by reference.

In addition to the outer sheath 50, the middle section delivery device 14 further comprises an inner compression member 41. The delivery device 14 (and, thus, the outer sheath 50 and inner compression member 41) may be constructed to have any diameter and length required to fulfill its intended purposes.

The outer sheath 50, for instance, may be available in a variety of lengths, outer diameters, and inner diameters. In one embodiment, the outer sheath 50 may have a substantially uniform outer diameter in the range from approximately 2 French to approximately 7 French, and in one embodiment the diameter is from approximately 4 French to approximately 5 French in diameter. Otherwise stated, the outer sheath 50 may range from about 0.010 inches to about 0.090 inches in diameter, and in one embodiment the diameter is approximately 0.050 inches.

- 28 -

Likewise, the passageway 59 may be available in a variety of diameters. In one embodiment, the inner diameter ranges from about 0.032 inches to about 0.040 inches, and in a preferred embodiment the passageway 59 is approximately 0.032 inches. The diameter may be more or less than these examples, however, depending on the intended vessel passageway for the device. For instance, a larger vessel passageway (e.g., greater expandable inner diameter) may tolerate a bigger device with an outer sheath 50 having a correspondingly greater diameter. Conversely a narrower vessel passageway may require a thinner outer sheath 50. Likewise, the overall length may vary. In one embodiment, the outer sheath 50 will have a length from about 50.0 cm (or about 19.685 inches) to about 125.0 cm (or about 49.213 inches), and more particularly between about 70.0 cm (or about 27.559 inches) and about 105.0 cm (or about 41.339 inches), and in yet another embodiment the length is approximately 100.0 cm (or about 39.370 inches).

The inner compression member 41 comprises an elongated pusher bar, stiffening member, or stiff polymer that helps to "push" the stent by pushing the stent carrying inner guide channel member at or near the distal end 13 in order to counter the urge for the stent or stent carrying member to move as a result of an outer sheath or outer guide channel member being pulled over the stent; thereby "pushing" holds the stent in place at the desired deployment site within the patient's body. The inner compression member 41 "pushes" the stent by helping to prevent or minimize the inner guide channel member from prolapsing, recoiling, kinking, buckling, or moving; thereby keeping the inner guide channel member's stent platform on which the stent is disposed (discussed later) substantially stationary, for the most part, relative to the proximal retraction of the distal outer guide channel member (discussed below) that exposes and, thus, deploys the stent. The phrase "at or near" as used herein to describe an embodiment of the invention includes a location that is at, within, or a short distance such as about 0.1 cm to about 15.0 cm, although other ranges may apply, for instance from about 0.5 cm to about 10.0 cm.

The overall length of the inner compression member 41 may vary, as desired. In one embodiment the inner compression member 41 has a length from

- 29 -

about 50.0 cm to about 175.0 cm, and more particularly between about 75.0 cm and 150.0 cm, and in one embodiment the length is approximately 125.0 cm to about 140.0 cm. A portion of the inner compression member 41 (e.g., the proximal end 40 and/or middle section 40') may be contained within the handle 30 and the stylet 20, as explained above (Fig. 2).

Likewise, the diameter or width of the inner compression member 41 may vary. In one embodiment, the inner compression member 41 has a diameter or width ranging from about 0.010 inches to about 0.030 inches, by way of example only and not by way of limitation. In one embodiment, the inner compression member 41 has a diameter or width that is approximately 0.016 inches. The diameter or width may be more or less than these illustrative ranges. For example, a deeper target site within a patient may require a thicker inner compression member 41 for greater pushability, but may tolerate lesser flexibility. In addition, the material that the inner compression member 41 comprises determines whether a smaller and more flexible inner compression member 41 will give suitable flexibility, and also determines whether a wider inner compression member 41 may have the flexibility of a thinner inner compression member 41 made of different material. Furthermore, the inner compression member 41 may have a curved transverse cross-section, such as, for example, a circular cross-section, or it may have a polygonal cross-section, such as, for example, a rectangular cross-section. Alternatively, the transverse cross-section of the inner compression member may include both curved and straight portions. According to one embodiment, the inner compression member 41 may have a nonuniform diameter or width along its length. These various diameters, widths, and cross-sections may occur at the inner compression member proximal end 40, the inner compression member middle section 40', and/or the inner compression member distal mating end 48. The diameter, width, and/or cross-section of the inner compression member distal mating end 48 may taper.

Also, an inner compression member 41 may have an outer surface comprising a lubricious PTFE material and/or an inner surface 44 of the outer sheath 50 may comprise a lubricious PTFE material against the inner compression member 41, in order to allow easy retraction of the outer sheath 50, which is in

- 30 -

communication with a distal outer guide channel member to deploy a self-expanding stent, as will be explained later.

Generally, the inner compression member 41 and outer sheath 50 may optionally be approximately the same in length, and the axial length of coil 43 will be less than the length of the inner compression member and outer sheath. In one embodiment, however, the inner compression member 41 comprises a proximal end 40 that extends proximal relative to the outer sheath. In yet another embodiment, the inner compression member distal mating end 48 extends to a position that is distal the outer sheath. In still another embodiment, the inner compression member 41 stops short of extending all the way to the distal tip of the delivery system 10, and may stop generally from 10 to 40 cm short of the distal tip of the delivery system 10, and in one embodiment it stops approximately 20 to 25 cm short of the distal tip of the delivery system 10, where the distal end of the inner compression member 41 is operatively coupled to a proximal portion of an inner guide channel member.

SYSTEM DISTAL END 13

Now turning to embodiments of a distal end 13 of medical device delivery systems according to the invention, Figures 4, 5, 6, and 7 show the distal end 13 to be a relatively tubular body. Given the configuration of vessels, vessel passageways, a working channel of an endoscope, or an external accessory channel device used with an endoscope to be navigated, a mostly tubular distal end with a distal tapered, rounded, chamfered, or arrowhead shape may be better tolerated by the patient. Further, in certain embodiments, the distal portion of the distal end 13 may be soft, rounded, and flexible so as to provide further protection for and care to the patient.

Figure 4 illustrates an embodiment of the distal end 13 of a delivery system for the rapid insertion of self-expanding stents (for example) comprising an inner guide channel member 70, an outer guide channel member 80 axially slideable relative to the inner member 70, a self-expanding deployment device mounting region 90 (e.g., a stent mounting region), and a transition region 60. As used in connection with describing embodiments of the inner and outer guide channel members 70, 80,

- 31 -

respectively, the term "guide channel" is understood to be any aperture, bore, cavity, chamber, channel, duct, flow passage, lumen, opening, orifice, or passageway that facilitates the conveyance, evacuation, flow, movement, passage, regulation, or ventilation of fluids, gases, or a diagnostic, monitoring, scope, catheter, other instrument, or more particularly a wire guide (Fig. 6) or another component of the distal end (e.g., an inner member 70 relative to the outer member channel 81).

The distal end 13, according to the delivery system 10 and shown in Figures 4, 5, 6, and 7, may be made of any suitable material (natural, synthetic, plastic, rubber, metal, or combination thereof) that is rigid, strong, and resilient, although it should be understood that the material may also be pliable, elastic, and flexible. By way of illustration only and not by way of limitation, the distal end may comprise one or a combination of the following materials: metals and alloys such as nickel-titanium alloy ("nitinol") or medical grade stainless steel, and/or plastic and polymers such as polyether ether-ketone ("PEEK"), polytetrafluoroethylene (PTFE), nylon and/or a polyether block amide ("PEBA"), polyimide, polyurethane, cellulose acetate, cellulose nitrate, silicone, polyethylene terephthalate ("PET"), polyamide, polyester, polyorthoester, polyanhydride, polyether sulfone, polycarbonate, polypropylene, high molecular weight polyethylene, polytetrafluoroethylene, or mixtures or copolymers thereof, polylactic acid, polyglycolic acid or copolymers thereof, polycaprolactone, polyhydroxyalkanoate, polyhydroxy-butyrate valerate, polyhydroxy-butyrate valerate, or another polymer or suitable material. Where it will not contact the patient (e.g., it is contained within a sheath, working channel of an endoscope, or an external accessory channel device used with an endoscope), the middle section delivery device 14 and distal end 13 do not need to be biocompatible. In contrast, where there is the possibility of patient contact, the material may need to be biocompatible or capable of being made biocompatible, such as by coating, chemical treatment, or the like.

The inner and outer guide channel members 70, 80, respectively, may be made of any suitable material described above for use with the distal end 13. In one embodiment, the inner guide channel member 70 and the outer guide channel member 80 comprise PEEK material, which has the advantage of softening under

- 32 -

heat before burning or degrading. PEEK tubing may be purchased from many suppliers, such as Zeus, Inc. in Orangeburg, South Carolina for instance.

Beginning with the inner guide channel member 70, a description will follow relating to features common to embodiments of a distal end 13 of a delivery system 10 for the rapid insertion of "stents" according to the invention. The inner guide channel member 70 is generally tubular and comprises a first end 78 and a second end 77 defining a wire guide channel 71 therebetween. Optionally, the inner guide channel member 70 is configured to be slidably nested, fitted, secured, or otherwise positioned within the outer guide channel member 80 such that at least one of the inner guide channel member first or second ends 78, 77, respectively, is axially intermediate an outer guide channel member first end 88 and an outer guide channel member second end 87.

The first end 78 of the inner guide channel member 70 further comprises a wire guide entry port 72, and the second end 77 has a wire guide exit port 73. The entry and exit ports 72, 73, respectively, define and are in communication via the wire guide channel 71. A port, in describing an embodiment of an inner guide channel member 70 and an outer guide channel member 80 according to the invention, includes any structure that functions as an entry or exit aperture, cutout, gap, hole, opening, orifice, passage, passageway, port, or portal. The inner guide channel member entry port 72 is sized to receive a wire guide into the inner member guide channel 71, and the inner guide channel member 70 is configured so that the wire guide may exit proximally out the inner guide channel member exit port 73. Optionally, the exit port 73 is located at or near the transition region 60. In one embodiment of the present invention, the inner member 70 is a cannula (or catheter) having an entry port 72 and an exit port 73 as previously described and defining a guide channel 71 therebetween.

The inner guide channel member 70 further comprises an outer self-expanding deployment device mounting region 90 (e.g., an outer stent mounting region) positioned intermediate the inner guide channel member entry and exit ports 72, 73, respectively. The length of the inner guide channel member 70 of any of the embodiments of the present invention may vary generally from about 10.0 to about

- 33 -

40.0 cm. In one alternative embodiment, the length of the inner guide channel member 70 is approximately 15.0 to approximately 25.0 cm. In another embodiment, the length of the inner guide channel member 70 is approximately 20.0 cm. Also, the length of the inner guide channel member 70 may depend on the intended stent, and in another embodiment the length of the inner guide channel member 70 is approximately 15.0 cm for an 8.0 cm stent.

The inner guide channel member 70 further comprises inner and outer diameters. In one embodiment, both diameters are substantially uniform over the entire length of the inner guide channel member 70. By way of example, an internal diameter 74 might measure approximately 0.0205 inches at or near the inner guide channel member proximal second end 77, at or near the inner guide channel member distal first end 78, and intermediate the first and second ends 78, 77, respectively. Likewise, an inner guide channel member 70 might have an outer diameter 75 that measures approximately 0.0430 inches. Thus, the outer diameter 75 might measure approximately 0.0430 inches at or near the inner guide channel member proximal second end 77, at or near the inner guide channel member distal first end 78, and intermediate the first and second ends 78, 77.

In an alternative embodiment to an inner guide channel member 70 having a substantially uniform outer diameter 75 along its length from about the second end 77 to about the first end 78, the inner guide channel member may also comprise a tapered outer diameter 76. In one embodiment, the inner guide channel member tapers distally to a second outer diameter 76' at or near the inner guide channel member first end 78 or intermediate the inner guide channel member first and second ends 78, 77, respectively. The taper 76 has a decreased cross section, diameter, width, height, area, volume, thickness, and/or other configuration, shape, form, profile, structure, external outline, and/or contour relative to the outer diameter 75. In other words, the inner guide channel member second outer diameter 76' is smaller in cross section, diameter, width, height, area, volume, thickness, and/or other configuration, shape, form, profile, structure, external outline, and/or contour than the outer diameter 75.

- 34 -

Figure 4 further shows an optional atraumatic tip 170 coupled to the inner guide channel member first end 78. Extending distally from the inner guide channel member first end 78, the atraumatic tip 170 is tapered, rounded, chamfered, or arrowhead shape to be better tolerated by the patient. The atraumatic tip 170 comprises a distal first end 178 with a wire guide entry port 172 and a proximal second end 177 with a wire guide exit port 173, whereby the entry and exit ports define an atraumatic tip guide channel 171. The ports 172, 173 and channel 171 are sized to slideably receive a wire guide.

The atraumatic tip second end 177, as shown in Figure 4, may abut the outer guide channel member distal end 88 and, thereby, extend entirely distally beyond a distal opening 89 of the outer guide channel member first end 88. Optionally, the outer guide channel member distal opening 89 is spaced from the atraumatic tip 170 sufficient to allow delivery system to be flushed with saline that exits the distal end to remove air in order to help keep air out of the patient, as explained above. In the alternative and as shown in Figure 5, the atraumatic tip 170 may be configured to have a second end 177 that is beveled such that the atraumatic tip second end 172 is partially positioned within the outer member guide channel 81 and partially proximal to the outer guide channel member distal opening 89. The beveled design of the atraumatic tip second end 177 forms a proximal stop against the outer guide channel member distal opening 89 while permitting the atraumatic tip second end 177 to be partially slidably nested, fitted, secured, or otherwise positioned within the outer guide channel member first end 88 so that the outer guide channel member first end 88 overlaps the atraumatic tip 170 to form a suitable seal that substantially occludes passage of a wire guide between the atraumatic tip 170 and the distal opening 89 of the outer member first end 88 (Fig. 5). Furthermore, the atraumatic tip second end 177 comprises a stent distal restraint 93' as explained below.

In Figure 4, the outer guide channel member 80 also is generally tubular and comprises a first end 88 and a second end 87. The outer guide channel member 80 further comprises a wire guide entry port 82 proximal to the first end 88 and a proximal wire guide exit port 83 located at or near the second end 87. The entry and

- 35 -

exit ports, 82, 83, respectively, define a guide channel 81 of the outer guide channel member 80, wherein the ports 82, 83 and channel 81 are sized to slideably receive a wire guide. The entry port 82 is configured to receive a wire guide into the outer member guide channel 81, and in one embodiment, the entry port 82 is defined by the inner guide channel member exit port 73. In that embodiment, the wire guide moves proximally through the inner member guide channel 71 and egresses from the inner guide channel member exit port 73, wherein the proximal passage of the inner guide channel member exit port 73 is designated as the outer guide channel member wire guide entry port 82. The outer guide channel member proximal wire guide exit port 83 is configured so that a wire guide may egress proximally out the outer member exit port 83. In one embodiment, the outer guide channel member distal opening 89 and exit port 83 define the guide channel 81 therebetween.

In one embodiment, the Flexor® sheath, manufactured and sold by Cook Incorporated of Bloomington, Indiana, may be adapted for use with the distal end 13 and/or the middle section delivery device 14. Otherwise stated, the Flexor® sheath, as shown in Figure 3 and described above, may be provided for the distal end 13 and/or the middle section delivery device 14. For instance, the distal end 13 may be constructed as comprising an integral Flexor® sheath tube with the middle section delivery device 14. Alternatively, a Flexor® tubing may be used for either the middle section delivery device 14 or the distal end 13, or both. Then, the separable middle section delivery device 14 and distal end 13 may be attached, adjoined, joined, or combined as taught in the United States Provisional Patent Application filed on April 20, 2005 entitled, "Delivery System and Devices for the Rapid Insertion of Self-Expanding Devices" and having an application serial number 60/673,199, and the non-provisional application filed on April 20, 2006 by the same title and claiming the benefit of the filing date application serial number 60/673,199 under 35 U.S.C. §119(e), the disclosures of which are incorporated in its entirety, and/or the United States Provisional Patent Application filed on January 23, 2006 entitled, "Melt-Bonded Joint for Joining Sheaths Used in Medical Devices, and Methods of Forming the Melt-Bonded Joint" and having an application serial number 60/761,594, and the non-provisional application filed on April 20, 2006 by the same title and claiming the

- 36 -

benefit of the filing date application serial number 60/761,594 under 35 U.S.C. § 119(e), the disclosures of which are incorporated in its entirety.

The Flexor® sheath has a PTFE inner lining 44 that provides a slick, smooth surface for sliding the outer sheath 50 and/or the outer guide channel member 80 proximally. With regard to the distal end 13, the outer guide channel member 80 slides relative to the inner guide channel member 70, and the outer guide channel member inner surface 92 would be the inner layer 44 described above, thereby resulting in minimal friction to a stent 17 on the stent platform 91. The slidable inner surface 92 of the Flexor® sheath exhibits a second benefit of minimizing damage or misalignment to the stent. Indeed, because self-expanding stents continuously exert an expanding force against the inside surface 92 of the outer guide channel member 80, any substantial friction or drag between the stent and the inner surface 92 of the outer guide channel member 80 as the outer guide channel member 80 withdraws may damage the stent or cause the stent to be deployed slightly off of the target site.

The thin flat wire reinforcing coil 43 of the Flexor® sheath provides the outer guide channel member 80 with the necessary radial strength to constrain the stent over long periods of storage time. In contrast, where the inner surface 92 of an outer guide channel member 80 does not comprise the Flexor® sheath inner layer 44 or equivalent, the stent over time may tend to become imbedded in the inner surface 92 and, as a result, interfere with retraction of the outer guide channel member 80 at the time of deployment. In an outer guide channel member 80 that comprises a Flexor® sheath, in addition to the inner layer 44 and the reinforcing coil 43, the outer guide channel member 80 has a Flexor® sheath outer layer 42. The outer layer 42 comprises nylon, PEBA, and/or PEBAX to provide the necessary stiffness for pushability, retraction, and control of the outer member 80 to facilitate proper deployment of the constrained self-expanding stent. Therefore, the Flexor® sheath is one non-limiting example of an embodiment of an outer sheath 50 and/or an outer guide channel member 80.

While Figure 4 shows an outer guide channel member 80 having the exit port 83 proximal to the entry port 82 in one embodiment of the outer guide channel

- 37 -

member 80, the relative axial distances between the entry and exit ports 82, 83, respectively, vary when the outer guide channel member 80 is in a non-deployed state versus a deployed state, because the outer guide channel member 80 moves axially relative to the inner guide channel member 70. Otherwise stated, Figure 4 shows an embodiment where the exit port 83 is proximal to the entry port 82 in either a non-deployed stent position or in a deployed stent position. In a non-deployed stent position of another embodiment, however, the exit port 83 may be substantially co-planar to or aligned with the entry port 82. In the fully deployed stent position, the exit port 83 may likewise be proximal, co-planar, or aligned with the entry port 82. Optionally, the entry port 82 and exit port 83 are located at or near the transition region 60 to be discussed below.

Furthermore, the outer guide channel member 80 has a stepped 84, 85 profile, whereby the outer guide channel member 80 comprises a first outer diameter 84 intermediate the outer guide channel member first and second ends 88, 87, respectively, and a second smaller outer diameter 85 located at or near the outer guide channel member second end 87 in the vicinity of the transition region 60 and the breech position opening 65. The stepped 84, 85 profile includes an embodiment where the outer guide channel member 80 transitions to the distal end portion 58 of the outer sheath 50 of the middle section delivery device 14. In describing embodiments of the invention, however, the stepped 84, 85 profile shall be discussed in reference to the outer guide channel member 80 in particular, but it should be understood as including a stepped 84, 85 profile in reference to the transition region 60 of the distal end 13 relative to the middle section delivery device 14 where the middle section delivery device 14 and distal end 13 are formed from separate units such as, by way of example only and not by way of limitation, separate "Flexor®" sheaths where one comprises a first outer diameter 84 and the other comprises a second smaller outer diameter 85.

As shown in Figure 4, the second smaller outer diameter 85 of the outer guide channel member 80 is located proximal to the larger first outer diameter 84 and, thereby, comprises a stepped 84, 85 profile. Having a second smaller outer diameter 85 reduces the profile of the outer guide channel member 80 and/or the

- 38 -

outer guide channel member 80 transition to the middle section delivery device 14, which is advantageous in procedures involving narrow vessel passageways, endoscope working channels, or accessory channels for use with endoscopes. The difference in the first diameter 84 and the second diameter 85 may vary. By way of illustration, the second diameter 85 may be approximately one-fourth to approximately nine-tenths that of the first diameter 84. In another embodiment, the second diameter 85 may be about one-half that of the first diameter 84. In another embodiment, the first diameter 84 is roughly 5 French while the second diameter 85 is roughly 4 French.

In one embodiment of the stepped 84, 85 profile of the outer guide channel member 80, the second smaller outer diameter 85 is located at or near the outer guide channel member second end 87. The second end 87 may decrease precipitously from the first outer diameter 84 to the second smaller diameter 85. In a precipitous step, the change from the diameters occurs over a short length along the longitudinal axis of the distal end 13. In a further example of a precipitous step, the plane formed by the exit port 83 may be substantially perpendicular to the longitudinal axis of the outer guide channel member 80. In an alternative embodiment, the second end 87 may decrease gradually from the first outer diameter 84 to the second smaller diameter 85. In a gradual step, the change from the two diameters occurs over a length of more than 1.0 millimeter ("mm") along the longitudinal axis of the distal end 13 at or near the transition region 60 and breech position opening 65, and in one instance this change occurs over a length from about 1.0 mm to about 10.0 mm. In a further example of a gradual step, the plane formed by the exit port 83 may be at an angle other than 90 degrees relative to the longitudinal axis of the distal end 13.

Figure 4 also shows a breech position opening 65 located at or near the second end 87 of the outer guide channel member 80 comprising the wire guide exit port 83. In other words, rather than the exit port 83 being an aperture in a lateral sidewall of the outer guide channel member 80 intermediate the first and second ends 88, 87, respectively, in a breech position opening 65 embodiment the exit port 83 is at the rear, back, or proximal part of the distal end 13 at or near the outer

- 39 -

member second end 87 and the stepped 84, 85 profile such that it opens in the direction of the outer surface of the outer sheath 50.

The breech position opening 65 may be used for front-loading and the more common procedure of back-loading a wire guide (or catheter, for instance). In a back-loading procedure for a delivery system having a breech position opening 65, the wire guide may pass proximally through the guide channel 71 of the inner guide channel member 70, proximally through the guide channel 81 of the outer guide channel member 80, and leave the exit port 83 of the second end 87 of the outer guide channel member 80 from a breech position opening 65 in a rear, back, or proximal part of the distal end 13. Conversely, in a front-loading procedure for a delivery system having a breech position opening 65, the physician may feed the wire guide distally into a breech position opening 65 at the rear, back, or proximal part of the distal end 13 by entering the exit port 83 of the second end 87 and the guide channel 81 of the outer guide channel member 80 and through the guide channel 71 of the inner guide channel member 70, where the wire guide may exit from the wire guide entry port 72 of the inner guide channel member 70 and/or wire guide entry port 172 of the atraumatic tip 170.

In a distal end 13 having a breech position opening 65 that comprises an exit port 83 located at a breech position of the transition region 60 according to the invention, the wire guide does not need to make any sharp turns away from the longitudinal axis of the distal end 13 that may result in kinking of the wire guide. The breech position opening 65—comprising an exit port 83 according to embodiments of the invention, as those shown in Figures 4, 5, 6, and 7 by way of example and not by way of limitation—is located proximal to the inner guide channel member second end 77 and may be transverse or angled relative to the tubular distal end 13 longitudinal axis. In other words, the wire guide exit port 83 may be positioned at or near a breech position opening 65 of the distal end 13, wherein the exit port 83 is located at or near the rear, back, or proximal part of the outer guide channel member 80 and/or second end 87, rather than being positioned exclusively on the side (e.g., outer circumferential cylinder wall) of the outer guide channel member 80.

- 40 -

In Figure 4, the breech position opening 65 comprises an exit port 83 that is illustrated as being oblique, although other configurations of the exit port may be utilized to aid the wire guide in exiting the rear of the outer member. In one example, the exit port 83 may form a plane substantially perpendicular to the longitudinal axis of the outer guide channel member second end 87. In another example, the plane formed by the exit port 83 may be at an angle other than 90 degrees relative to the longitudinal axis of the distal end 13. Optionally, the oblique exit port 83 of a breech position opening 65 has lateral walls 83a, 83b that act as guide rails to direct a wire guide proximally toward the middle section delivery device 14 and to run along the outside of the outer sheath 50.

The overall axial length of the exit port 83 of the breech position opening 65 may vary. In one embodiment, the length is approximately from about 1.0 mm to about 10.0 mm. Another embodiment has a length of approximately 5.0 mm. The overall width of the exit port 83 may also vary. In one example, the width of the exit port is approximately 1 French. In yet another instance, the width of the exit port 83 ranges from about 1 French to about 4 French. In another example, the width of the exit port 83 may be the approximate difference between the first outer diameter 84 and the second outer diameter 85 of the outer guide channel member 80.

At the transition region 60, the exit port 73 of the inner guide channel member 70 is in communication with the outer guide channel member 80 wire guide entry port 82, while the second end 77 is operatively coupled to the distal mating end 48 of the inner guide channel member 70 as explained below. The length of the transition region 60 may vary. For instance, the transition region 60 may be approximately from about 0.5 cm to about 10.0 cm. In another embodiment, the transition region 60 has the approximate length of about 5.0 cm. Furthermore, the length of the transition region 60 is variable: from a shorter axial length when the outer guide channel member 80 is in a non-deployed axial position; to a greater axial length when the outer guide channel member 80 retracts proximally to deploy the stent. Likewise, the overall length of the transition region 60 varies in the embodiment where the exit port 83 is distal to the entry port 82 when the outer

- 41 -

guide channel member 80 is in a non-deployed stent position, compared to the initial length of the transition region 60 in an embodiment where the exit port 83 is proximal to the entry port 82 when the outer guide channel member 80 is in a non-deployed stent position.

In one use of the transition region 60 according to an embodiment of the invention, the outer guide channel member entry port 82 receives a wire guide from the inner guide channel member exit port 73 and the wire guide thereby is received in the outer member guide channel 81. At the transition region 60, the inner member guide channel 71 and outer member guide channel 81 are approximately aligned relatively coaxially in one embodiment. Approximate alignment of the guide channels 71, 81 facilitates a smooth transition of the wire guide. Smooth transition optimally reduces any bending of the wire guide as the wire guide moves proximally from the inner member guide channel 71 to the outer member guide channel 81.

As shown in Figure 4, the distal end 13 also comprises a self-expanding deployment device mounting region 90. This mounting region 90 may be used for implantable prosthesis such as expandable (self-expanding, balloon expandable, or otherwise expanding) and nonexpanding stents, prosthetic valve devices, and other implantable articles for placement inside a patient's body (the implantable prostheses being referred to individually and collectively as "stents" without limiting the invention) and therefore may be referred to as a stent mounting region to include the foregoing implantable prostheses.

The stent mounting region 90 comprises a stent platform 91 on an outside surface of the inner guide channel member 70 located at or near the inner guide channel member second end 78. In describing embodiments of the invention, the platform 91 "at or near" the inner guide channel member second end 78 includes a region intermediate the inner guide channel member entry port 72 and the inner guide channel member exit port 73. The platform 91 may be any stent mounting surface, including but not limited to the outside surface of the inner guide channel member 70, a recess, or an indentation located at or near the first end 78 of the inner guide channel member 70. In a non-deployed state, a self-expanding stent for example

- 42 -

(not shown) compresses against the stent platform 91 and disposes around the outside of the inner guide channel member 70.

The stent mounting region 90 controls the lateral movement (e.g., transverse expansion away from the inner guide channel member longitudinal axis) to avoid premature deployment of the stent. In order to control the lateral movement of the stent, the stent is sandwiched between the platform 91 on the inner surface of the stent and the inner surface 92 of the outer guide channel member 80 to keep the stent in a compressed state. Because the stent is bound from above by the inner surface 92 of the outer guide channel member 80 and bound from below by the platform 91 of the inner guide channel member 70, the stent mounting region 90 maintains the stent in a substantially compressed state and controls premature deployment of the stent.

In addition to controlling a stent's lateral movement, the stent mounting region 90 restrains the axial movement of a stent to control the stent movement away from the target site. A proximal restraint 93 controls proximal axial movement of the stent. In one embodiment, the proximal restraint 93 is sized to be large enough to make sufficient contact with the loaded proximal end of the stent without making frictional contact with the inner surface 92 of the outer guide channel member 80. In addition to helping to stop the stent's proximal movement in the non-deployed state, this restraint 93 assists with "pushing" the stent out of the distal end 13 by helping to prevent the inner guide channel member 70 and/or the stent disposed on the stent mounting region 90 from migrating proximally when the outer guide channel member 80 retracts proximally relative to the stationary inner guide channel member 70 in order to expose and deploy the stent. Optionally, the restraint 93 may be radiopaque so as to aid in stent positioning within the vessel passageway at or near the target site within a patient. In one embodiment, an optional distal restraint 93' is large enough to make sufficient contact with the loaded distal end of the stent to control axially distal movement of the stent. Similarly, in another embodiment the proximal second end 177 of an optional atraumatic tip 170 controls the stent's distal axial movement. Indeed, because the medical device delivery system may be used for deploying an implantable prosthesis that comprises balloon

- 43 -

expandable or non-expanding stents, prosthetic valve devices, and other implantable articles at a selected location inside a patient's body, the proximal restraint 93 and distal restraint 93' control the axial distal movement of the implantable prosthesis. Optionally, the distal restraint 93' and/or atraumatic tip 170 may comprise radiopaque materials so as to aid in stent positioning within the vessel passageway at or near the target site within a patient.

Figure 4 also illustrates that the inner compression member 41 and inner guide channel member second end 77 may be operatively coupled by any suitable means. In one embodiment, a melt bond 47 (described below) operatively couples an inner compression member distal mating end 48 ("mating end 48") and the second end 77 of the inner guide channel member 70. A melt bond 47 provides surface-to-surface contact between an outer engaging surface 48' of the mating end 48 and the inner guide channel second end 77, thereby forming a more solid connection between the inner compression member 41 and the inner guide channel member 70.

In one embodiment, the inner compression member outer engaging surface 48' may form a melt bond 47 to an inner surface 101 of the inner guide channel member second end 77. Alternatively, the inner compression member outer engaging surface 48' may form a melt bond 47 to the outer surface 102 of the inner guide channel second end 77. In yet another embodiment, the distal mating end 48 of a solid inner compression member 41 as shown in Figure 4 is implanted 49 between (and/or melt bonded 47 between) inner and outer surfaces 101, 102, respectively, of the inner guide channel member second end 77, as taught in United States Provisional Patent Application filed on January 23, 2006 entitled, "Internal Joint for Medical Devices, and Methods of Making the Internal Joint," and having an application serial number 60/761,313, and the non-provisional application filed on April 20, 2006 by the same title and claiming the benefit of the filing date application serial number 60/761,313 under 35 U.S.C. §119(e), the disclosures of which are incorporated in their entireties. In still another embodiment, an insert body operatively couples the inner compression member 41 and the second end inner guide channel member 70, as taught in United States Provisional Patent Application

- 44 -

filed on January 23, 2006 entitled, "Internal Cannulated Joint for Medical Delivery Systems," and having an application serial number 60/761,565, and the non-provisional application filed on April 20, 2006 by the same title and claiming the benefit of the filing date application serial number 60/761,565 under 35 U.S.C. §119(e), the disclosures of which are incorporated in its entirety.

As used to describe an embodiment of the invention, melt bonding 47 (for shorthand purposes in describing embodiments according to the invention, melt bonding 47 includes implanting 49) comprises any suitable means for for melting, liquefying, softening, making semi-molten, molten, fusing, or making malleable, pliant, supple, moldable, ductile, or otherwise penetrable by another component or fused to melt bonding material comprising the other element. For instance, melt bonding 47 involves bringing two components together at an interface, wherein one (or preferably both) of the component interfaces are in the melted state. Strictly speaking, true melt bonding 47 requires that both of the components be melted at the interface and that they may be sufficiently chemically and physically compatible such that they fuse together upon cooling.

The melt bonding materials comprising the two components may be the same or substantially same materials. In the alternative, the melt bonding materials may be different, so long as they have substantially similar melting points at standard atmospheric pressure such that the materials soften (or liquefy) under heat and thereby fuse together in a solid state melt bond 47 joining the first and second melt bonding materials of the components. If the materials had melting points that were too different, then one material may degrade or burn and the like before the second material begins to melt.

Melt bonding 47 may be single layer interface whereby one component interface/surface mates to a second component interface/surface, or may be multi-layer interface whereby one component is implanted 49 into a second component and then surrounded by the second component. The chemical compatibility can best be expressed in terms of having similar values for surface energy and/or solubility parameter. In simple terms, similar materials tend to have a mutual affinity and a greater propensity to adhere to one another than do dissimilar materials. Melt

- 45 -

bonding includes bonding whereby one component is melted while the other component is at or above its melting point.

Melt bonding materials may have different "melt bonding" temperatures at which they soften and become almost tacky without substantial degradation. Melt bonding materials are available from vendors, including Zeus, Inc. in Orangeburg, South Carolina for instance; Cobalt Polymers in Cloverdale, California; and under the trade name of PEBAX® PEBA from the Arkema Group. The melt bonding materials may include one or a combination of a class of suitable materials comprising nylon, nylon natural tubing, polyether block amide, polyetheretherketone, thermoplastic, acrylonitrile-butadiene-styrene copolymer, polypropylene, polyamide, ionomer, polycarbonate, polyphenylene oxide, polyphenylene sulphide, acrylic, liquid crystal polymer, polyolefin, polyethylene acrylate acid, polyvinylidene fluoride, polyvinyl, and polyvinyl chloride.

In one embodiment, PEEK material is used for the melt bonding material. PEEK melts at about 633°F, so the material may be heated from about 628°F to about 638°F. For instance, a radiofrequency loop heater may be used for heating the melt bonding materials. Such a machine is available from Magnaforce, Incorporated and sold under the name and model Heatstation 1500. Another such machine is available from Cath-Tip, Inc. and is sold under the model and name Cath-Tip II. There is a rise dwell and cool down time for the process. The total rise time is approximately 20 seconds and dwell time is approximately 10 seconds. During the dwell time the temperature is approximately 600°F. In one embodiment where nylon, PEBA, or PEBAX are used, heating is at about 400°F, with dwell time of about 10 seconds.

Figures 4A and 4B present a schematic representation of a cross section 105 of components before and after melt bonding according to one embodiment of the invention. The cross section 105 of Figure 4A, for example, represents an inner component 106, a middle component 107, and an outer component 108. While all components are shown having interfaces in abutting physical contact, they need only be close enough to form a melt bond therebetween. Indeed, as previously explained in connection with the Flexor® sheath's outer layer 42 and inner layer 44, there may

- 46 -

even be a middle layer comprising a coil 43 having spacings 43' through which the melt bonding material of the outer layer 42 may move to be into contact with the inner layer 44.

In the example represented in Figure 4A, the middle and outer components 107, 108, respectively, are intended to be melt bonded. The middle component 107 comprises a first melt bonding material 109 while the outer component 108 comprises a second melt bonding material 109', which may be the same material or may be separate materials that have similar melting points at atmospheric pressure.

Figure 4B shows some of the first melt bonding material 109 of the middle component 107 moving into some of the second melt bonding material 109' of the outer component 108. Likewise, some of the second melt bonding material 109' of the outer component 108 moves into some of the first melt bonding material 109 of the middle component 107. It should be noted that both of the first and second materials 109, 109' need not move into the other. Rather, the first and second materials 109, 109' need only bond at an interface, with or without mixing and the like. By way of example, the Flexor® sheath's outer layer 42 may melt to the middle layer coil 43 (which has not melted) and bond to the outer surface of the inner layer 44 with or without the outer surface of the inner layer 44 melting into the outer layer 42.

Figure 4B further shows that the first and second melt bonding materials 109, 109', respectively, of the middle component 107 and the outer component 108 or other components that have been melt bonded, upon cooling to solid state will form a melt bond 47 operatively coupling the components and/or the melt bonding materials that comprise the components. This results in additional strength and helps to form a more solid connection to the melt bonded components, because a solid-state bond results from using a suitable form of heat for melting and solidifying (e.g., fusing and/or cross-linking bonds formed at the melt bonded material interfaces).

Figure 5 illustrates a schematic view showing an alternative embodiment of a distal end 13 of a delivery system for the rapid insertion of stents comprising an inner guide channel member 70, an outer guide channel member 80 axially slideable relative to the inner member 70, a deployment device mounting region 90 (e.g., a

- 47 -

stent mounting region), and a transition region 60. Like elements from the previous drawings, embodiments, and description from above are labeled the same. In this embodiment, the inner compression member 41 optionally comprises a passageway 45 (e.g., hollow, having a lumen) that facilitates the conveyance, ventilation, flow, movement, blockage, evacuation, or regulation of medication and/or fluids or accommodates the insertion of a diagnostic, monitoring, scope, or other instrument.

The tubular inner compression member 41 may have a uniform inside diameter ranging from about 0.0527 to about 0.132 inches. The wall thickness of the tubular inner compression member 41 is approximately 0.0015 inch. These dimensions are illustrative only, and the inner diameter and wall thickness may be constructed to be of any size necessary to accomplish the purposes for which the delivery system is to be employed (i.e., limited by the vessel passageway or working channel in which the device is to be used).

In addition, this inner compression member 41 has an optional distal one-way valve 61. Thus, the valve 61 may serve a dual function. First, a one-way valve is relatively resistant to contamination from bodily fluids entering the inner compression member passageway 45. Second, it allows the movement of medication and/or fluids to exit distally the inner compression member 41 passageway 45 at or near the transition region 60 and may direct medication and/or fluids into the inner member guide channel 71 and/or the outer member guide channel 81.

Indeed, the inner compression member passageway 45 may facilitate using the medical device delivery system for deploying an implantable prosthesis that comprise balloon expandable stents, prosthetic valve devices, and other implantable articles (individually and collectively, "stent") at a selected location inside a patient's body. The stent is disposed at the deployment device mounting region 90 intermediate the proximal restraint 93 and distal restraint 93' to control the axial distal movement of the implantable prosthesis.

In one embodiment for using the delivery system with a balloon expandable implantable prosthesis, the inner compression member distal mating end engaging surface 48' operatively couples to the inner guide channel member outer

- 48 -

surface 102 (or is welded to an outer surface of a metal cannula that has the inner guide channel member second end 77 glued within the cannula lumen), and an inflation member (e.g., a balloon) extends distally from the inner compression member distal mating end and is disposed over the proximal restraint 93 and distally about the platform 91 of the stent mounting region 90 such that the balloon is located under the stent. The stent is positioned within the vessel passageway at or near the target site within a patient, wherein the outer sheath 50 and outer guide channel member 80 is axially slideable relative to the inner compression member 41 and inner guide channel member 70 upon corresponding axial slideable movement of the handle 30, thereby exposing and, ultimately, deploying the stent from the stent mounting region 90. The stylet 20 may be adapted to receive a syringe for allowing inflation fluid, such as saline, to travel from and through the proximal end 40 of the inner compression member 41 and out the valve 61 at the distal end 48 in order to fill the inflation chamber of the balloon. Therefore, balloon expands under the stent and, as a result, the stent expands radially to plastically deform the stent into a substantially permanent expanded condition. The physician then deflates the balloon and removes the inner guide channel member 70 and remainder of the delivery system from the patient's body. This description of using the delivery system for balloon expandable implantable prosthesis is given by way of example and not by way of limitation. Alternatively, a tubular inflation fluid carrying device is in the outer sheath passageway 59 and extends from the system proximal end 12 to the system distal end 13 and operatively couples to an inflation member disposed under the stent.

In one embodiment of the distal end 13 of a delivery system illustrated in Figure 5, an internal joint 46 comprises a melt bond 47 that operatively couples the inner guide channel member distal mating end 48 and the second end 77 of the inner guide channel member 70. For example, the inner compression member outer engaging surface 48' may form a melt bond 47 to the inner surface 101 (or alternatively to the outer surface 102) of the inner guide channel member second end 77, as taught above.

- 49 -

The embodiment shown in Figure 5 also illustrates that the exit ports 83 and 73 may have various configurations. First, these exit ports curve, and second, compared to Figure 4 they slope over a longer overall axial length to aid the wire guide in exiting the inner member and outer member, respectively. Furthermore, the exit port 83 thereby has longer axial lateral walls 83a, 83b for acting as guide rails to direct a wire guide proximally toward the middle section 14 and to run along the outside of the outer sheath 50.

Moving to the atraumatic tip 170 as illustrated in Figure 5, this is a little less arrowhead-shaped compared to the atraumatic tip 170 shown in Figure 4. Instead, the atraumatic tip in Figure 5 has a second end 177 that comprises a right cylindrical tubular configuration. Furthermore, the sides of the atraumatic tip second end 177 are more uniformly parallel and do not form a proximal stop against the outer guide channel member distal opening 89 as in a beveled embodiment of the atraumatic tip second end 177 as illustrated in Figure 4. The atraumatic tip second end 177 optionally comprises a stent distal restraint 93' for controlling distal axial movement of the implantable prosthesis when the medical device delivery system is used for deploying balloon expandable or non-expanding stents, prosthetic valve devices, and other implantable articles at a selected location inside a patient's body.

Turning now to Figure 6, that figure shows a partially sectioned distal end 13 in accordance with an embodiment of the device according to Figure 5 with a wire guide 16 inserted therein. In a back-loading procedure, the wire guide 16 enters the guide channel 171 of the atraumatic tip 170 and travels proximally toward the inner guide channel member 70. The wire guide 16 then enters the inner member guide channel 71 and travels proximally toward the outer guide channel member 80 via the entry port 82 and enters the outer member guide channel 81 and out the exit port 83. The less common front-loading procedure could be described as above but conversely stated.

In Figure 6, the inner and outer guide channels 71, 81, respectively, are substantially aligned coaxially along an approximate center longitudinal axis of the distal end 13. Because the channels 71, 81 are substantially aligned, the wire guide 16 moves through the inner member guide channel 71 to the outer member guide

- 50 -

channel 81 and out the outer guide channel member exit port 83 at or near the breech position opening 65 with relatively little kinking, bending, buckling, or bowing. It should be noted that for the ease of showing the wire guide 16, the wire guide 16 proximal to the exit port 83 is shown slightly offset from outer sheath 50, though the wire guide 16 may actually run along the outside of the outer sheath 50 or in a groove (not shown) in the outer sheath 50.

Figure 7 illustrates a longitudinally sectioned side view showing an alternative embodiment of a distal end 13 of a delivery system for the rapid insertion of stents comprising an inner guide channel member 70, an outer guide channel member 80 axially slideable relative to the inner member 70, a deployment device mounting region 90 (e.g., a stent mounting region), and a transition region 60. Like elements from the previous drawings, embodiments, and description from above are labeled the same. This embodiment represents an alternative embodiment of a joint 46 for operatively coupling the inner compression member 41 and inner guide channel member 70 with a cannula 95.

In one embodiment, the cannula 95 is a hollow, rigid tube, cylinder, ring, cannula (with or without a trocar), or other coupling device comprising metal such as medical grade stainless steel or super-elastic alloys (e.g., nitinol) to name but a few non-limiting examples. In one embodiment, the cannula 95 comprises a generally right cylindrical configuration or is elliptical, hyperbolic, parabolic, curved, polygonal, rectangular, or irregular in shape or cross section. The cannula 95 is sized for receiving the inner guide channel second end 77 and/or the inner guide channel second end outer diameter 75. The outer surface 102 of the inner guide channel second end 77 is operatively coupled to an inner engaging surface of the securing body 95 by glue, adhesives, resins, chemical bonding materials or combinations thereof and the like (collectively and individually, "glue"). By way of example only, the glue may be Loctite 4061 instant adhesive, formulated to polymerise rapidly in thin films between two surfaces to form rigid thermoplastics. Loctite 4061 instant adhesive is a medical device adhesive particularly suitable for a wide variety of substrates such as rubber, plastics, and metals, and it is available from the Loctite Corporation.

- 51 -

In addition to securing the outer surface 102 of the inner guide channel member second end 77 to an inner engaging surface of the cannula 95, the cannula 95 also operatively couples the inner guide channel member distal mating end 48. An outer engaging surface 48' of the mating end 48 is in an abutting relationship (e.g., touching, in contact directly or by intervening parts, or adjacent) to an outer engaging surface of the cannula 95, and the mating end 48 and cannula 95 are operatively coupled by any suitable means, including but not limiting to welding, soldering, brazing, or fusing. Soldering and brazing are used if a semi-permanent connection between the distal mating end 48 and the cannula 95 is desired, because solder or braze metals have a lower melting point than the metals that are joined. Thus, when sufficient heat is applied to melt the solder or braze metal, they form an alloy with the surfaces of the mating end 48 and the cannula 95 and, upon solidification, thus form a joint that can be unfastened during manufacturing (e.g., to redo in the event of a poor connection) by reheating without destroying the parts that have been joined. In contrast, welding involves melting the outer engaging surface 48' of the mating end 48 and an outer engaging surface of the cannula 95 at the interface, or involves combining temperature and pressure so as to cause localized coalescence. Consequently, in most instances higher temperatures are involved than for soldering, and the union is permanent.

Where the inner compression member distal mating end 48 and the cannula 95 are connected, an optional tube may be disposed about the joint 46. The tubing has the advantage of minimizing some of the sharp edges created by a welded, soldered, or fused joint. In one embodiment, the tube is a melt bonding tube disposed about and melt bonded to the joint 46. Whereas Figure 7 shows the distal most tip of the distal mating end 48 flush with (e.g., substantially co-planar) the distal end of the cannula 95, it may alternatively be set back approximately 0.5 mm proximally from the distal end of the cannula 95. The set back arrangement allows solder, weld, or fusion to form a smooth transition and fill the space between that distal end tip and the cannula 95. This would also minimize the profile compared to placing more of a circumferential solder, weld, or fusion about the joint.

- 52 -

According to Figures 7, 7A, 7B, and 7C, the distal mating end 48 comprises a contoured configuration 48" that is complementary to an outer engaging surface 95' of the cannula 95. Thus, in an embodiment comprising a cannula 95 that is curved or otherwise circular in cross-section, then Figure 7A shows that the contoured configuration 48" is fluted so that the outer engaging surface 48' is capable of being in an abutting relationship (e.g., touching, in contact directly or by intervening parts, or adjacent) relative to a curved or circular outer engaging surface 95' of the cannula 95. A fluted contoured configuration 48" comprises any curved, shoehorn shape, celery shape, semicircular shape, crescent shape, wishbone shape, saddle shape, C-shaped, V-shaped, U-shaped, or other arcuate configuration. In another embodiment, an outer engaging surface 95' of the cannula 95 could have a flat portion, and Figure 7B shows that the contoured configuration 48" is likewise flat so that the outer engaging surface 48' is capable of being in an abutting relationship (e.g., touching, in contact directly or by intervening parts, or adjacent) relative to the flat portion of the outer engaging surface of the cannula 95. Even when the outer engaging surface 95' of the cannula 95 is curved or circular in cross section, however, Figure 7C shows that the inner compression member contoured configuration 48" could be flat, because the soldering, brazing, or fusing may fill in the space between the outer engaging surface 48' and a tangent that the flat configuration 48" forms to the curved portion of the outer surface 95' of the cannula 95. Similarly, if welding 96 is used, then the flat configuration 48" will form to a curved or circular outer engaging surface 95' of the cannula 95.

In addition, the contoured configuration 48" maintains low profile, high-strength, and flexibility of the connection between the inner compression member distal mating end 48 and the cannula 95. The contoured configuration 48" is in contrast to a rounded inner compression member distal mating end 48, which would have a greater diameter at the connection between the inner compression member distal mating end 48 and the cannula 95.

In order to create the contoured configuration 48", the inner compression member distal mating end 48 may be formed, sheared, casted, or molded. By way of example only, forming can be done both hot and cold (except for stamping, which

- 53 -

is always done cold) in order to modify the shape and/or physical properties of the material comprising the inner compression member distal mating end 48. Common forming processes include rolling the distal mating end 48 (between one or two rollers), stretching, forging, straight bending, and stamping.

Additional embodiments of the joint 46, cannula 95, and inner compression member distal mating end 48 comprising a contoured configuration 48" are described in the United States Patent Application filed on April 20, 2006 entitled, "Joint for Operatively Coupling a Contoured Inner Compression Member and an Inner Guide Channel Member for Medical Device Delivery Systems" and having a client reference number PA-5930-RFB, and attorney docket number 8627/1355, the disclosure of which is incorporated in its entirety.

TAPERED INNER COMPRESSION MEMBER

Turning to Figure 8, a schematic perspective side view of an elongate inner compression member 41 according to an embodiment of the invention is shown, whereby like elements from the previous drawings, embodiments, and description from above are labeled the same. The inner compression member 41 may have dimensions (e.g., diameters, lengths) as previously described. Similarly, the inner compression member 41 may comprise materials as previously described.

In one embodiment, the inner compression member 41 comprises a proximal end 40, an optional middle section 40', and a distal mating end 48. The distal mating end 48 is located distal to an inner compression member first portion 41'. The inner compression member first portion 41' has a cross section shown along the line 8A-8A (Fig. 8A). The distal mating end 48 comprises a tapered portion 51 having a cross section shown along the line 8B-8B (Fig. 8B). In one embodiment, the tapered portion 51 tapers to the distal tip of the distal mating end 48. In an alternative embodiment of the invention, the distal mating end 48 further comprises an inner compression member distal mating end second portion 51' having a cross section shown along the lines 8C-8C, 8D-8D, 8E-8E, 8F-8F (Figs. 8C, 8D, 8E, 8F), whereby the tapered portion 51 tapers distally to a position at or near the second portion 51'. The inner compression member distal mating end 48 further comprises an outer engaging surface 48' disposed on the tapered portion 51 in an embodiment,

- 54 -

on the optional inner compression member distal mating end second portion 51', or at least partially on both the tapered portion 51 and the second portion 51' of the distal mating end 48.

The terms "tapering," "taper," "tapered," "tapers," and variations thereof describe embodiments of the invention, rather than to provide any lexicographic definitions. The inner compression member 41 may taper over a partial length (or in another embodiment over the entire length) of the inner compression member distal mating end 48 in a variety of ways. By way of example only and not by way of limitation, a distal mating end tapered portion 51 when compared to an inner compression member first portion 41' has a decreased, reduced, lesser, and/or smaller (individually and collectively, hereafter "smaller") cross sectional area, mean diameter, perimeter, volume over a given length, thickness in height and width, and/or other smaller configuration, shape, form, profile, structure, external outline, and/or contour (individually and collectively, "cross sectional area") during manufacturing, processing, molding, casting, forming, extruding, drawing, or as a result of post-manufacture machining, stretching, bending, forging, stamping, grinding, cutting, sawing, shearing, trimming, piercing, chipping, drilling, milling, shaping, planing, boring, reaming, abrading, swaging, laser, and/or any combination thereof or equivalents thereto. Similarly, the distal mating end second portion 51' has a smaller cross sectional area relative to the tapered portion 51.

The tapered portion 51 may taper to the distal tip of the inner compression member distal mating end 48. In one embodiment, the tapered portion 51 tapers to a uniform cross sectional area of the distal mating end 48. For example, the tapered portion 51 may taper to a distal mating end second portion 51' having a generally uniform cross sectional area. In an alternative embodiment, the cross sectional area of the distal mating end 48 might even increase somewhere along the length of the distal mating end 48, as when the tapered portion 51 tapers to a flare, barb, ridge, protrusion, or other configuration formed integrally with, or operatively coupled to, the distal mating end 48. Furthermore, the mating end 48 may comprise more than one tapered portion 51.

- 55 -

The overall length of the distal mating end 48 may vary. In one embodiment, it is from about 1.0 mm to about 10.0 mm. In another embodiment, it is approximately 3.0 mm. Also, the length of the distal mating end tapered portion 51 may vary, and the length of the distal mating end second portion 51' also may vary. In one embodiment, the distal mating end tapered portion 51 is from about 0.1 mm to about 5.0 mm in length, and in another embodiment it is approximately 0.5 mm in length. The distal mating end second portion 51' may vary from about 0.5 mm to about 5.0 mm in length, and in another embodiment it is approximately 2.5 mm in length. The tapered portion 51, second portion 51', and distal mating end 48 may be greater or less than these illustrative lengths.

The diameter or thickness of the inner compression member first portion 41' and the inner compression member distal mating end 48 also may vary. In one embodiment, the inner compression member first portion 41' has a diameter or thickness ranging from about 0.020 inches to about 0.030 inches, by way of example only and not by way of limitation. In another embodiment, the inner compression member first portion 41' has a diameter or thickness that is approximately 0.024 inches. In one embodiment, the distal mating end as may portion 51 has a diameter or thickness ranging from about 0.010 inches to about 0.020 inches, by way of example only and not by way of limitation. In another embodiment, the distal mating end tapered portion 51 has a diameter or thickness that is approximately 0.016 inches. In one embodiment, the distal mating end second portion 51' has an outer diameter or thickness of approximately 0.008 inches. The diameters and thicknesses may be more or less than these illustrative ranges, and obviously the tapered portion has a variable diameter or thickness.

The distal mating end outer engaging surface 48' may extend a partial length (or in another embodiment over the entire length) of the distal mating end 48. In one embodiment, the distal mating end outer engaging surface 48' is located along a portion of the distal mating end tapered portion 51, or in another embodiment over the entire distal mating end tapering portion 51. In another embodiment, the distal mating end outer engaging surface 48' is located along a portion of the distal mating

- 56 -

end second portion 51', or in another embodiment over the entire distal mating end second portion 51'.

By outer engaging surface 48', it should be understood to comprise the outer perimeter and/or surface area (regularly or irregularly shaped, textured, or treated) as well as any coating comprising a substance, compound, molecule, or material (whether comprising a solid, liquid, fluid, gel, gas, or vapor) chemically bonded via covalent bonds, ionic bonds, or intermolecular bonds (such as ion-dipole forces, dipole-dipole forces, London dispersion forces, and/or hydrogen bonding), adhered, or otherwise applied by the method(s) of laminating, taping, dipping, spraying, depositing, vapor deposition, wrapping (thermally fusing together), painting and curing, and the like. In addition, mechanical or chemical etching, sandblasting, laser-cutting, machining, milling, drilling, chemically treating, or otherwise preparing the outer engaging surface 48' of the mating end 48 may be used to improve the bonding properties of the outer engaging surface 48'.

Figure 8A shows a cross sectional area of one embodiment of the inner compression member first portion 41' taken along the line 8A-8A. The inner compression member first portion 41' is located proximal to the distal mating end 48. In one embodiment, the inner compression member first portion 41' has an outer diameter or thickness of approximately 0.024 inches, although it could be greater or lesser than this embodiment.

Figure 8B, by comparison, shows a cross sectional area of one embodiment of the distal mating end tapered portion 51 taken along the line 8B-8B, which tapered portion 51 has a smaller cross sectional area than the cross sectional area of the inner compression member first portion 41' (Fig. 8A). It should be noted that, while Figure 8B shows a cross section having uniform radially inward taper (e.g., a two-sided beveled structure, or working end of a regular screwdriver), Figure 8B could be shown with only the lower taper or only an upper taper (e.g., Fig. 7 configuration illustrated by distal mating end 48). Also, while the outer engaging surface 48' is shown just once at the upper portion of Figure 8B, it could be shown at the lower portion or both the upper and lower portions (e.g., Fig. 9F), and the same would be true for the other figures showing an outer engaging surface 48'

(e.g., Fig. 8C-8E, 9C, 9E). In one embodiment, the distal mating end tapered portion 51 has an outer diameter from the upper to lower portion or thickness of approximately 0.016 inches, although it could be greater or lesser than this embodiment.

Figures 8C, 8D, 8E, and 8F by further comparison, show cross sectional areas of embodiments of the distal mating end second portion 51' taken along the lines 8C-8C, 8D-8D, 8E-8E, and 8F-8F, which second portions 51' have smaller cross sectional areas than the cross sectional area of the tapered portion 51 (Fig. 8B). Figure 8C comprises a generally fluted shape. Figure 8D comprises a curved segment with a flat engaging surface 48'. Figure 8E comprises a generally flat shape. Figure 8F comprises a generally crescent shape. In one embodiment, the distal mating end second portion 51' has an outer diameter or thickness of approximately 0.008 inches, although it could be greater or lesser than this embodiment.

Figures 9A through 9F show various embodiments of an inner compression member 41 having an inner compression member first portion 41' and further comprising a distal mating end 48. The distal mating end 48 comprises a tapered portion 51, an outer engaging surface 48', and an optional second portion 51'.

Figure 9A shows that the inner compression member distal mating end 48 can have a uniform distally tapered portion 51 that is roughly cylindrical in shape and ground with a rough finish, although in another embodiment the surface need not be roughed up. As shown, the first portion 41' has one cross sectional area and the distal mating end 48 has a smaller cross sectional area as a result of a step down to the distally tapered portion 51. In one embodiment, the tapered portion 51 is substantially constant in cross sectional area, albeit it may be rough and uneven at places, over the length of the mating end 48. The tapered portion 51 optionally extends the entire length of the distal mating end 48. The tapered portion 51 of Figure 9A may be easily manufactured by holding the mating end 48 up to a grinder and then rotatably grinding the outer circumference down a substantially fixed distance.

- 58 -

Some or all of the distal mating end 48 of Figure 9A may be implanted into the proximal second end 77 of the inner guide channel member 70, wherein the mating end 48 according to this embodiment is easily aligned for pushing into inner guide channel member second end 77 such that the mating end 48 is substantially equally positioned between a second end inner surface 101 and a second end outer surface 102 (Figure 10, and discussion below). Alternatively, some or all of the distal mating end 48 and may be welded, soldered, brazed, or otherwise fused, bonded, or glued either to an outer engaging surface 95' of the cannula 95 (Figs. 7, 7A)

Figure 9B shows that the inner compression member distal mating end 48 can have a distally tapered portion 51 that is rounded, like the writing end of a wooden pencil or a candle by way of schematic examples only and not by way of limitation. In other words, the first portion 41' is greater in cross sectional area than the cross sectional area of the tapered portion 51, because the tapered portion 51 gradually tapers distally such that the outer diameter and cross section get smaller and smaller, albeit allowing for rough and uneven surfaces, over the length of the mating end 48. The tapered portion 51 optionally extends the entire length of the distal mating end 48. This tapered portion 51 may be easily manufactured by holding the mating end 48 up to a grinder at an angle and then rotatably grinding the outer circumference down a substantially fixed distance. For reasons similar to the mating end 48 according to Figure 9A, the distal mating end 48 according to Figure 9B is easily aligned between inner and outer surfaces 101, 102, respectively, of the inner member second end 77 during implantation, and alternatively some or all of the distal mating end 48 may be welded, soldered, brazed, or otherwise fused, bonded, or glued either to an outer engaging surface 95' of the cannula 95 (Figs. 7, 7A) or to one of the second end inner or outer surface 101, 102, respectively, of the inner guide channel member second end 77 shown in Figures 4, 5, and 7.

Figure 9C shows that the inner compression member distal mating end 48 can have a one-sided beveled outer engaging surface 48'. The first portion 41' has a greater cross sectional area than a distally tapered portion 51, because the tapered portion 51 of the distal mating end 48 gradually tapers distally such that the cross

- 59 -

section gets smaller and smaller, albeit allowing for rough and uneven surfaces, over the length of the mating end 48. This tapered portion 51 may be achieved by swaging or stamping, for example. The tapered portion 51 optionally extends the entire length of the distal mating end 48. In one embodiment, the distal mating end 48 can have a two-sided beveled outer engaging surface 48' (like a working end of a regular screw driver by way of schematic example). During implanting of some or all of the distal mating end 48 into the inner member second end 77, the beveled outer engaging surface 48' of the distal mating end 48 according to Figure 9C optionally is aligned directionally toward the second end inner surface 101 or the second end outer surface 102 (Figs. 4, 5, 7), or aligned directionally toward the outer engaging surface 95' of the cannula 95 (Figs. 7, 7A).

Figure 9D shows that the inner compression member distal mating end 48 can have a distally tapered portion 51 that is dish shaped along the length of the distal mating end 48. In other words, the first portion 41' has a greater cross section than the gradually tapered portion 51 of the distal mating end 48. The sloping portion 51 optionally extends the entire length of the distal mating end 48. This tapered portion 51 may be easily manufactured by grinding, machining, and the like. During implanting of some or all of the distal mating end 48 into the inner member second end 77, the beveled mating surface 48' according to Figure 8D optionally is aligned directionally toward the second end inner surface 101 or the second end outer surface 102 (Figs. 4, 5, 7), or aligned directionally toward the outer engaging surface 95' of the cannula 95 (Figs. 7, 7A).

Figure 9E shows an embodiment of an inner compression member 41 comprising a first portion 41' having a greater cross section than the cross section of a tapered portion 51 of a distal mating end 48. In Figure 9E, the tapered portion 51 tapers distally to a position at or near the second portion 51'. The second portion 51' is fluted, whereby fluted comprises any curved, shoehorn shape, celery shape, round, circular, semicircular shape, crescent shape, wishbone shape, saddle shape, C-shaped, V-shaped, U-shaped, or an arcuate configuration that curves radially inward or curves radially outward. One or both of the second portion 51' and tapered portion 51 of a distal mating end 48 may be easily manufactured by

- 60 -

stamping, swaging, milling, and the like. During implanting of some or all of the distal mating end 48 into the inner member second end 77, the outer engaging surface 48' according to Figure 9E optionally is aligned directionally toward the second end inner surface 101 or the second end outer surface 102 (Figs. 4, 5, 7), or aligned directionally toward the outer engaging surface 95' of the cannula 95 (Figs. 7, 7A).

Figure 9F shows an embodiment of an inner compression member 41 comprising a first portion 41' having a greater cross section than the cross section of a tapered portion 51 of a distal mating end 48. In Figure 9F, the tapered portion 51 tapers distally to a position at or near the second portion 51'. The second portion 51' is substantially flat, whereby flat comprises having a generally planar surface such as, by way of example and not by way of limitation, a one-sided beveled structure (e.g., Fig. 7 configuration illustrated by distal mating end 48), a two-sided beveled structure, or working end of a regular screwdriver. The tapered portion 51 of a distal mating end 48 may be manufactured by stamping, swaging, milling, and the like. The second portion 51' may be formed by swaging, stamping, forging, or rolling between two rollers. During implanting of some or all of the distal mating end 48 into the inner member second end 77, the outer engaging surface 48' according to Figure 9F optionally may be substantially equally positioned between a second end inner surface 101 and a second end outer surface 102 (Figure 10, and discussion below). In an alternative embodiment, the outer engaging surface 48' of the distal mating end 48 is positioned in an abutting relationship (e.g., touching, in contact directly or by intervening parts, or adjacent) to the second end inner surface 101 (Figs. 4, 5, 7), the second end outer surface 102 (Figs. 4, 5, 7), or the outer engaging surface 95' of the cannula 95 (Figs. 7, 7A), and then welded, soldered, brazed, or otherwise fused, bonded, or glued.

Figures 9G and 9H illustrate embodiments of an inner compression member 41 comprising a first portion 41' and distal mating end 48 according to the invention, where a tapered portion 51 and/or a second portion 51' may be wider than, while still having a smaller cross sectional area than, the first portion 41'. For example,

- 61 -

the second portion 51' and tapered portion 51 may be manufactured by stamping, swaging, rolling, and the like, and material removed if necessary.

INTERNAL JOINT

Figure 10 shows an inner compression member 41 comprising a first portion 41' and a distal mating end 48, wherein the distal mating end 48 comprises a tapered portion 51, an outer engaging surface 48', and an optional second portion 51'. Like elements from the previous drawings, embodiments, and description from above are labeled the same.

An internal joint 46 may be formed by positioning the outer engaging surface 48' of the distal mating end 48 in an abutting relationship (e.g., touching, in contact directly or by intervening parts, or adjacent) to the second end inner surface 101 (Figs. 4, 5, 7), the second end outer surface 102 (Figs. 4, 5, 7), or the outer engaging surface 95' of the cannula 95 (Figs. 7, 7A). The distal mating end 48 may then be welded, soldered, brazed, or otherwise fused, bonded, or glued to the cannula 95 or the inner guide channel member second end 77.

In an alternative embodiment of an internal joint 46 according to the invention, an inner compression member distal mating end 48 becomes melt bonded 47 (described below) to the second end 77 of the inner guide channel member 70. As illustrated, the outer engaging surface 48' forms a melt bond 47 to an inner surface 101 of the inner guide channel second end 77. Alternatively, the outer engaging surface 48' may form a melt bond 47 to the outer surface 102 of the inner guide channel second end 77. Briefly, a melt bond 47 provides surface-to-surface contact between the outer engaging surface 48' of the tapered portion 51 and/or second portion 51' of the mating end 48 and the inner guide channel second end 77, thereby forming a more solid connection between the inner compression member 41 and the inner guide channel member 70. In another aspect of the invention, the outer engaging surface 48' of the tapered portion 51 and/or second portion 51' may be implanted 40 between inner and outer surfaces 101, 102, respectively, of the inner guide channel second end 77 such that the outer engaging surface 48' operatively couples to inner guide channel member inner and outer contacting interfaces 103, 104, respectively, as explained below.

- 62 -

In Figure 10, the internal joint 46 joins the inner compression member 41 to the inner guide channel member 70. In particular, the tapered portion 51 and/or second portion 51' is implanted 49, such as through melt bonding 47 for example (described below), into the second end 77 of the inner guide channel member 70. By implanting 49, the tapered portion 51 and/or second portion 51' penetrates the inner guide channel member second end 77, and as a result, the tapered portion 51 and/or second portion 51' is embedded in the inner guide channel member second end 77.

Otherwise stated, the tapered portion 51 and/or second portion 51' of the inner compression member distal mating end 48 is inserted and inlaid between inner and outer surfaces 101, 102 of the inner guide channel member second end 77, which surfaces 101, 102 are relative to the wire guide channel 71 of the inner guide channel member 70. Therefore, the implanted 49 inner compression member distal mating end 48 defines an inner guide channel member second end 77 having one or more inner compression member engaging inner and outer contacting interfaces 103, 104 (hereinafter "inner contacting interface," "outer contacting interface," "contacting interface(s)") between its inner and outer surfaces 101, 102. This means that the inner contacting interface 103 of the inner guide channel member second end 77 would be between the implanted 49 inner compression member distal mating end 48 (i.e., the tapered portion 51 and/or second portion 51') and the inner guide channel member second end inner surface 101. Likewise, the outer contacting interface 104 of the inner guide channel member second end 77 would be between the implanted 49 inner compression member distal mating end 48 (i.e., the tapered portion 51 and/or second portion 51') and the inner guide channel member second end outer surface 102.

Because implanting 49 the inner compression member 41 sets the tapered portion 51 and/or second portion 51' into the material comprising the inner guide channel member second end 77. The tapered portion 51 and/or second portion 51' is enveloped by the inner guide channel member second end's outer contacting interface 104 and the inner contacting interface 103, thereby providing surface-to-surface contact between an outer engaging surface 48' of the mating end 48 and the

- 63 -

inner guide channel second end 77. This results in additional strength to the internal joint 46, and helps to form a more solid connection between the inner compression member 41 and the inner guide channel member 70. A solid-state bond results from using a suitable form of heat for melting and solidifying (e.g., fusing and/or cross-linking bonds formed at the melt bonded material interfaces) the material of the inner and outer contacting interfaces 103, 104 of the inner guide channel member second end 77 about the inner compression member distal mating end 48. In addition, mechanical or chemical etching, sandblasting, laser-cutting, machining, milling, drilling, chemically treating, or otherwise preparing the outer engaging surface 48' of the distally tapering portion 48" of the mating end 48 improves its bonding properties to the inner guide channel member second end's inner contacting interface 103 and outer contacting interface 104.

In another embodiment of the internal joint 46 (e.g., Figure 5), a distal mating end 48 becomes melt bonded 47 to the second end 77 of the inner guide channel member 70 at inner guide channel member second end contacting interfaces 103, 104. As illustrated in Figure 5, for example, the outer engaging surface 48' of the distal mating end 48 forms a melt bond 47 to an inner contacting interface 103 of the inner guide channel second end 77. Alternatively, the outer engaging surface 48' of the distal mating end 48 may form a melt bond 47 to the outer contacting interface 104 of the inner guide channel second end 77. A melt bond 47 provides surface-to-surface contact between the outer engaging surface 48' of the distal mating end 48 and the inner guide channel second end 77, thereby forming a more solid connection between the distal mating end 48 and the inner guide channel member 70.

An internal joint 46 may be formed from melt bonding 47 without implanting 49 (e.g., Fig. 5). Alternatively, an internal joint 46 may be formed from melt bonding 47 plus implanting 49 (e.g., Figs. 4, 10). Tacking and/or bonding between the outer engaging surface 48' (e.g., of the tapered portion 51 and/or second portion 51', e.g., Fig. 10) and the inner or outer contacting interfaces 103, 104 is almost instantaneous once the melting temperature is reached, resulting in a solid-state bond (e.g., fusing, chemical bonding, and/or cross-linking bonds formed

- 64 -

at the melt bonded material interfaces) between the material of the outer engaging surface 48' the inner and outer contacting interfaces 103, 104. A melt bond 47 according to embodiments of the invention provides a strength of at least 5 newtons and preferably a strength of at least 20 newtons. In one embodiment, the strength of the melt bond 47 may be measured by providing a pull apart strength of the inner compression member distal mating end portion 48 and the inner guide channel member second end portion 77 of at least 5 newtons and preferably at least 20 newtons.

According to the present invention, a joint 46 comprising the inner compression member 41 having a first portion 41' and a distal mating end tapered portion 51 (and/or second portion 51') has many advantages. On the one hand, the joint 46 is sufficiently rigid to resist kinking, recoil, buckling, prolapse and the like during stent deployment and, therefore, to allow the doctor to change the direction of the device 10 and to the physician to "push" the stent advance or retract the inner compression member/inner guide channel member assembly to advance the wire guide into position.

On the other hand, an operator must navigate the device through a vessel passageway that at times may define a tortuous path due to the presence of natural bends and/or curves, or unnatural impediments, such as tumors, build-ups, and/or strictures. Flexibility of the distal mating end 48 may vary in use as a result of any of the following properties and characteristics: physical configuration, cross-sectional configuration, material composition; or a combination thereof. Various bending and stiffness properties of the mating end 48 are therefore related to its geometry. Consequently, a tapered portion 51 and/or the second portion 51' have improved flexibility, i.e., decreasing the cross sectional area is inversely related to flexibility.

Also, the taper is directly related to the uniform flexibility properties of the joint 46, i.e., there is no sudden change at the region where the joint 46 joins the inner guide channel member to the inner compression member because the tapered portion 51 and/or the second portion 51' have decreased cross sectional areas and, therefore, improved flexibility. In other words, the tapered portion 51 and/or the

- 65 -

second portion 51' have increased flexibility to offset or approximately compensate for any increased rigidity at the joint 46 as a result of a solid-state bond that joins the inner guide channel member second end 77 about the inner compression member distal mating end 48. As a result, the joint 46 is sufficiently flexible to allow the device 10 to negotiate this tortuous path and to avoid obstacles during insertion and use of the distal end 13 at sites within the patient's body.

Figure 10A shows that the internal joint 46 according to an embodiment described above may vary in length as desired. A longer internal joint 46 generally increases joint strength but is less flexible, while a shorter internal joint 46 may have a lesser joint strength (compared to the longer joint) but improves flexibility. In one embodiment, the joint 46 has a length 146 from approximately 2.0 millimeters ("mm") to approximately 10.0 mm. In another embodiment, the joint 46 has a length 146 is from approximately 3.0 mm to approximately 7.0 mm, and in still another embodiment the joint is approximately 5.0 mm.

Figure 10A further shows that the inner compression member 41 optionally has more than one taper. For instance, the inner compression member 41 has a first portion 41' proximal to a first tapered portion 51 of a distal mating end 48. The joint 46 comprises the first tapered portion 51 implanted 49 into the inner guide channel member second end 77. The inner compression member 41 optionally may have a second tapered portion 51" proximal to the joint 46 and intermediate the first portion 41' and the distal mating end 48.

The tapered second portion 51" may have any suitable length 141. In one embodiment the tapered second portion 51" has a length 141 from about 1.0 cm to about 5.0 cm, although this length 141 may be greater or lesser, as desired. The tapered second portion 51" may taper as described above relating to the tapered portion 51 of the distal mating end 48 (see Figures 9A-9F and corresponding description). Thus, the tapered second portion 51" along length 141 provides transitional change (e.g., increase) in flexibility in the region just proximal to the joint 46 and inner guide channel member second end 77. Meanwhile, the implanted 49 tapered portion 51 of the distal mating end 48 provides a composite uniform flexibility in the joint along the length of the joint.

TAPERED INNER GUIDE CHANNEL MEMBER

Figure 10 also shows one embodiment of the distal end 13 according to another aspect of the invention. The inner guide channel member 70 has a guide channel 71 comprising a substantially uniform internal diameter 74, an outer diameter 75 at or near the inner guide channel member second end 77, and a taper 76. In one embodiment, the taper 76 may be located at or near the inner guide channel member first end 78. In another embodiment, the taper 76 may be located intermediate the inner guide channel member first and second ends 78, 77, respectively. The term "intermediate" is intended to describe embodiments of the taper that is intermediary, intervening, lying or occurring between two extremes, positions, or states—though not necessarily equidistant—from the distal tip of the first end 78 or first end opening 72 (Figs. 4, 5, 7) to the proximal tip of the second end 77 or second end opening 73 (Figs. 4, 5, 7).

The taper 76 extends from the outer diameter 75 distally to a tapered portion 76' that has a decreased, reduced, lesser, and/or smaller (hereafter, "smaller") cross sectional area, wall thickness, and/or mean outer diameter relative to the outer diameter 75. In one embodiment, the taper 76 further extends from at or near the outer diameter 75 through the length of the tapered portion 76' and to a second outer diameter 76" at or near a self-expanding deployment device mounting region 90 (previously described), the second outer diameter 76" is smaller in cross sectional area, wall thickness, and/or mean outer diameter than the tapered portion 76'.

In one embodiment, as the inner guide channel member 70 tapers 76, the wall defined by the inner diameter 74 from at or near the outer diameter 75 through the length of the tapered portion 76' becomes thinner (and therefore more flexible) compared to the thicker walls at the inner member second end 77 defined by the inner diameter 74 and the outer diameter 75. In other words, the resistance to longitudinal bending may be stated, in general terms, as a function of the product "EI," where "E" is Young's modulus of elasticity and "I" is the moment of inertia for that section. More specifically, it will be appreciated that the moment of inertia

- 67 -

decreases with decreasing cross section, wall thickness, and/or outer diameter—thus reducing the resistance to longitudinal bending.

The taper 76 enhances flexibility in many ways. The inner guide channel member 70 has an improved flexibility at the taper 76, because flexibility increases by decreasing the outer diameter (e.g., the wall thickness) from the outer diameter 75 distally to a smaller tapered portion 76' and to a smaller yet second outer diameter 76". Otherwise stated, a thinner wall thickness will be more flexible than the inner guide channel member of the same composition but having a greater wall thickness. Consequently, the inner guide channel member first end 77 has a greater cross section and thicker wall, by way of example, compared to the tapered portion 76', and the tapered portion 76' is therefore more flexible. Furthermore, the inner guide channel member 70 is even more flexible at the second outer diameter 76" (which is smaller than the outer diameter 75) than the tapered portion 76'.

Such tapering 76 also decreases the profile of the inner guide channel member 70. In addition, by tapering the inner guide channel member 70 in the stent mounting region 90 (e.g., the inner member has a second outer diameter 76") the inner member may receive a compressed stent without substantially increasing its profile. Furthermore, the more flexible second outer diameter 76" of the inner guide channel member 70 compensates for the increased rigidity resulting from a compressed stent.

As shown in Figure 10, the outer diameter 75 may become or transition distally to the tapered portion 76' and then to the second outer diameter 76" via any suitable means. For instance, such tapering means may include grinding, skiving, laser-cutting, machining, electric discharge machined, stamping, shearing, slicing, shaving, pressing, milling, and/or formed by other known shaping processes. The steepness and location of the tapering 76 is determined by the desired application of the device 10. For example, use of the device in coronary arteries will typically benefit from a smaller outer diameter, compared to use of the device in a bile duct, both for gross size and flexibility.

The length of the inner guide channel member 70 may vary depending on the length of the stent to be used with the inner member. For example only, a stent

- 68 -

might be from about 2.5 cm in length to about 14.0 cm in length, although the inner guide channel member 70 may be cut to length for stents shorter or longer than this range. In one embodiment, the inner guide channel member 70 is approximately 15.0 cm in length for an 8.0 cm long stent.

The inner and outer diameters of the inner guide channel member 70 may also vary. In one embodiment, the inner guide channel member 70 has an internal diameter 74 that measures approximately 0.0205 inches. In an exemplary embodiment, the inner guide channel member proximal second end 77 has an outer diameter 75 that measures approximately 0.043 inches. In one embodiment, a second outer diameter 76" measures approximately 0.029 inches at or near the distal first end 78 of the inner guide channel member 70. A taper 76 that is uniform increases flexibility gradually distally toward the first end 78.

The length over which the inner guide channel member 70 may taper 76 also varies. In one embodiment, the outer diameter 75 of approximately 0.043 inches is relatively constant over a length 275 of approximately 5.0 cm for an inner guide channel member 70 that is about 15.0 cm in length. In one embodiment, the inner guide channel member 70 may taper 76' from approximately an outer diameter of 0.043 inches to an outer diameter of about 0.0205 inches gradually over a length 276' of approximately 5.0 cm. The relatively uniform second outer diameter 76" of about 0.0205 inches may extend over a length 276" of approximately 5.0 cm. Alternatively, the inner guide channel member 70 tapers 76 distally over a length equal to the length of the stent plus 2.0 cm to a second outer diameter 76". These dimensions are illustrative only, and may be shorter for an inner guide channel member 70 intended for a shorter stent, or may be longer for a longer stent.

Figure 10 shows that one embodiment of a distal end 13 further comprises a pusher collar 79 that is disposed about and secured to the inner guide channel member 70 at or near the second outer diameter 76". The collar 79 may be any symmetric or asymmetric attachment structure or device (e.g., tubular, circular or non circular, slotted or circumferential, ringed, band clamp, sleeve) comprising an inner guide channel member receiving lumen 79', an inner guide channel member abutting face 79", and, as previously described, a proximal restraint 93. The pusher

- 69 -

collar lumen 79' receives the inner guide channel member 70 at or near the second outer diameter 76", and the abutting face 79" secures to the inner member outer surface 102 by any suitable means, such as by clamping, clutching, gripping, pinching, fastening, hooking, joining, or by glue, adhesives, resins, welding, soldering, brazing, adhesives, chemical bonding materials or combinations thereof and the like. The collar 79 is made from any appropriate metal or plastic described above, may be any suitable length, and may be any suitable diameters sized to be slidable within the outer guide channel member 80 without making frictional contact with the inner surface 92 of the outer member 80.

Furthermore, as shown in Figure 10, the proximal second end 77 of the inner guide channel member 70 may have an oblique acute angle q . In one embodiment, the second end may be skived to give the second end an angle q from about 40 degrees to about 50 degrees, and in another embodiment the angle is about 45 degrees.

METHOD

Methods of manufacturing and of providing a joint 146 for use in a medical device delivery system for delivering a implantable prosthesis (e.g., a self-expanding, balloon expandable, or non-expanding stent; prosthetic valve devices, and other implantable articles) at a selected location inside a patient's body are also provided.

Figures 11A, 11B, 11C, 11D, and 11E are schematic diagrams illustrating a method 300 of providing an internal joint 146 for operatively coupling an inner guide channel member mating end 48 of an inner compression member 41 to an inner guide channel member 70 to be used with a delivery apparatus for the rapid insertion of medical devices that includes a proximal end, elongate flexible middle section delivery device having said inner compression member, and a distal end having an outer guide channel member and said inner guide channel member. In general, the internal joint 146 is formed by implanting 49 (and optionally melt bonding 47) a portion of an inner compression member 41 as described above into an inner guide channel member 70 as described above.

In Figure 11A, an elongate inner compression member 41 (see Figs. 2, 2C, 4, 5-8, 10) is provided (step 302). The inner compression member 41 comprises a

- 70 -

proximal end 40, an optional middle section 40', and a distal mating end 48. A first portion 41' is proximal to a distal mating end 48, wherein the distal mating end 48 comprises a tapered portion 51, an outer engaging surface 48', and an optional second portion 51'. Like elements from the previous drawings, embodiments, and description from above are labeled the same. The tapered portion 51 gradually decreases relative to (and smaller than) in cross sectional area relative to the cross sectional area of the first portion 41' that is proximal to the mating end 48. The optional second portion 51' has an even smaller cross sectional area relative to the tapered portion 51.

Indeed, a stainless steel stylet available from Cook Incorporated may be used for the inner compression member. In one embodiment, the inner compression member 41 is solid. The length may vary, and in one embodiment may be about 139 cm for a delivery system 10 for the rapid insertion of an 8.0 cm self-expanding stent. For stents that are longer, the inner compression member 41 may be longer, because the shorter stent usually takes a shorter inner guide channel member 70. The inner compression member outer diameter may vary. In one embodiment, the outer diameter is approximately 0.024 inches. Through centerless grinding, the mating end 48 that is melt bonded to the inner guide channel member second end 77 PEEK tubing is tapered down to an outer diameter approximately .016 inches over a length of approximately 5.0 cm.

In Figure 11B, an inner guide channel member 70 (see Figs. 4, 5-7, 10) is provided (step 304). The inner guide channel member 70 comprises a proximal second end 77 with an entry port 72 and a distal first end 78 with an exit port 73, and defining a channel 71 therebetween. The outer guide channel member second end 77 comprises an inner surface 101 and an outer surface 102. In one embodiment, this comprises PEEK tubing. In another embodiment, the inner guide channel member 70 is a plastic cannula.

In Figure 11C, the inner guide channel member second end 77 is melted (step 306) by any suitable means, such as heat. For instance, a radiofrequency loop heater may be used to melt 306 the inner guide channel member second end 77. Such a machine is available from Magnaforce, Incorporated and sold under the name

- 71 -

and model Heatstation 1500. Another such machine is available from Cath-Tip, Inc. and is sold under the model and name Cath-Tipe II.

It should be noted that the inner compression member distal mating end 48 may be implanted 49 (and optionally melt bonded 47) into the second end 77 of the inner guide channel member 70. In other words, the inner compression member 41 may be "melted" (step 306) and, thereby, melt bonded to the inner guide channel member 70 without being implanted into the inner guide channel member 70. As shown in Figure 5, for example, an outer engaging surface 48' of the distal mating end 48 may form a melt bond 47 to an inner surface 101 of the inner guide channel second end 77 or, alternatively, to the outer surface 102 of the inner guide channel second end 77.

As explained above, materials have different "melt bonding" temperatures at which the material will soften and become almost tacky without substantial degradation. In one embodiment where PEEK tubing is used, because PEEK melts at about 633°F, the inner guide channel member second end 77 is heated from about 628°F to about 638°F. There is a rise dwell and cool down time for the process. The total rise time is approximately 20 seconds and dwell time is approximately 10 seconds. During the dwell time the temperature is approximately 600°F.

Figure 11B further shows skiving (step 312) and tapering (step 314). The inner guide channel member second end 77 is skived (step 312) to give it an oblique angle q (Fig. 11C) from about 40 degrees to about 50 degrees, and in another embodiment the angle is about 45 degrees. The inner guide channel member is tapered (step 314) by any suitable means, such as grinding, skiving, laser-cutting, machining, electric discharge machined, stamping, shearing, slicing, shaving, pressing, milling, and/or formed by other known shaping processes. Alternatively, inner guide channel member 70 is purchased with a preexisting taper (step 314).

Turning to Figure 11C, at or near the end of the dwell time, the inner guide channel member second end 77 has softened. The tapered portion 51 and/or the optional second portion 51' of the inner compression member distal mating end 48 is implanted (step 308) into the softened inner guide channel member second end

- 72 -

77. Otherwise stated, the second end tubing under heat has softened and, before the tubing burns or degrades, the tapered portion 51 and/or the optional second portion 51' of the inner compression member distal mating end 48 is moved quickly into the wall of the softened PEEK between the inner and outer surfaces 101, 102, respectively. The outer engaging surface 48' of the inner compression member distal mating end 48 becomes operatively coupled by compression forces resulting from being implanted 49 between—or by being melt bonded 47 to—inner and outer contacting interfaces 103, 104 between the inner and outer surfaces 101, 102 of the inner guide channel member second end 77. Alternatively, the outer engaging surface 48' may be melt bonded 47 to the inner surface 101 of the inner guide channel second end 77 (see Fig. 5) or melt bonded 47 to the outer surface 102 of the inner guide channel second end 77.

The implanted inner compression member distal mating end 48 and inner guide channel member second end 77 are cooled (step 310) (Figure 11C). As used to describe an embodiment of the invention, cooling (step 310) is any means for allowing the melted inner guide channel member second end 77 to return to solid state (e.g., become solid, again). Thus, the joined mating end 48 and inner member second end 77 may be brought back down to room temperature. In one embodiment, the cool down time is approximately 30 seconds. As a result, the mating end has become implanted into the melted wall of the tubing. This forms a solid joint, because when PEEK (for example) melts it expands, and when it cools it shrinks and grips tighter onto the outer engaging surface 48' of the tapered portion 51 and/or the optional second portion 51' of the inner compression member distal mating end 48. This gives additional mechanical bonding as described above.

Optionally, as Figure 11D shows that an inner guide channel member 70 may have a mandrel 330 positioned (step 316) within at least a portion of the guide channel 71 of the inner guide channel member second end 77 for helping to maintain patency of the second end 77 during melting (step 306) and/or implanting (step 308). In one embodiment, the mandrel 330 is a stainless steel mandrel having a Teflon coating, a round cross-section, and a diameter that measures approximately 0.0205 inches.

- 73 -

Optionally, also shown in Figure 11D, a tool 340 is disposed about (step 318) at least a portion of the inner guide channel member second end 77 for helping to maintain patency of the inner guide channel member second end 77 during melting (step 306) and/or implanting (step 308) and to conduct heat during melting (step 306). In one embodiment, the tool 340 is a metal cannula having an inner diameter that measures approximately 0.0430 inches.

At this point, the inner guide channel member second end 77 is sandwiched between the mandrel 330 and the tool 340. The assembly is then melted (step 306) by being placed within a radiofrequency heater loop until the inner guide channel member second end 77 softens. The inner compression member distal engaging end 48 is then implanted (step 308) by being pushed into the softened inner guide channel member second end 77.

Figure 11E shows the inner compression member distal mating end 48 implanted 49 between the inner and outer surfaces 101, 102, respectively, such that the outer engaging surface 48' of the inner compression member distal mating end 48 operatively couples by, for example, a melt bond 47 to inner and outer contacting interfaces 103, 104 between the inner and outer surfaces 101, 102 of the inner guide channel member second end 77. Alternatively, the outer engaging surface 48' may be melt bonded 47 to the inner surface 101 of the inner guide channel second end 77 (see Fig. 5) or melt bonded 47 to the outer surface 102 of the inner guide channel second end 77.

After cooling (step 310), the mandrel 330 is then removed (step 320) by any suitable means. Also, the tool 340 is removed (step 322) by any suitable means.

A method of manufacturing and of providing a medical device as taught herein for delivering a self-expanding stent need not be performed sequentially. For instance, in method 300, an inner guide channel member 70 may be provided (step 304), and then the inner compression member 41 provided (step 302). Also, a mandrel 330 may be positioned (step 316) before or after skiving (step 312), tapered (step 314), or the tool 340 is disposed (step 318) about the inner guide channel

- 74 -

member second end 77. Likewise, the mandrel 330 may be removed (step 320) before or after the tool 340 is removed (step 322).

Moreover, the inner compression member 41 may be an elongate catheter or any other elongate member (tubular or solid) comprising a mating end having an outer engaging surface. Furthermore, the tubular inner guide channel member 70 may be a second catheter or other tubular member comprising a first end and a second end, whereby the second end has inner and outer surfaces.

It is intended that the foregoing detailed description of the a medical device having a tapered inner guide channel member and inner joint with a tapered inner compression member be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, that are intended to define the spirit and scope of this invention. Terms are to be given their reasonable plain and ordinary meaning. Also, the embodiment of any figure and features thereof may be combined with the embodiments depicted in other figures. Other features known in the art and not inconsistent with the structure and function of the present invention may be added to the embodiments.

While particular elements, embodiments, and applications of the present invention have been shown and described, it will be understood, of course, that the invention is not limited thereto since modifications may be made by those skilled in the art, particularly in light of the foregoing teachings. Therefore, it is therefore contemplated by the appended claims to cover such modifications as incorporate those features which come within the spirit and scope of the invention.

- 75 -

Claims

1. A medical delivery device, comprising:
an elongate inner compression member having a proximal end and a distal mating end comprising an outer engaging surface;
an inner guide channel member having a distal first end and a proximal second end, the first end including an entry port and the second end including an exit port defining a guide channel therebetween, the inner guide channel member having an outer diameter at the second end and having a taper intermediate the first and second ends, the taper extends distally to a smaller second outer diameter at or near the inner guide channel member first end; and
an internal joint operatively coupling the inner compression member distal mating end outer engaging surface and the inner guide channel member second end.
2. The device of claim 1 wherein the guide channel comprises a substantially uniform internal diameter.
3. The device of claim 1 further comprising a pusher collar disposed about the inner guide channel member intermediate the inner guide channel member first and second ends.
4. The device of claim 1 wherein the inner guide channel member second end further comprises an inner surface and an outer surface.
5. The device of claim 4 wherein the joint comprises a melt bond operatively coupling the inner compression member distal mating end outer engaging surface and one of the inner guide channel member second end inner surface and outer surface.
6. The device of claim 4 wherein the joint comprises the inner compression member distal mating end being implanted into the inner guide channel member second end between the inner guide channel member second end inner and outer surfaces.
7. The device of claim 6 wherein the implanted inner compression member distal mating end forms inner and outer contacting interfaces in the inner guide channel member second end, the contacting interfaces and the inner compression member distal mating end outer engaging surface being operatively coupled.

- 76 -

8. The device of claim 1 wherein the inner guide channel member further comprises a deployment device mounting region for deploying stents, prosthetic valve devices, and other implantable articles inside a patient's body.

9. The device of claim 1 further comprising a rapid insertion catheter delivery system, the system comprising a proximal end comprising a handle and a distal end comprising a breech position opening, the inner compression member extending at least about 50.0 cm from the handle to the inner guide channel member located at the delivery system distal end, and the inner guide channel member second end exit port being located at or near the breech position opening, said opening configured for allowing a wire guide to exit said rapid insertion catheter delivery system at or near the delivery system distal end.

10. A medical delivery device, comprising:

an elongate inner compression member having a proximal end and a distal mating end, a first portion located proximally at or near the distal mating end and comprising a first cross sectional area, and the distal mating end comprising an outer engaging surface, a tapered portion, and a second portion, the tapered portion comprising a second cross sectional area smaller than the first cross sectional area and tapering distally to the second portion comprising a second portion cross sectional area smaller than the first and second cross sectional areas;

an inner guide channel member having a first end and a second end and defining a channel therebetween; and

an internal joint operatively coupling the inner compression member distal mating end and the inner guide channel member second end.

11. The device of claim 10 wherein the inner guide channel member further comprises an entry port at or near the first end and an exit port at or near the second end, the ports being in fluid communication with the channel therebetween.

12. The device of claim 11 wherein the inner guide channel member second end further comprises an inner surface and an outer surface.

13. The device of claim 12 wherein the joint comprises the inner compression member distal mating end second portion being implanted into the inner guide

- 77 -

channel member second end between the inner guide channel member second end inner and outer surfaces.

14. The device of claim 13 wherein the implanted inner compression member distal mating end second portion forms inner and outer contacting interfaces in the inner guide channel member second end, the contacting interfaces and the inner compression member distal mating end second portion outer engaging surface being operatively coupled.

15. The device of claim 13 wherein the joint provides a strength of at least 5 newtons.

16. The device of claim 12 wherein the joint comprises a melt bond formed between the inner compression member distal mating end second portion outer engaging surface and one of the inner guide channel member second end inner surface and outer surface.

17. The device of claim 16 wherein the melt bond comprises a melt-bonding material selected from the group consisting of nylon, nylon natural tubing, polyether block amide, polyetheretherketone, thermoplastic, thermosetting plastic, resin, polypropylene, polyethylene, polyester, polyamide, ionomer, polycarbonate, polyphenylene oxide, polyphenylene sulphide, acrylic, liquid crystal polymer, polyolefin, polyethylene acrylate acid, polyvinylidene fluoride, polyvinyl, polyvinyl chloride, and polytetrafluorethylene.

18. The device of claim 16 wherein the joint provides a strength of at least 5 newtons.

19. The device of claim 10 further comprising a handle, the elongate inner compression member extending at least about 50.0 cm from the handle to the inner guide channel member, wherein the inner guide channel member further comprises a deployment device mounting region for deploying stents, prosthetic valve devices, and other implantable articles inside a patient's body.

20. A delivery apparatus for the rapid insertion of medical devices, comprising:
an elongate longitudinal flexible middle section extending intermediate a system proximal end and a system distal end, the middle section having an outer sheath containing a passageway;

- 78 -

an elongate compression member extending through the outer sheath passageway and to the system distal end, the inner compression member having a proximal end and a distal mating end comprising a tapered portion;

an inner guide channel member arranged at the system distal end, the inner guide channel member comprising a first end having an entry port and a second end having an exit port and defining a channel therebetween, the second end having an inner surface and an outer surface, an outer diameter at or near the second end, and a taper intermediate the first and second ends;

an internal joint operatively coupling the inner compression member distal mating end and the inner guide channel member second end;

an outer guide channel member axially slideably coupled to the inner guide channel member, the outer guide channel member comprising a distal first end having an entry port and a proximal second end having an exit port and defining a guide channel therebetween, the outer guide channel member configured to have a stepped profile comprising a first outer diameter intermediate the distal first end and the proximal second end and a second smaller outer diameter located at or near the proximal second end;

a self-expanding deployment device mounting region disposed at the system distal end within the outer guide channel member, the mounting region including a proximal restraint, an inner guide channel member outside surface, and an outer guide channel member inner surface; and

a transition region arranged at the system distal end and being proximal to the self-expanding deployment device mounting region, wherein the inner guide channel member exit port is in communication with the outer guide channel member exit port, the inner guide channel member exit port further having a breech position opening located proximal to the inner guide channel member exit port.

21. The device of claim 20 wherein the joint comprises a melt bond operatively coupling the inner compression member distal mating end and one of the inner guide channel member second end inner surface and outer surface.

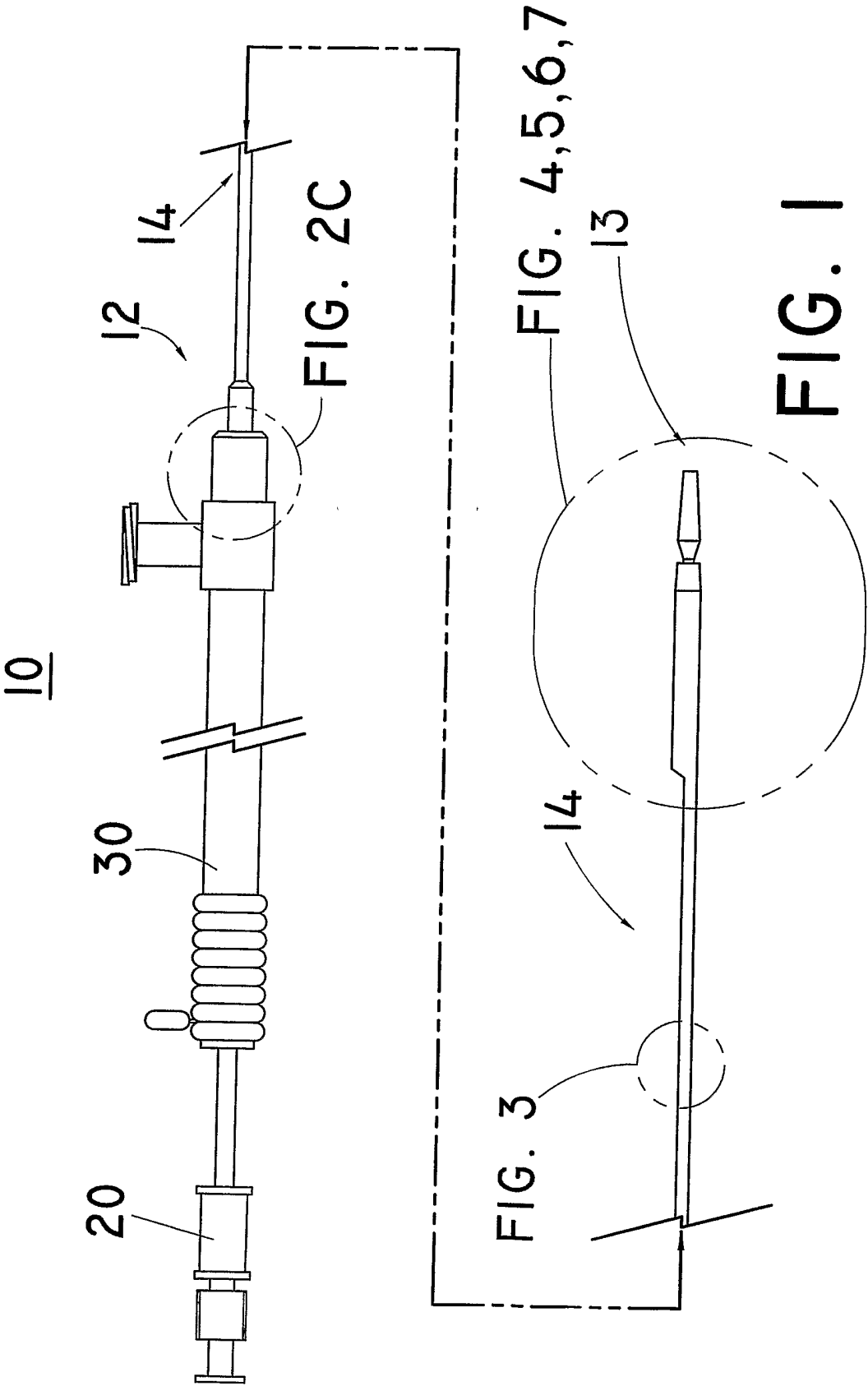
22. The device of claim 20 wherein the joint comprises a portion of the inner compression member distal mating end being implanted into the inner guide channel

- 79 -

member second end between the inner guide channel member second end inner surface and outer surface.

23. The device of claim 20 wherein the inner compression member further comprises a first portion proximal to the inner compression member distal mating end tapered portion, the first portion being greater in cross sectional area than a tapered portion cross sectional area, wherein the tapered portion is more flexible than the first portion.

24. The device of claim 20 wherein the inner guide channel member tapered portion extends from the second end outer diameter to a smaller second outer diameter at or near the first end, the distally tapered portion being more flexible at or near the second end outer diameter than the flexibility of second end at or near the second end outer diameter.



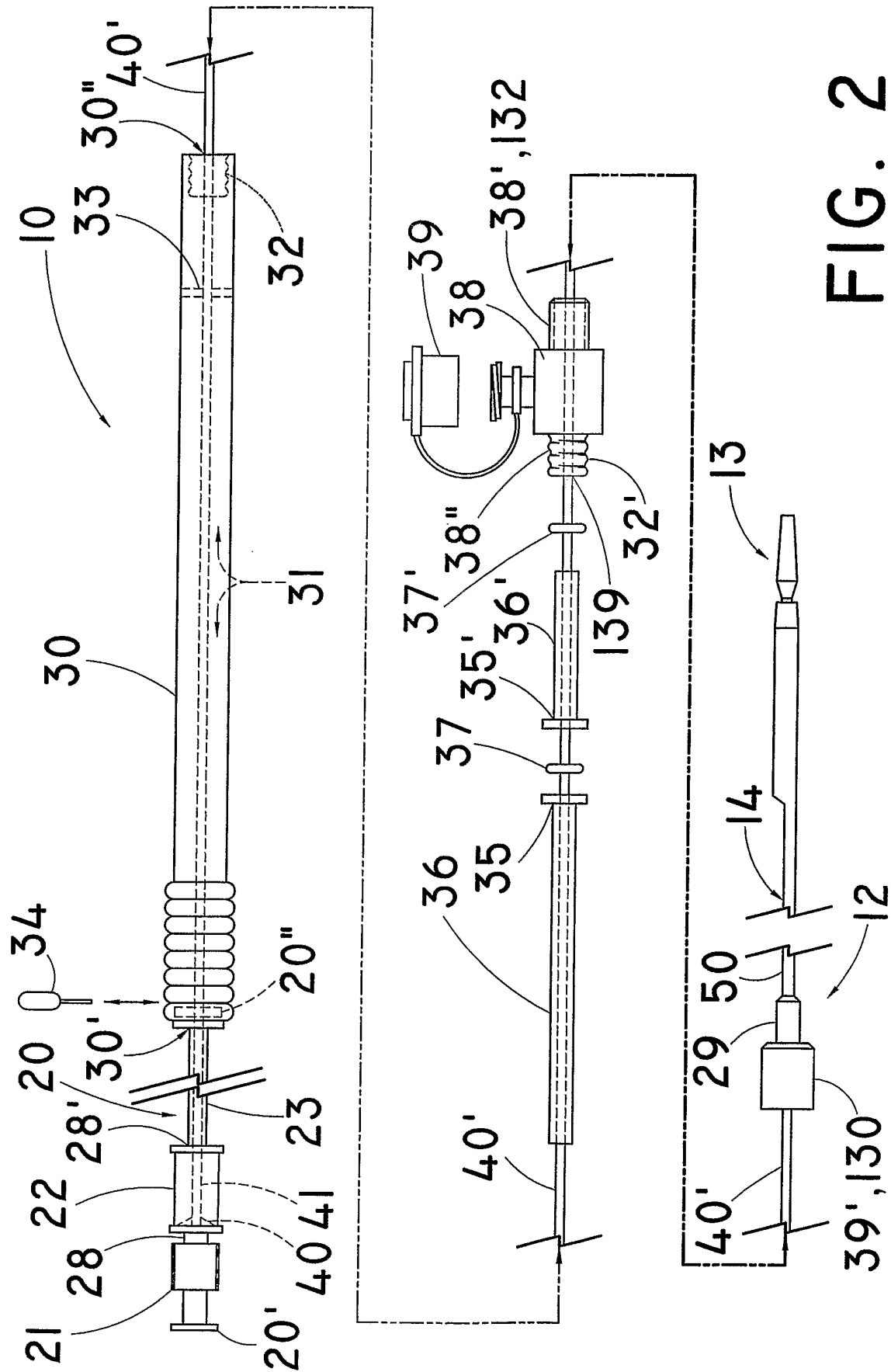


FIG. 2

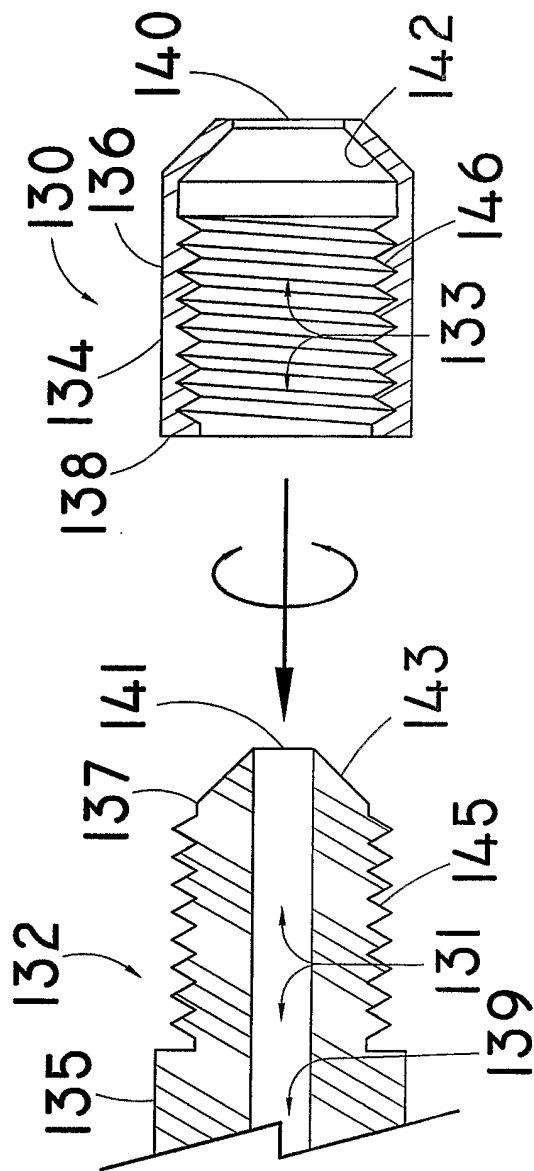


FIG. 2A

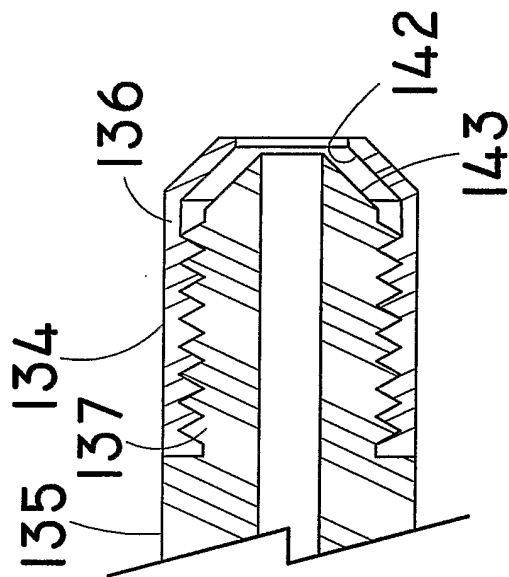
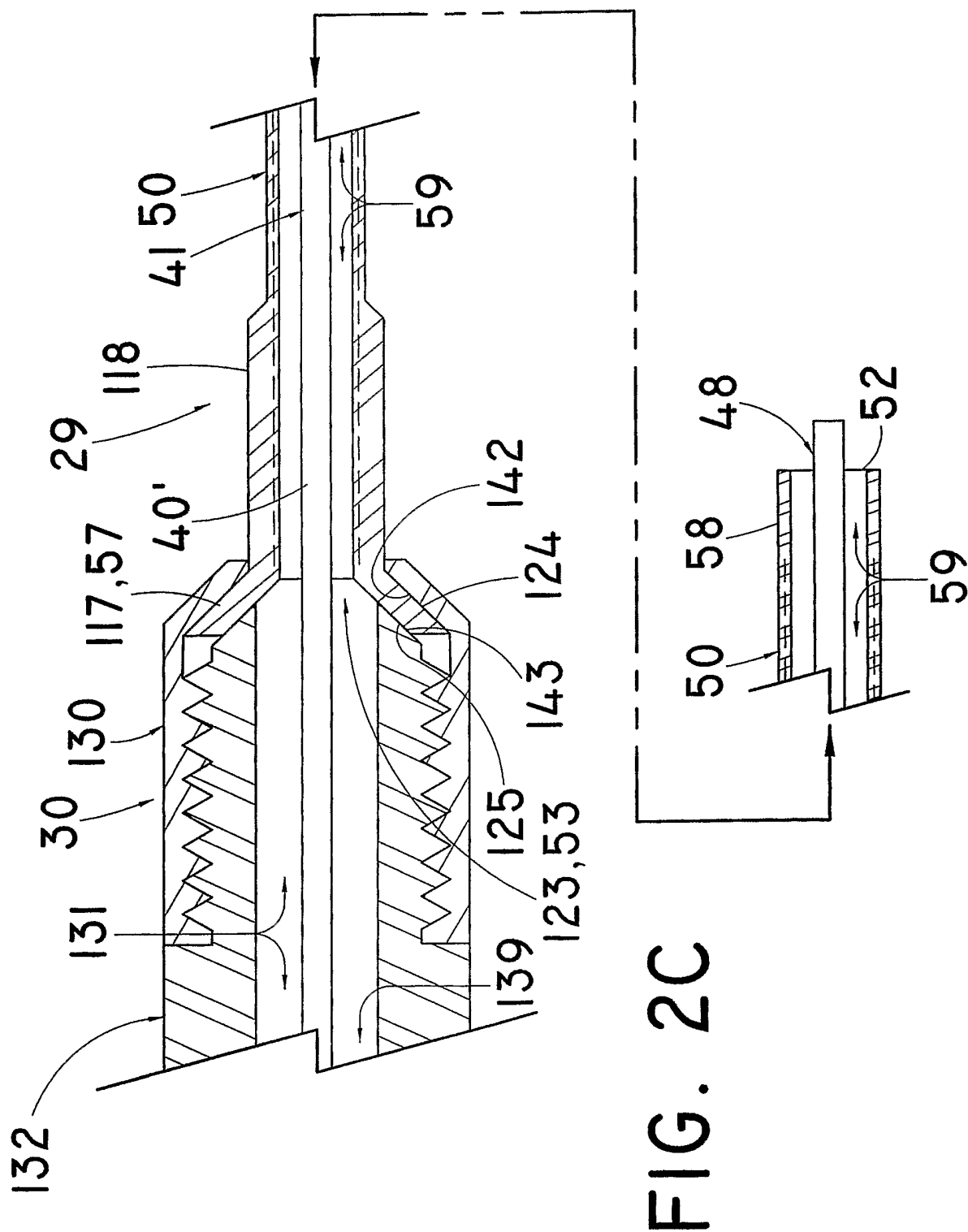


FIG. 2B



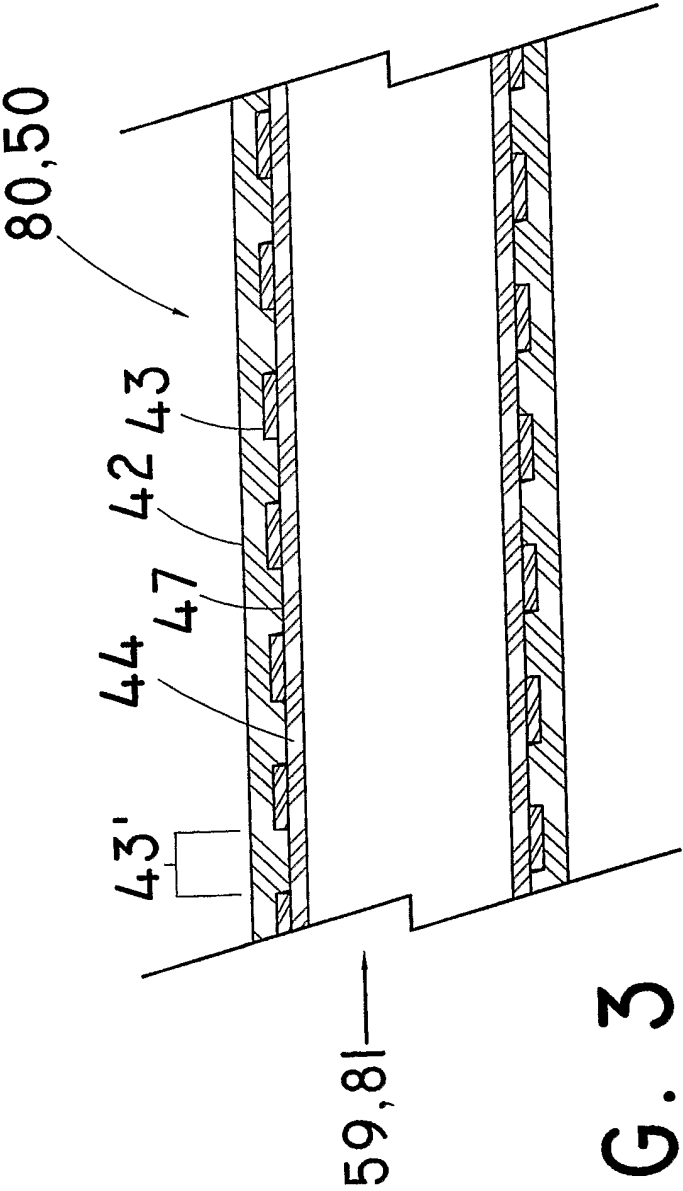


FIG. 3

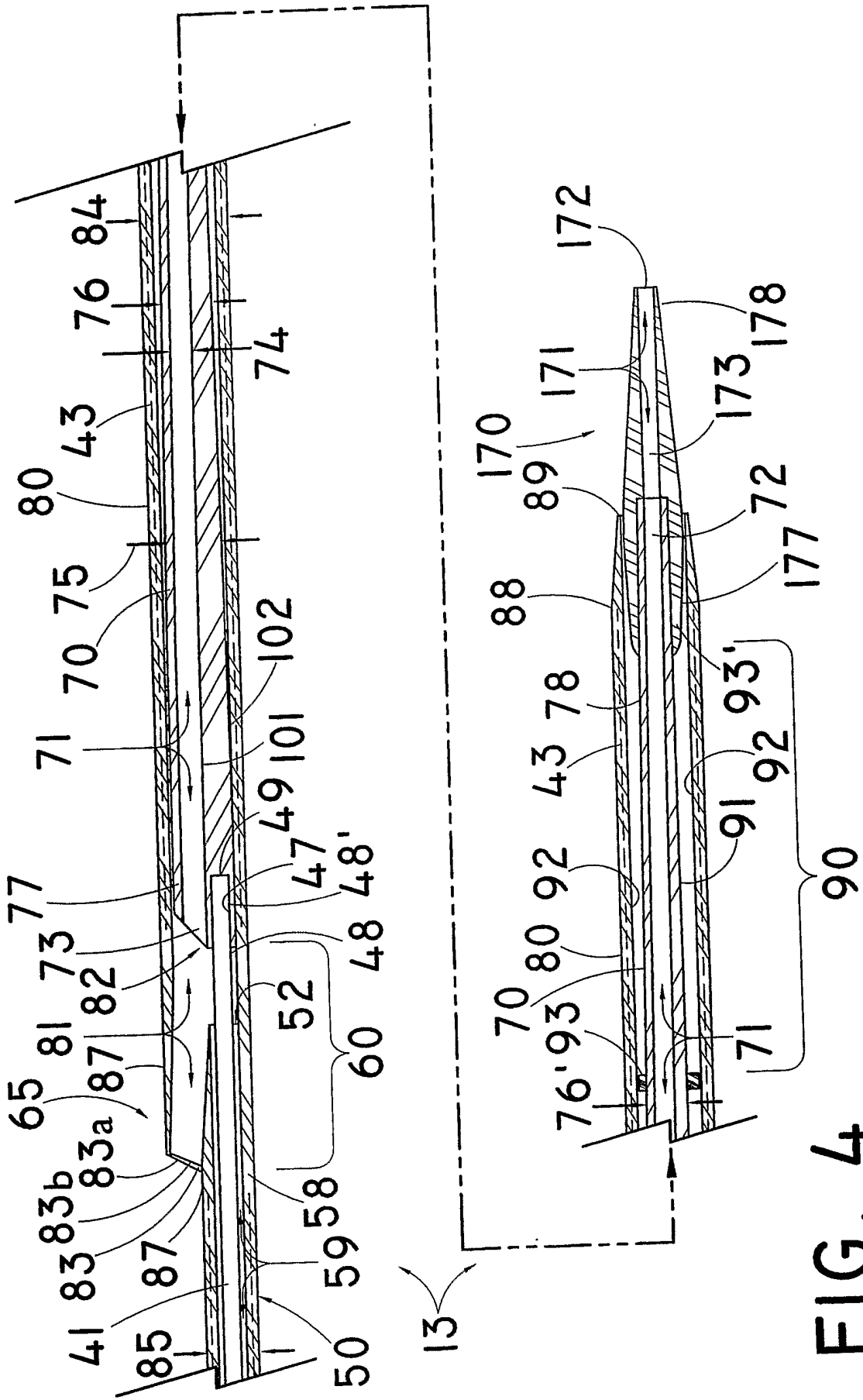


FIG. 4

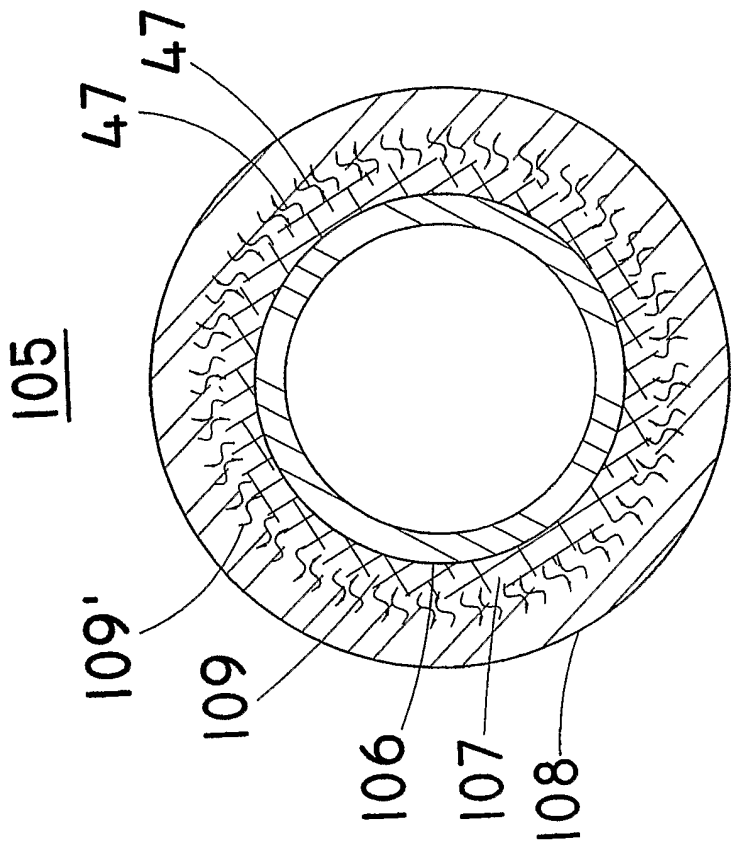


FIG. 4B

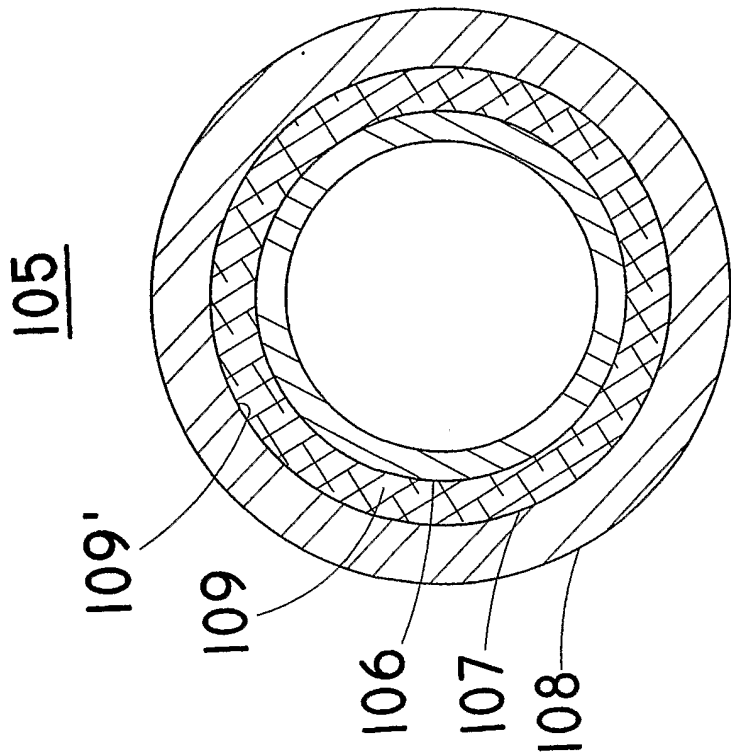
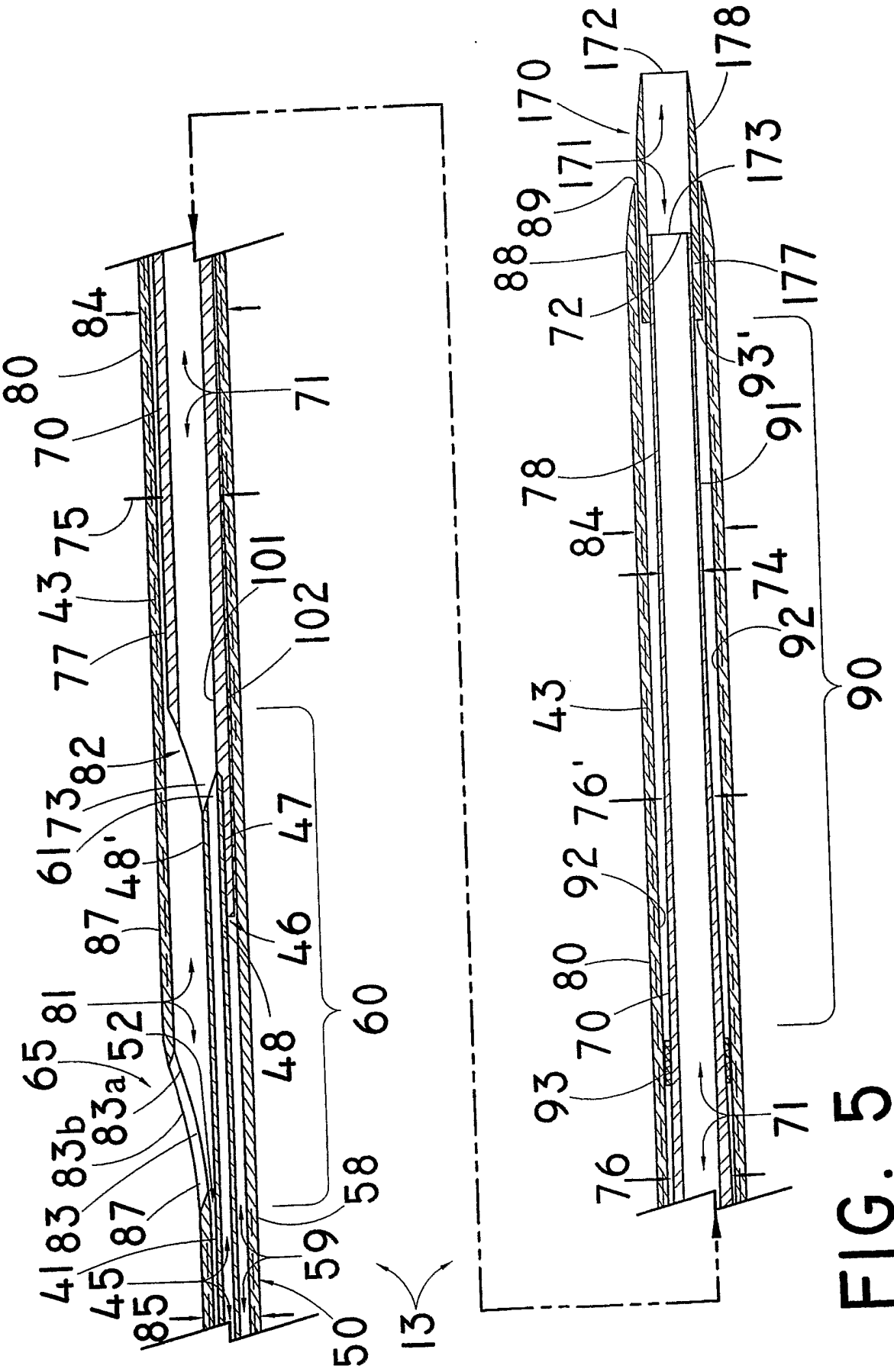
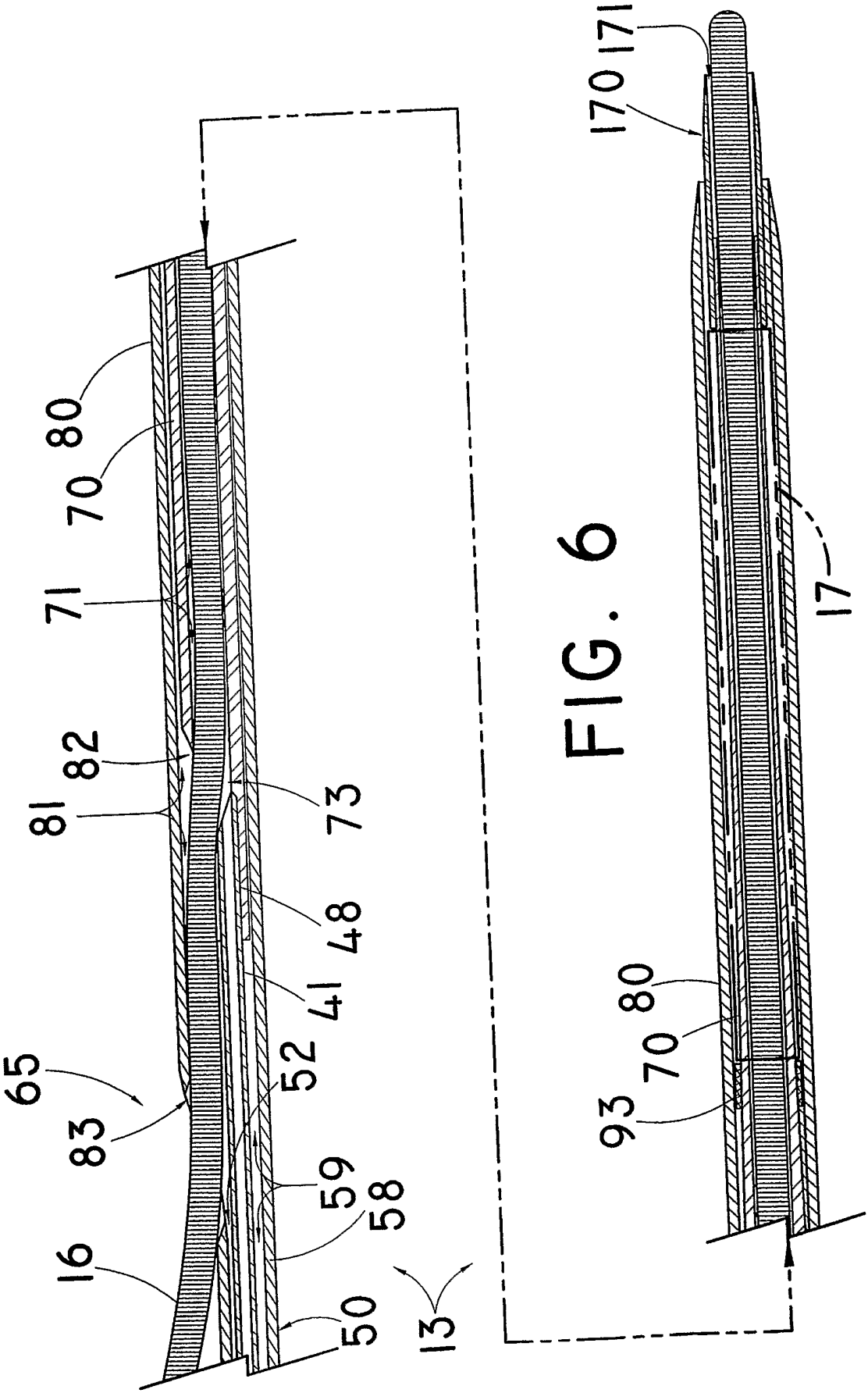
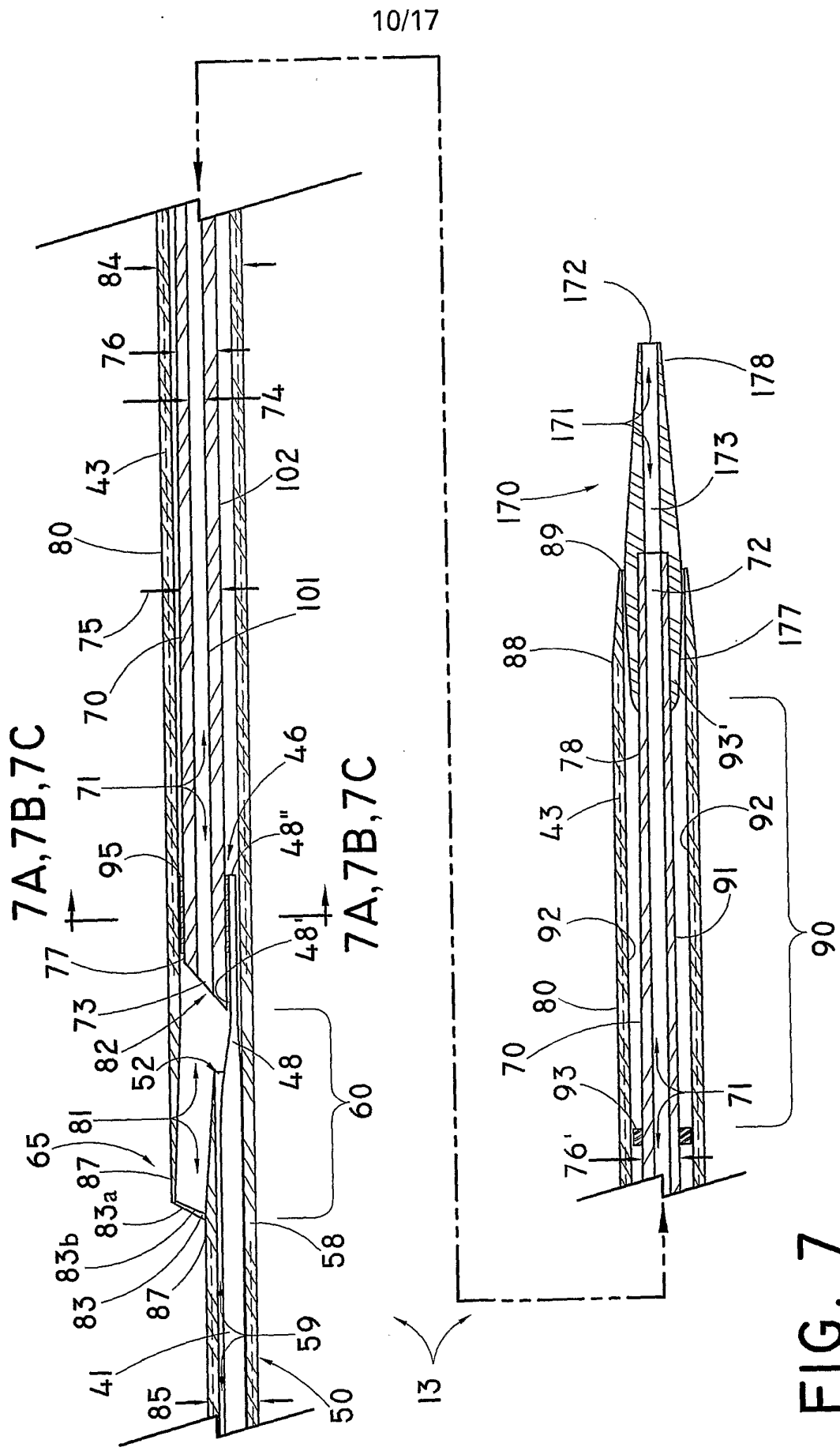


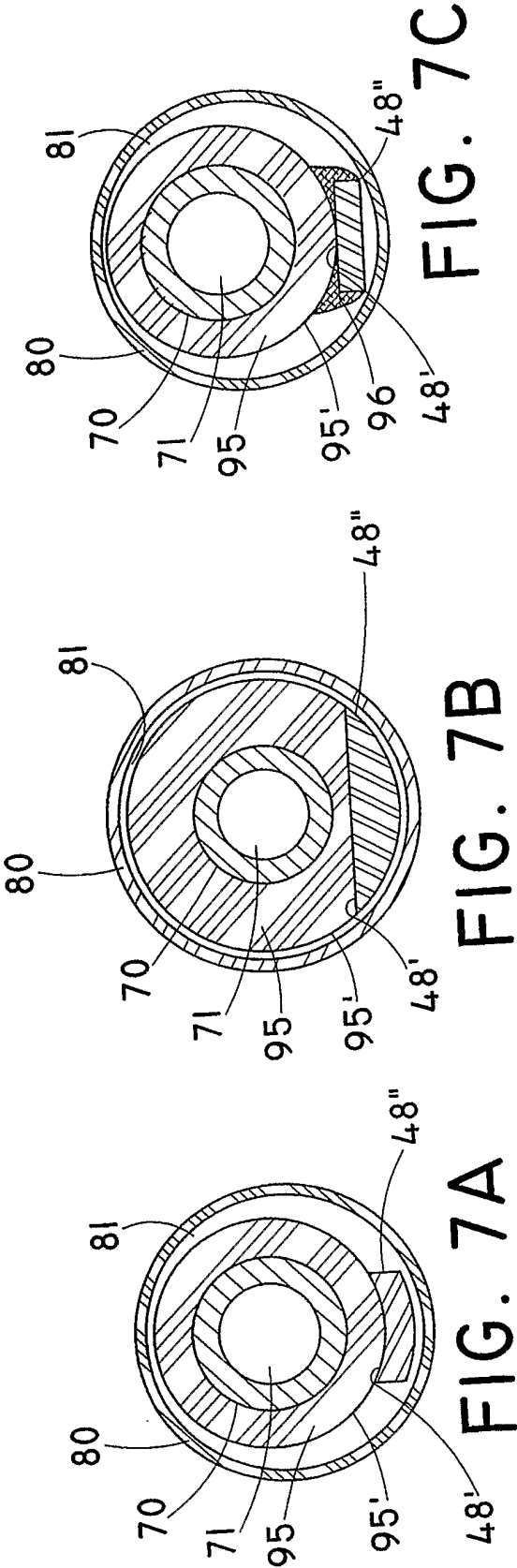
FIG. 4A



9/17







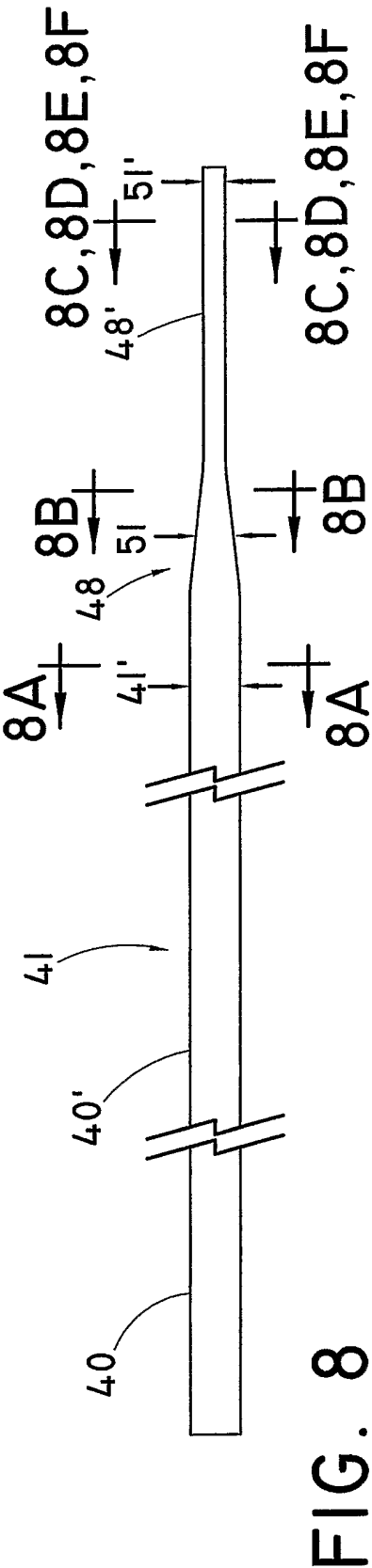


FIG. 8

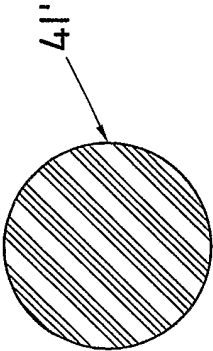


FIG. 8A

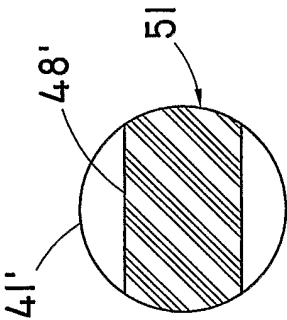


FIG. 8B

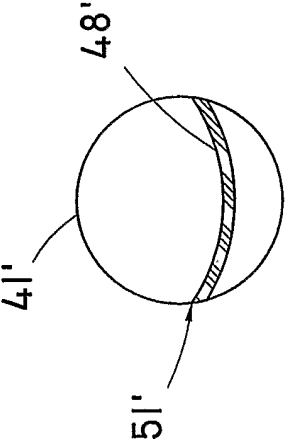


FIG. 8C

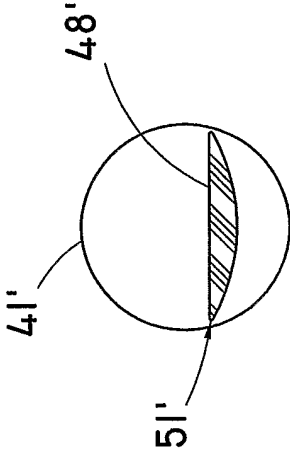


FIG. 8D

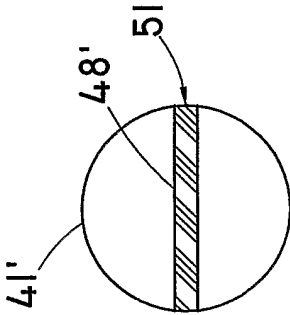


FIG. 8E

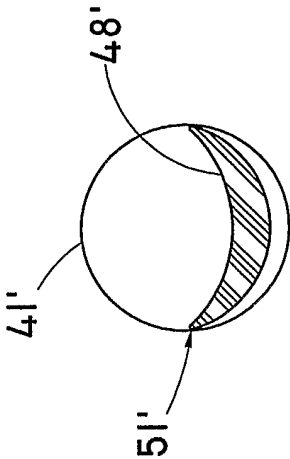
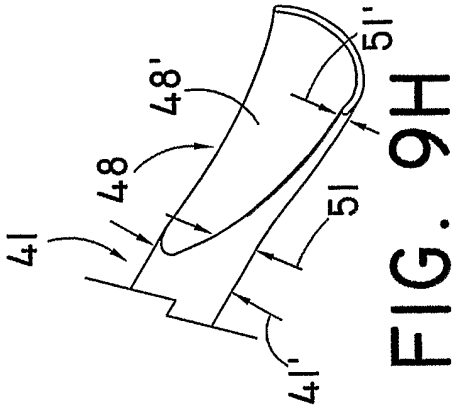
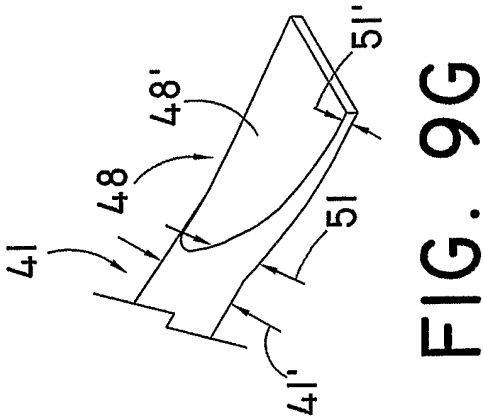
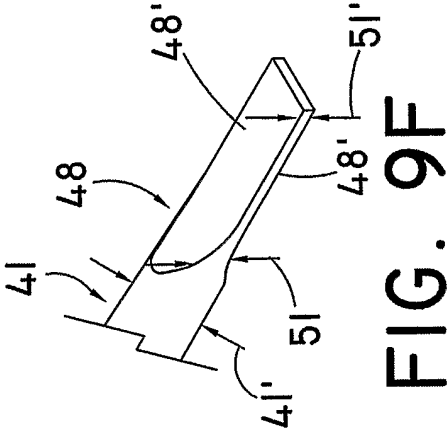
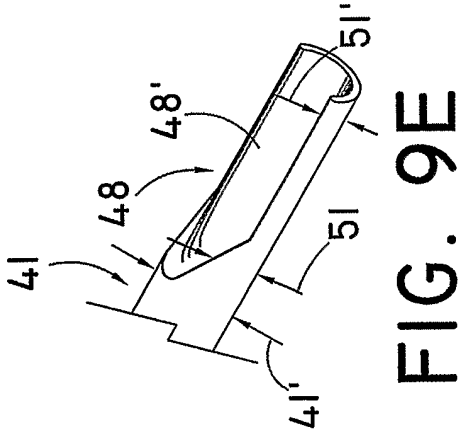
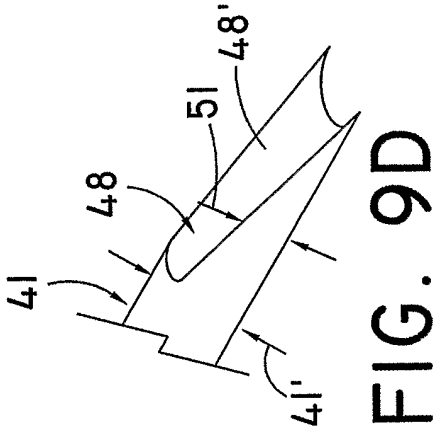
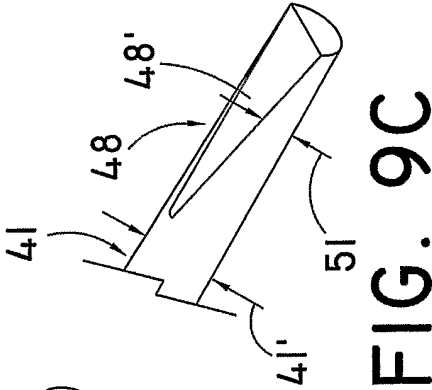
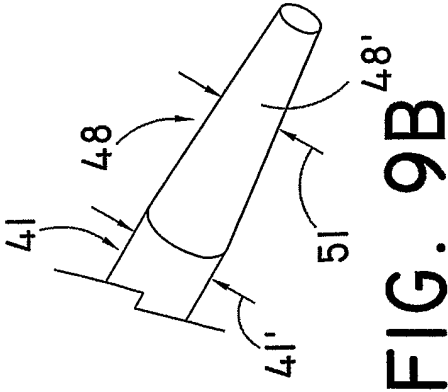
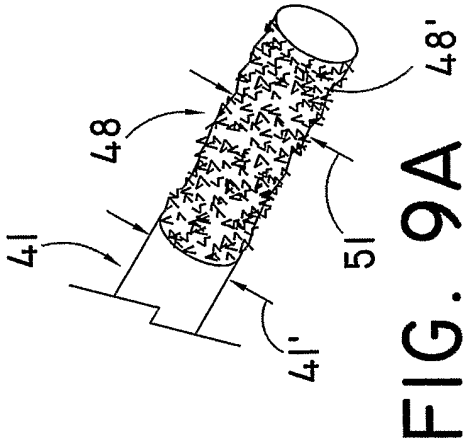
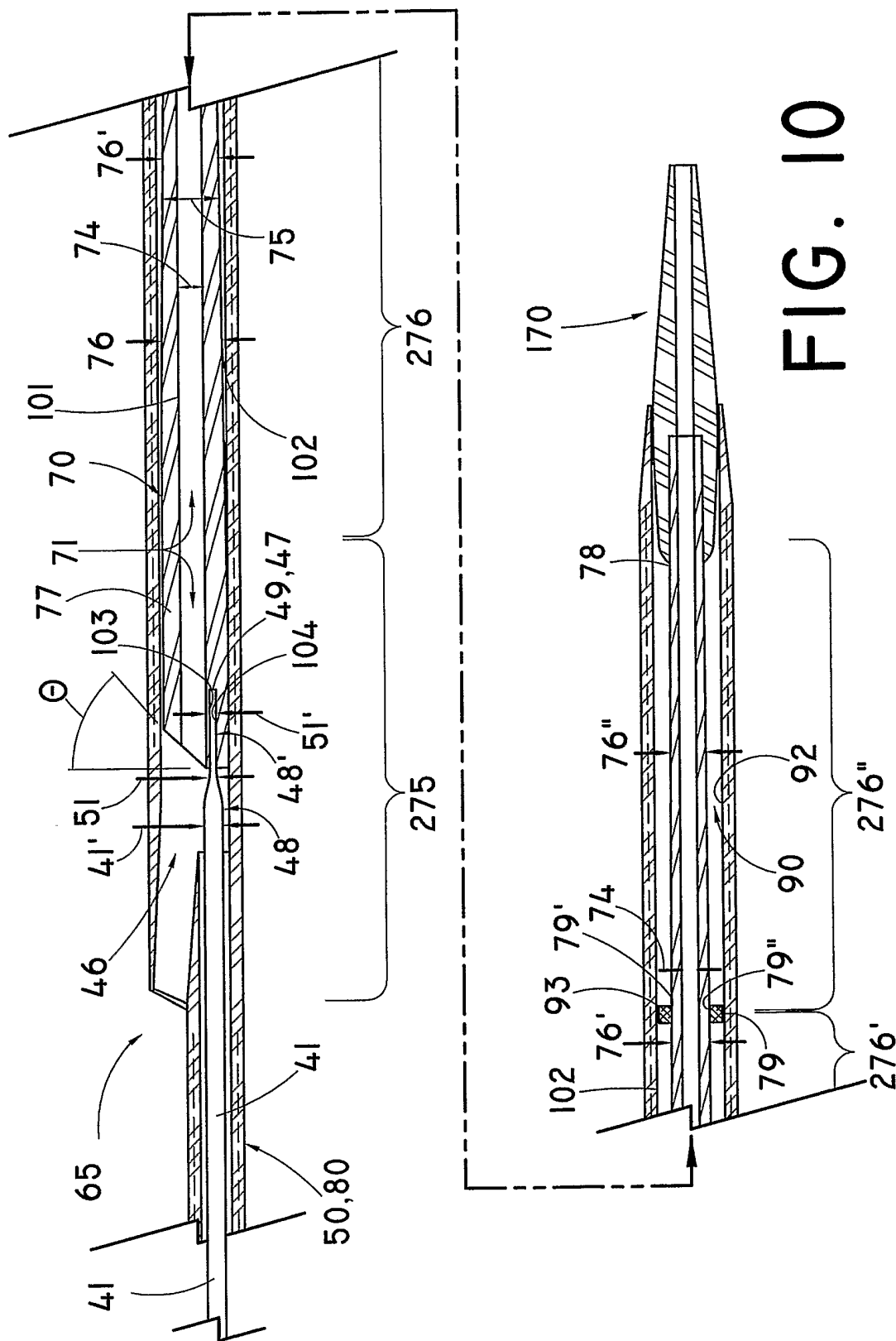
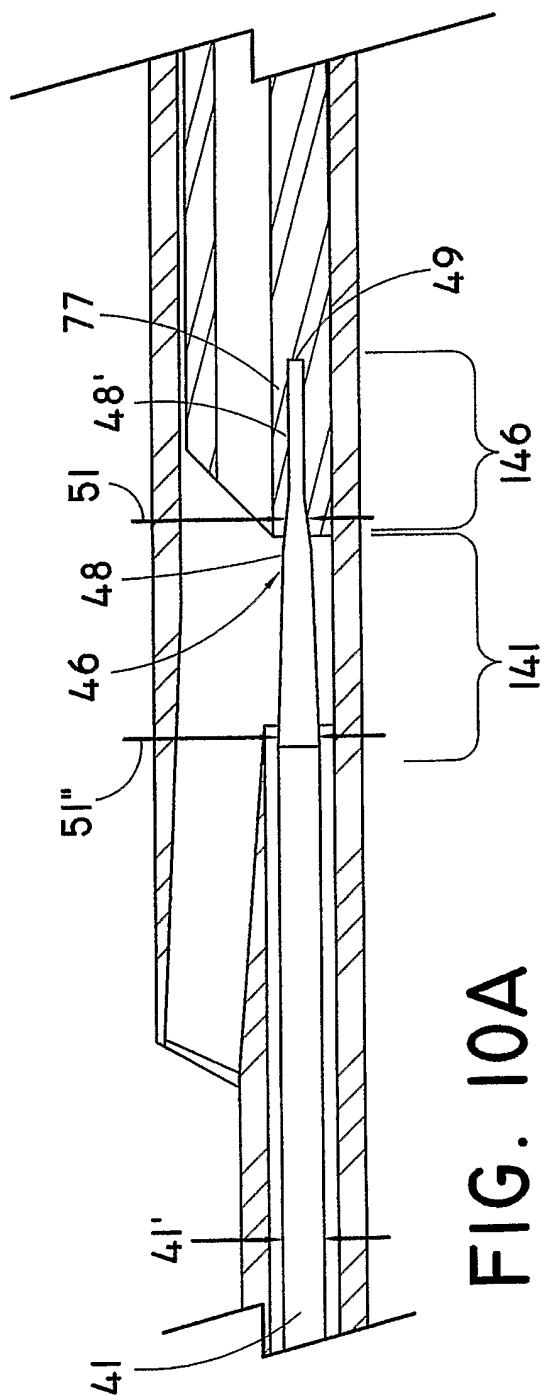


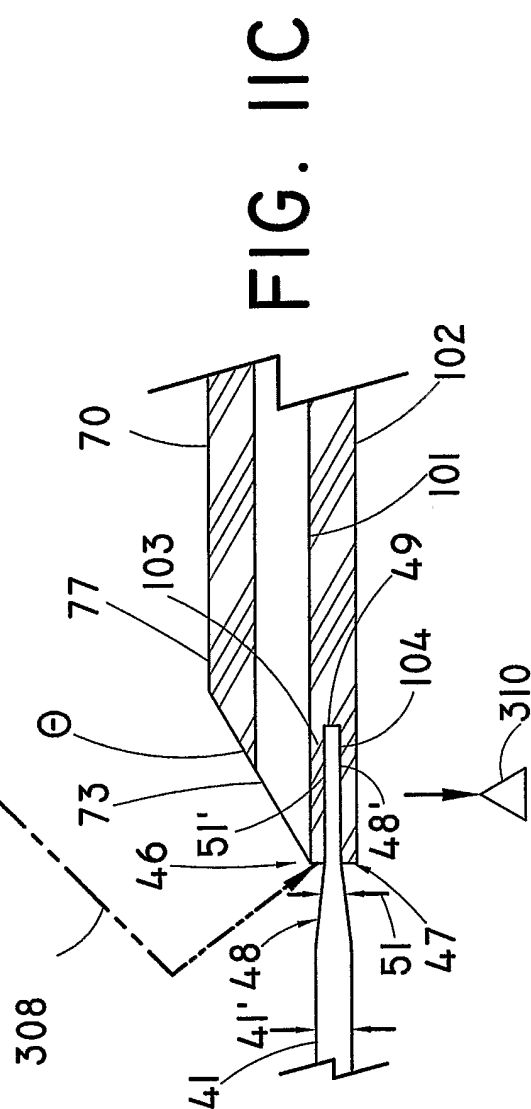
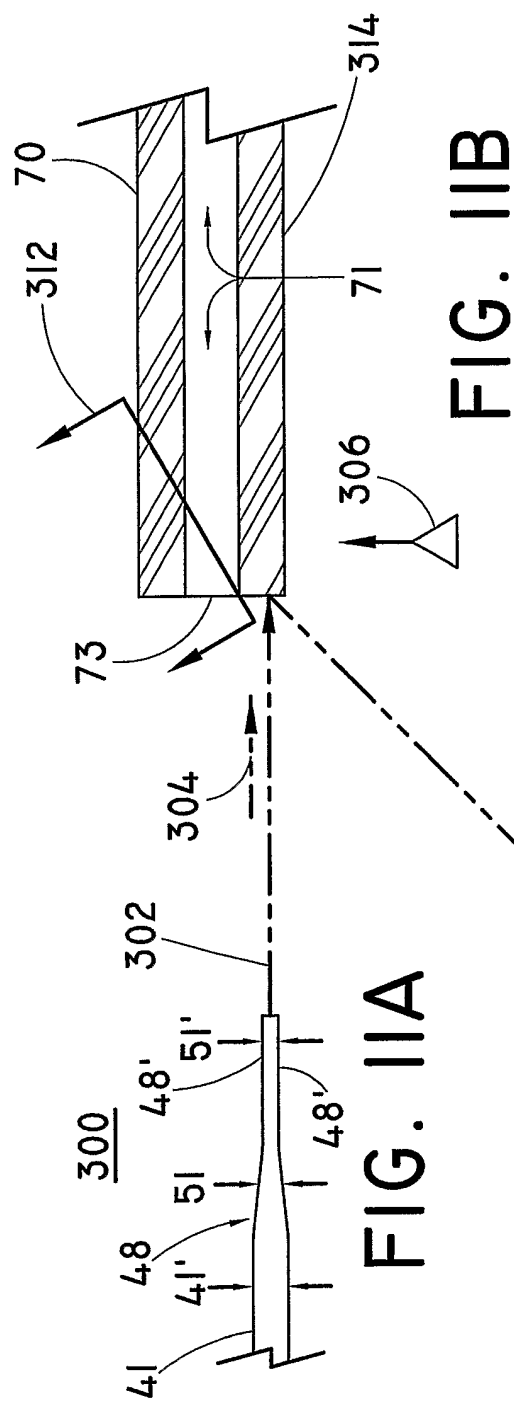
FIG. 8F





15/17





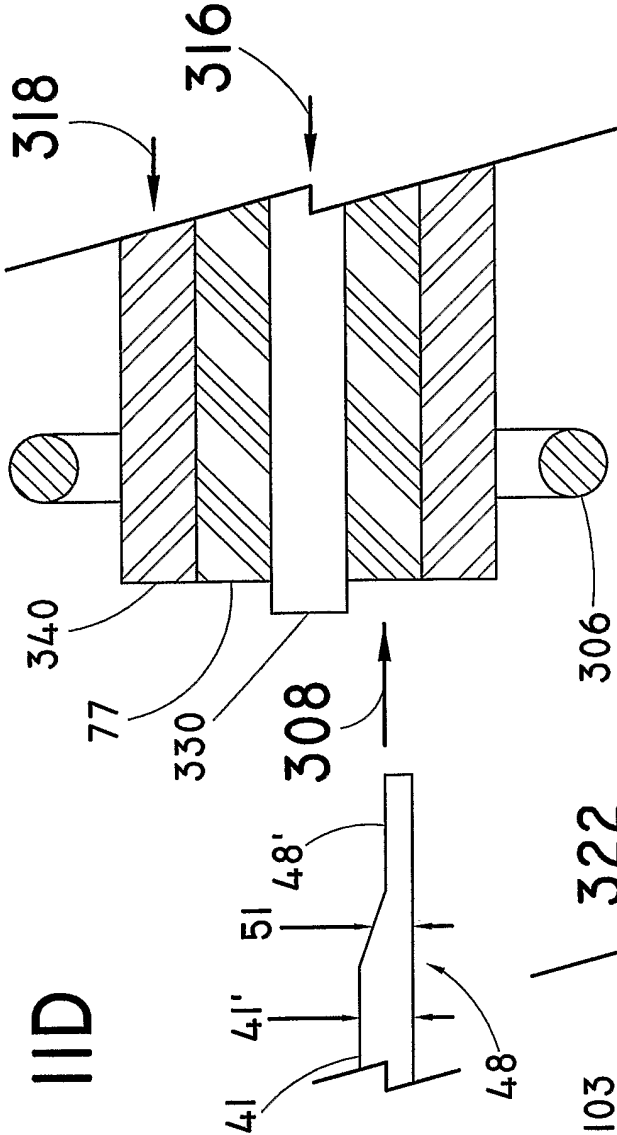


FIG. IID

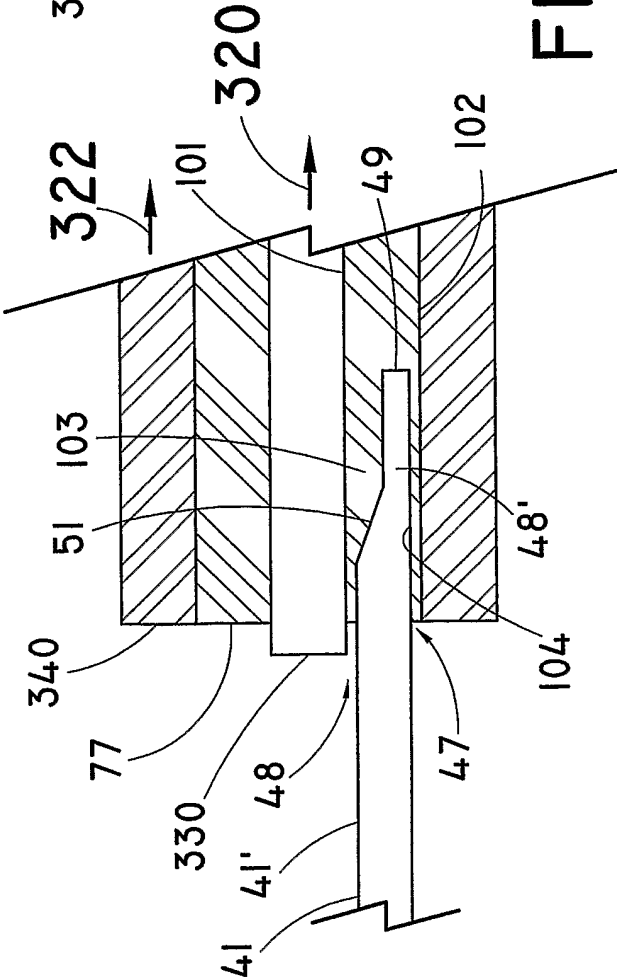
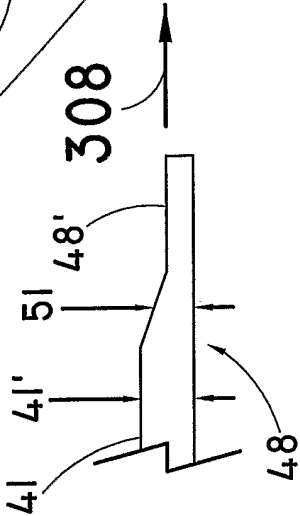


FIG. IIE