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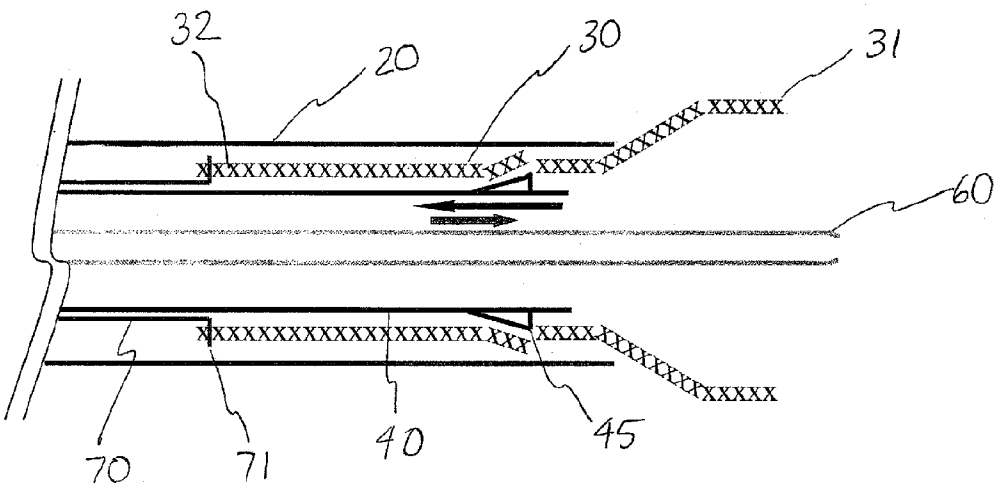

(57) Abstract: Devices and methods for stent advancement, including methods for instructing another or others how to advance a stent into an anatomical structure or into a testing/demonstration synthetic structure, such as a polymer tube. The advancement may be achieved by at least two periods of stent engagement that drive a stent distally from a sheath separated by a period of non-engagement.

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DEVICES AND METHODS FOR STENT ADVANCEMENT

CROSS-REFERENCE(S) TO RELATED APPLICATION(S)

This application claims priority to U.S. Provisional Patent Application Serial No. 60/862,456, filed October 22, 2006, the entire contents of which are expressly incorporated by reference.

BACKGROUND

1. Field

The present invention relates generally to devices and methods for stent placement, such as in a body vessel or duct or in a structure used for testing or demonstration (such as a polymer tube), and to methods of instructing one or more individuals on stent placement.

2. Description of Related Art

Examples of stent delivery devices are included in U.S. Patent Nos. 5,372,600; 5,433,723; 5,707,376; 5,772,668; 5,776,142; 5,968,052; 6,514,261; 6,599,296; 7,052,511; 7,122,050; U.S. Pat. App. Pub. No. 20030040772; and U.S. Pat. App. Pub. No. 20050021123.

SUMMARY OF THE INVENTION

Some embodiments of the present devices (which also may be characterized as stent deployment devices) include an outer sheath; a stent disposed within the outer sheath, the stent having a distal end and a proximal end; a stent-engaging element positioned at least partially within the lumen of the stent; and a stent-retention element coupled to the proximal end of the stent; where the device is configured such that: the stent-engaging element can be operated in a reciprocating manner to engage and advance

the stent distally at least partially out of the outer sheath; and the stent-retention element will stay in contact with the stent during proximal movement of the stent-engaging element provided that the proximal end of the stent is disposed within the outer sheath.

Some embodiments of the present devices include an outer sheath; a stent disposed within the outer sheath, the stent having a lumen, a distal end and a proximal end; an inner element positioned at least partially within the lumen of the stent, the inner element being configured to accept a guidewire; and a stent-engaging element positioned at least partially within the lumen of the stent and being capable of moving distally and proximally while the inner element is stationary; where the device is configured to distally drive the stent at least partially out of the outer sheath through at least two periods of engagement of the stent by the stent-engaging element that are separated by a period of non-engagement that does not drive the stent distally.

Some embodiments of the present devices include an outer sheath; a handle coupled to the outer sheath such that the outer sheath cannot move relative to the handle, the handle having a proximal end; a stent disposed within the outer sheath, the stent having a lumen, a distal end and a proximal end; and a stent-engaging element positioned at least partially within the lumen of the stent; where the device is configured such that: a user can advance the stent distally out of the outer sheath through at least two periods of engagement of the stent by the stent-engaging element that drive the stent distally and that are separated by a period of non-engagement that does not drive the stent distally; and the user's proximal-most point of contact with the device that causes each period of engagement is located at or distal of the proximal end of the handle.

Some embodiments of the present devices include an outer sheath; a stent disposed within the outer sheath, the stent having a distal end and a proximal end; a reciprocating element disposed at least partially within the outer sheath, the reciprocating element having a stent-engaging portion (which also may be characterized as a stent-engaging element); a user-actuatable element coupled to the reciprocating element; and a stent-retention element coupled to the proximal end of the stent; wherein: the stent-engaging portion is operable in a reciprocating manner to engage and advance the stent distally at least partially out of the outer sheath; and the stent-retention element stays in contact with the stent during proximal movement of the stent-engaging portion provided that the proximal end of the stent is disposed within the outer sheath.

Some embodiments of the present devices include an outer sheath; a stent disposed within the outer sheath, the stent having a distal end and a proximal end; a device body coupled to the outer sheath; a reciprocating element disposed at least partially within the outer sheath, the reciprocating element having a stent-engaging portion; and a user-actuatable element mounted on the device body and coupled to the reciprocating element; wherein the device is configured such that the stent-engaging portion is operable in a reciprocating manner to engage and advance the stent at least partially out of the outer sheath, and the outer sheath need not move relative to the device body in order for the stent-engaging portion to advance the stent.

Some embodiments of the present devices include an outer sheath; a stent disposed within the outer sheath, the stent having a distal end and a proximal end; a device body coupled to the outer sheath; a hollow reciprocating element disposed at least partially within the outer sheath, the hollow reciprocating element having a stent-

engaging portion; a user-actuatable element mounted on the device body and coupled to the hollow reciprocating element; a stent-retention element coupled to the proximal end of the stent; and an inner tube disposed at least partially within the outer sheath, a portion of the inner tube being at least partially within the hollow reciprocating element; wherein: the hollow reciprocating element is operable to move (a) distally in response to a user moving the user-actuatable element distally and (b) proximally in response to a user moving the user-actuable element proximally; the stent-engaging portion is operable in a reciprocating manner to engage and advance the stent at least partially out of the outer sheath; the outer sheath need not move relative to the device body in order for the stent-engaging portion to advance the stent; the stent-retention element stays in contact with the stent during proximal movement of the stent-engaging portion provided that the proximal end of the stent is disposed within the outer sheath; and the stent-retention element is operable to withdraw the stent proximally back into the outer sheath provided that a proximal portion of the stent is disposed within the outer sheath.

Some embodiments of the present stent advancement methods include advancing a stent disposed within a sheath disposed within a body vessel using a multiple reciprocating movements of a reciprocating element, where: each reciprocating movement includes a distal movement of the reciprocating element and a proximal movement of the reciprocating element; the stent is advanced distally in response to each distal movement of the reciprocating element; the stent is not advanced in response to each proximal movement of the reciprocating element; and each distal movement of the reciprocating element does not coincide with a separate proximal movement of the sheath.

Some embodiments of the present stent advancement methods include distally driving a stent out of a sheath and into a tubular structure by repeatedly engaging the stent between its distal and proximal ends with a stent-engaging element, where at least two of the engagements are separated by a period of non-engagement; and as the stent is distally driven out of the sheath, varying the axial density of the stent within the tubular structure by varying the axial position of the sheath relative to the tubular structure.

Some embodiments of the present stent advancement instruction methods include instructing a person on how to use a stent delivery device that includes a sheath and a stent disposed in the sheath, the instructing including demonstrating the following steps to the person: distally driving the stent out of the sheath and into a tubular structure by repeatedly engaging the stent between its distal and proximal ends with a stent-engaging element, where at least two of the engagements are separated by a period of non-engagement; and as the stent is distally driven out of the sheath, varying the axial density of the stent within the tubular structure by varying the axial position of the sheath relative to the tubular structure.

Any embodiment of any of the present devices and methods may consist of or consist essentially of—rather than comprise/include/contain/have—the described features and/or steps.

Details associated with these embodiments and others are provided below.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings illustrate by way of example and not limitation. They illustrate two different embodiments of the present delivery devices, the second of which

appears in FIGS. 13 and 14. They also illustrate the manner in which stent density can be altered during delivery (FIGS. 15A-15C), and a schematic of one of the present demonstration techniques (FIG. 16).

FIGS. 1, 2A, 2B, 2C, 3A, 3B, 3D, 3E, 4-7, 11, 12A, 13, and 14 are drawn to scale (in terms of proportions), save the length of line 72, which can be varied as desired. Identical reference numerals do not necessarily indicate an identical structure. Rather, the same reference numeral may be used to indicate a similar feature or a feature with similar functionality. Not every feature of each embodiment is labeled in every figure in which that embodiment appears, in order to keep the figures clear.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

The terms "comprise" (and any form of comprise, such as "comprises" and "comprising"), "have" (and any form of have, such as "has" and "having"), "contain" (and any form of contain, such as "contains" and "containing"), and "include" (and any form of include, such as "includes" and "including") are open-ended linking verbs. As a result, a device or method that "comprises," "has," "contains," or "includes" one or more elements possesses those one or more elements, but is not limited to possessing only those one or more elements or steps. Likewise, an element of a device or a step of a method that "comprises," "has," "contains," or "includes" one or more features possesses those one or more features, but is not limited to possessing only those one or more features. Furthermore, a structure that is configured in a certain way must be configured in at least that way, but also may be configured in a way or ways that are not specified.

Any embodiment of any of the present devices and methods may consist of or consist essentially of—rather than comprise/include/contain/have—the described features and/or steps.

The terms "a" and "an" are defined as one or more than one unless this disclosure explicitly requires otherwise. The terms "substantially" and "about" are defined as at least close to (and include) a given value or state (preferably within 10% of, more preferably within 1% of, and most preferably within 0.1% of).

An illustrative embodiment of the present devices appears in perspective in FIG. 1. Device 10 includes outer sheath 20 and device body 90 (which, in this embodiment, is a handle configured to be held in one hand) coupled to outer sheath 20. In this embodiment, the outer sheath is coupled to the handle such that the outer sheath cannot move relative to the handle (that is, the two are coupled to each other in a fixed relationship). Outer sheath 20 is a hollow member configured such that a stent can be disposed within it when the stent is in a constrained (e.g, elongated) state prior to delivery.

A portion of the embodiment of FIG. 1 near device body 90 is illustrated in perspective in FIG. 2A and in cross-section in FIG. 3. These figures show that device 10 includes user-actuatable element 50 that is coupled to (and, in this embodiment, mounted on so as to be slidable with respect to) device body 90 and also coupled to element 40, which in this embodiment has a passageway and is configured to fit within outer sheath 20. In the embodiment shown in FIGS. 2A and 3A, user-actuatable element 50 is slidably mounted on device body 90 and coupled to element 40 via block 51. In some embodiments, block 51 may include a biasing element (such as a spring) that biases user-

actuatable element 50 toward the position shown in FIG. 3A. In other embodiments, block 51 does not include a biasing element.

User-actuatable element 50, block 51, and element 40 of device 10 are moveable in the proximal and distal directions (which is along the longitudinal axis (not shown) of the device), and are generally constrained in other directions. Thus, proximal movement of user-actuatable element 50 (towards proximal side 92) results in proximal movement of element 40, and distal movement of user-actuatable element 50 (towards distal side 91) results in distal movement of element 40. In the depicted embodiment, the distance that user-actuatable element 50 moves (either proximally or distally) will translate into movement of element 40 by the same distance. This translation could be geared up or down as desired. As explained in greater detail below, element 40 is coupled to stent-engaging element 45, which engages and drives the loaded stent distally from the outer sheath during at least a portion of the time the stent-engaging element is moved distally within the lumen of the stent.

FIG. 2A also shows that device 10 may include an element 25 that is coupled (slidably) to the outside of outer sheath 20. Element 25 can be configured to slide relatively freely along the outer surface of the outer sheath, and it can be configured to interface with a hemostasis valve of an introducer (see FIG. 3B). Specifically, in can be configured to fit partially inside the introducer and interface with the hemostasis valve such that fluid does not flow back toward the handle of the device yet the outer sheath of the device can slide relatively freely within element 20 and the introducer. Effectively, element 25 can act to reduce the friction between the outer sheath of the device and an

introducer through which the outer sheath of the device is inserted, while maintaining a substantial fluid seal between the outer sheath and the exterior of the patient.

Referring to FIGS. 1, 4 and 5, outer sheath 20 extends distally from device body 90. Device 10 also includes inner element 60, a portion of which is located within outer sheath 20. Inner element 60 (and, more specifically in the preferred embodiment, inner sleeve 61 as shown in FIG. 2D, described below) is coupled at its distal end to nose cone 150. Inner element 60, which is not constrained axially by sheath 20 (in that the two have sufficiently different diameters that they do not touch), facilitates motion of nose cone 150 relative to outer sheath 20 and it is sized such that a guidewire may be passed through it (as is nose cone 150). Radiopaque marker 27 may be placed at any suitable location along outer sheath 20 in order to provide a means for aiding deployment of a stent. For example, the distance from the distal end of outer sheath 20 and marker 27 may be the nominal length of the stent being delivered in its deployed state. FIG. 5 illustrates distal end 31 of stent 30 within outer sheath 20. In some embodiments, neither element 40 nor stent-engaging element 45 is attached to inner element 60. As a result, element 40 may be moved proximally and over inner element 60 while inner element 60 is stationary. Similarly, stent-engaging element 45 may be moved proximally and distally over inner element 60 while inner element 60 is stationary.

Returning to FIGS. 2A and 3A and referring also to FIG. 2C, the allowable proximal-distal travel of user-actuatable element 50 is constrained by the length of slot 52 in device body 90, as well the position of stopper 120. First position 121 of stopper 120 shown in FIG. 2A limits the distal travel of user-actuatable element 50 to less than the full length of slot 52. Preferably, first position 121 corresponds to a distal-most position

of user-actuatable element 50 where the stent-engaging element 45 remains within outer sheath 20. This corresponds to the proper configuration for advancement of stent 30. Stopper 120 is preferably biased to first position 121 with, e.g, a spring. In FIGS. 2C and 3A, stopper 120 has been rotated to a second position 122 (labeled as such in FIG. 2C) that allows user-actuatable element 50 to slide past it, as shown.

FIG. 2D is a cross-sectional view of a sub-assembly of a preferred embodiment of device 10, which sub-assembly includes a preferred embodiment of inner element 60 in the form of an inner sleeve 61 that extends the length of inner element 60 and that is configured to accept a guidewire. Inner element 60 may also include intermediate sleeve 62 that may be secured at its distal end (or any other suitable location) to inner sleeve 61 in any suitable fashion, such as Loctite® 4014 adhesive. Intermediate sleeve 62 (which may be a hypotube) also may extend to the proximal end of inner element 60. Inner element 60 may also include outer sleeve 63 (which may be a hypotube) connected at its distal end (or any other suitable location) to intermediate sleeve 62 in any suitable manner, such as through soldering; outer sleeve 63 also may extend to the proximal end of inner element 60. Inner element 60 may also include a travel-limiting sleeve 64 connected at its distal end (or any other suitable location) to outer sleeve 63 in any suitable manner, such as through soldering. Sleeve 64 may be configured to restrict the travel of inner element 60 with respect to device body 90. More specifically, sleeve 64 can be configured to interfere (due to its size) with the proximal opening (not labeled) of cavity 55 of device body 90 (see FIG. 3A), and it can be configured to interfere distally with block 51 (if Luer fitting 100 does not first interfere with Y-adapter 95).

FIG. 3B is an enlarged, cross-sectional view, showing the interaction between element 25 and introducer 35, where element 25 is interfacing with seal 31 of the hemostasis valve of introducer 35.

FIG. 3C is a cross-sectional view of a sub-assembly of a preferred embodiment of device 10, which sub-assembly includes a preferred embodiment of element 40 in the form of proximal hypotube 41 secured in any suitable fashion to block 51, such as by a press fit that terminates at shoulder 57 or with a suitable adhesive, such as one of the Loctite® adhesives (e.g., 4014, 4305, 3321, etc.). Block 51 is secured to user-actuatable element 50 through pin 54, which can be bonded to element 50 and press fit or bonded to block 51. Element 40 may also include an intermediate tube 42 that is connected at its proximal end to proximal hypotube 41 in any suitable manner, such as through Loctite® 4305, and at its distal end to support tube 46 (that is in turn connected to stent-engaging element 45 in any suitable fashion, such as an adhesive) in any suitable manner, such as through an adhesive. Element 40 may also include a support tube 43 that is positioned over intermediate tube 42 and that abuts the distal end of proximal hypotube 41. Support tube 43 may be connected at any suitable location to intermediate tube 42 using any suitable adhesive. The support tube may be configured to increase the rigidity of intermediate tube 42. Element 40 may also include resheathing stop 44 that is threaded over intermediate tube 42 and that abuts the distal end of support tube 43. Resheathing stop 44 may be connected at any suitable location to intermediate tube 42 using any suitable adhesive. Resheathing stop 44 may be configured to prevent proximal movement of the stent that is enclosed by outer sheath 20 (not shown in this figure) should the stent be re-sheathed during the delivery process. The depicted sub-assembly

also includes a silicone seal 56 that is designed to prevent the backflow of fluid around the outside of inner element 60 (and, more specifically, an outer hypotube that is part of a preferred embodiment of inner element 60) and that is held in place by a stainless steel retainer 58.

Referring to FIG. 6, element 40 extends such that a portion of it is located within outer sheath 20. Preferably, element 40 is hollow and its passageway accommodates a portion of inner tube 60 being located within it. Alternate embodiments of this element may be non-hollow.

Referring to FIGS. 6-7, element 40 is coupled to a stent-engaging element 45, which, in this embodiment, is shaped like a shovel or scoop. More specifically, in the depicted preferred embodiment, intermediate tube 42 of element 40 is connected to support tube 46, which is connected to stent-engaging element 45. Stent-engaging element 45 is positioned at least partially within the lumen of stent 30. As element 40 moves distally in response to distal movement of user-actuatable element 50, stent-engaging element 45 engages stent 30, advancing it along outer sheath 20. In a preferred embodiment, proximal motion of stent-engaging portion 45 results in no motion of stent 30. Repeated reciprocating distal and proximal motion of element 40 in this manner results in advancement of stent 30 until it exits outer sheath 20. Thus, those of ordinary skill in the art will understand that the illustrated embodiment of device 10 is configured such that a user can advance stent 30 distally out of outer sheath 20 through multiple engagements of the stent by stent-engaging element 45, where each engagement: occurs between the proximal and distal ends of stent 30, drives stent 30 distally without a mechanized concomittant withdrawal of outer sheath 20, and is separated from any

subsequent engagement by a period of not driving stent 30 distally; and the user's proximal-most point of contact with device 10 that causes each engagement (which occurs at user-actuatable element 50) is located at or distal of the proximal end of device body 90. Stent-engaging element 45 may include a flex slot 48 provided with rounded, dumbbell-shaped ends that help alleviate fatigue stress fractures and the like and that allow element 45 to fold inwardly as it slides proximally within the lumen of stent 30. Preferably, the performance of stent-engaging portion 45 is achieved by appropriate shape selection, as depicted in FIG. 7. Alternate embodiments may employ stent-engaging portions that flex, are hinged, or otherwise change shape to achieve stent advancement. The configuration of the stent-engaging portion may be chosen to best suit the type of stent to be deployed. When stent 30 is a woven, self-expanding stent, such as the kind disclosed in U.S. patent No. 7,018,401, which is incorporated by reference, stent-engaging element 45 is preferably configured (as shown in the figures) so as to (a) engage wire intersections on opposing sides of stent 30 when driving the stent distally, and (b) fold inwardly (due, at least in part, to flex slot 48 of the stent-engaging element) and slide proximally within the stent's lumen.

FIG. 8 provides a schematic depiction of the stent advancement process. Distal end 31 of stent 30 has exited outer sheath 20 and has expanded. Element 40 moves proximally and distally, as indicated by arrows. As stent-engaging element 45 travels distally, it engages and advances stent 30, thus driving it out of outer sheath 20. No advancement of stent 30 occurs when stent-engaging element 45 travels proximally due to the shape of stent-engaging element 45. Instead, the configuration of stent-engaging element 45 enables it to bend inwardly as it moves over and encounters portions (e.g.,

wire portions) of stent 30 during the proximal movement of user-actuatable element 50 without disturbing the axial position of the stent relative to the outer sheath. Preferably, advancement of stent 30 is achieved without a mechanized concomittant withdrawal of outer sheath 20 and without motion of outer sheath 20 relative to device body 90 (aside from incidental motion caused by patient's body movements, vibrations, etc.).

FIGS. 9-10 illustrate schematically stent deployment in a body vessel. FIG. 9 depicts stent 30 in a constrained, or elongated, configuration. This is an example of a configuration of stent 30 when it is within outer sheath 20 of device 10. FIG. 10 shows stent 30 in an expanded state in body vessel 160, which is one state a self-expanding stent may take when it exits outer sheath 20.

In some embodiments, the present devices may also include a stent-retention element configured to allow an operator to re-sheath the stent during the advancement and/or deployment process, provided the stent has not been advanced completely out of the sheath. Referring to FIGS. 11 and 12A, device 10 includes stent-retention element 70 coupled to proximal end 32 of stent 30. In a preferred embodiment, contact between distal portion 71 of stent-retention element 70 and stent 30 exists as long as proximal end 32 of stent 30 is within outer sheath 20, even during proximal movement of stent-engaging element 45. When proximal end 32 of stent 30 is advanced outside of outer sheath 20, stent 30 expands to a radius larger than the greatest width (taken in the radial direction shown in the figures) of distal portion 71 of stent-retention element 70. As a result, contact between stent 30 and stent-retention element 70 ceases, and deployment of stent 30 is completed. Accordingly, stent-retention element 70 is operable to withdraw stent 30 proximally back into outer sheath 20 (through action by an operator) provided

that a proximal portion of stent 30 (specifically, the proximal portion coupled to stent-retention element 70) is disposed within outer sheath 20.

Referring to FIGS. 2A, 3A and 11-12, proximal portion 72 (also visible in FIG. 3B) of stent-retention element 70 is a cable or similar device that facilitates withdrawal of stent 30 proximally back into outer sheath 20 and that may be characterized as a stent-retention line, provided that a proximal portion of stent 30 is disposed within outer sheath 20. Distal portion 71 of stent-retention element 70 may be a piece of tubing (such as hypotube) that is provided with multiple, radially-projecting prongs 73 that engage openings in woven versions of stent 30. The tubing may be coupled in any suitable fashion (such as through soldering) to proximal portion 72.

As shown in FIGS. 1 and 2A, Y-adapter 95 may be coupled to the proximal portion of device body 90. Inner tube 60 may be placed through straight arm 96 and proximal portion 72 may be placed through angled arm 97 of Y-adapter 95. As shown in FIG. 2B, a stent-retention element position marker 93 may be coupled to line 72 and positioned along the line to the relative position of the stent that is coupled to the stent-retention element. For example, the marker, which may be a piece of heat shrink tubing, may be positioned along the line such that when it extends into the perimeter of angled arm 97 the stent will completely exit outer sheath 20. In this way, an operator has a visual indicator that conveys how far the stent has exited the outer sheath. FIGS. 1 and 2A also show that the stent-retention element may include a finger element 98 coupled to line 72 in any suitable manner (e.g., though LOCTITE® adhesive), to provide a user with something to hold to enable manipulation of the stent-retention element. FIG. 12B shows a preferred embodiment of stent-retention element 70, which finger element 98 in cross-

section and showing an example connection location 99 (for adhesive or the like) between line 72 and finger element 98 (which may have inner and outer components, as shown, that are threaded together).

Preferably, device 10 comprises side port 110 (coupled to device body 90) and Luer fitting 100 (coupled to proximal end 62 of inner tube 60) to allow for flushing of outer sheath 20 and inner tube 60, respectively. The flushing may be with saline and may occur prior to a procedure. Alternate embodiments of the present devices may include alternate designs for flushing outer sheath 20 and inner tube 60, or may not be configured to allow for flushing. FIG. 3D is a top view of device 10 and identifies a cutaway detail near the distal end of device body 90 that is shown in greater detail in FIG. 3E.

Referring to FIG. 2C, second position 122 of stopper 120 allows user-actuatable element 50 to travel distally the full length of slot 52. The distal-most position of user-actuatable element 50 corresponds to a position where stent-engaging element 45 is outside (distal to) outer sheath 20, and therefore in a region where stent 30 will be driven out of outer sheath 20 and in its expanded state. A stent in this position that is de-coupled from distal portion 71 of stent-retention element 70 can no longer be withdrawn into outer sheath 20. Furthermore, a stent in an expanded condition will have radial clearance over stent-engaging element 45. Alternate embodiments of the present devices may employ other designs to limit the travel of user-actuatable element 50, or have no adjustable travel-limiting feature.

FIGS. 13-14 depict another embodiment of the present devices that includes capture device 80 coupled to proximal portion 72 of stent-retention element 70. Capture device 80 serves to release appropriate amounts of proximal portion 72 as stent-engaging

element 45 advances stent 30. Capture device 80 includes a stop that serves to halt distal advancement of stent 30 prior to full deployment of stent 30 from outer sheath 20. The stop (which can be a piece of tubing, such as hypotube, that is coupled at an appropriate location to proximal portion 72) provides operator feedback at the point where further advancement would result in stent deployment (thus, the stop can be used as an indicator of the location at which stent withdrawal will no longer be possible). Here, the operator may choose to withdraw stent 30 into outer sheath 20 for repositioning by pulling proximally on stent-retention element 70, or proceed with stent deployment by depressing deployment stop lever 81 (which allows the stop to bypass the deployment stop lever and permits continued distal advancement of the stent-retention element) and continuing with advancement via user-actuatable element 50.

If the operator chooses to withdraw stent 30 into outer sheath 20 for repositioning, the operator can actuate retention pull lever 84, which (in the depicted embodiment) de-couples capture device 80 from device body 90 and allows the operator to proceed with withdrawing stent 30 by pulling proximal portion 72 of stent-retention element 70 proximally. After withdrawal of stent 30 into outer sheath 20, retention pulley 82 and spring 83 of capture device 80 operate to accumulate excess slack of stent-retention element 70. In this embodiment, proximal portion 72 of stent-retention element 70 may be threaded through a portion of device body 90 that is not centrally disposed within the device body. Alternate embodiments of the present devices that include capture devices may include capture devices that are configured differently from capture device 80, such as automated capture devices. Furthermore, capture device 80 may be coupled to angled arm 97 in the embodiment of device 10 shown in FIG. 1, in place of finger element 98.

The present devices may be disposable and packaged in a bag, pouch, box, or other suitable container, after having been sterilized using any suitable technique, such as sterilization using ethylene oxide gas. There may be a small gap between the distal end of the outer sheath and the proximal end of the nose cone to allow for the sterilizing gas to flow throughout the device. The container may include instructions for using the device that are printed on the container or included inside the container. After the device is removed from its container, saline may be used to flush the outer sheath and its contents and the inner tube. The gap between the nose cone and the outer sheath can then be closed by pulling proximally on the inner tube to which the nose cone is coupled. If the procedure involves stenting a blood vessel, any suitable technique for positioning the device in the appropriate location may be used (e.g, such as the Seldinger technique). The nose cone of the device (which may be any suitable flexible tip) may be radio opaque and may represent a distal-most marker for the device. Another radio opaque marker made from any suitable material (such as a platinum band, or a band made from any suitable platinum alloy) may be coupled to a portion of the device that is proximal to the nose cone, such as to the outer sheath (as discussed above), element 40, or the inner element, to create a proximal-most marker for the device. These two markers may be used by the operator to position the device relative to the lesion of interest to enable accurate deployment of the stent.

The present methods include stent advancement methods for distally driving a stent out of a sheath (e.g., outer sheath 20) and into a tubular structure. In some embodiments, the tubular structure is animal tissue (such as a human blood vessel). In other embodiments, the tubular structure is not animal tissue and comprises a polymer

structure that can be used to test a given device technique or demonstrate stent advancement to one or more persons, such as a doctor considering using the device or stent advancement technique in his or her practice.

Some embodiments of the present stent advancement methods include distally driving a stent (e.g., stent 30) out of a sheath (e.g., outer sheath 20) and into a tubular structure by repeatedly engaging the stent between its distal and proximal ends with a stent-engaging element (e.g., stent-engaging element 45), where at least two of the engagements are separated by a period of non-engagement; and as the stent is distally driven out of the sheath, varying the axial density of the stent within the tubular structure by varying the axial position of the sheath relative to the tubular structure. As the stent is driven distally out of the sheath, the remainder of the device is withdrawn proximally by the operator relative to the tubular structure so that the deployed portion of the stent remains stationary relative to the tubular structure (e.g., human tissue) into which it is deployed. The rate at which the remainder of the device is withdrawn may be varied to vary the axial density of the stent: a slower withdrawal rate increases the axial density of the stent, whereas a faster rate decreases the axial density of the stent. It may be desirable to increase the axial density of the stent in, for example, a location where a greater hoop strength is required to maintain the patency of the tubular structure, such as along a stenosed region 210 of an artery 200 as shown in FIG. 15A. It may be desirable to decrease the axial density of the stent in, for example, a location where fluid flow into a section of the stent from the side is anticipated or desired, or at the location of penetration of a second stent, either of which may be true at an anatomical side branch 260 of a vessel 250 as shown in FIG. 15B.

Some embodiments of the present stent advancement methods include distally driving a stent (e.g., stent 30) out of a sheath (e.g., outer sheath 20) and into a tubular structure by repeatedly engaging the stent between its distal and proximal ends with a stent-engaging element (e.g., stent-engaging element 45), where at least two of the engagements are separated by a period of non-engagement; and engaging the stent at its proximal end with a stent-retention element (e.g., stent-retention element 70) that is positioned within the sheath.

In some embodiments, the engagements that drive the stent distally from the sheath may be achieved using a device that is configured to not mechanically concomittantly withdraw the sheath as the stent is driven distally, such as the versions of the present devices shown in the figures. The tubular structure in those embodiments can be an anatomical tubular structure, such as a vessel or duct, or a tubular structure that is not animal tissue, such as a polymer tube 300 (see FIG. 15C). Regardless, in some embodiments, the method may also include engaging the stent at its proximal end with a stent-retention element that is positioned within the sheath. The stent-retention element may include a stent-retention line, and the method may also include, after the stent is partially-driven out of the sheath, withdrawing the stent back into the sheath by moving the stent-retention line. An operator may accomplish the driving of the stent by moving a user-actuatable element (e.g., user-actuatable element 50) with the operator's thumb. The stent may be woven, a stent-engaging element may engage multiple wire intersections of the stent and move distally during the engagements that drive the stent, and the stent-engaging element may slide proximally within the stent's lumen during the period of non-engagement.

Some of the present methods are methods of instructing another or others on how to advance a stent out of sheath and into a tubular structure. Some embodiments of the present stent advancement instruction methods include instructing a person on how to use a stent delivery device (e.g., device 10) that includes a sheath (e.g., outer sheath 20) and a stent (e.g., stent 30) disposed in the sheath. The instructing may include demonstrating the following steps to the person: distally driving the stent out of the sheath and into a tubular structure by repeatedly engaging the stent between its distal and proximal ends with a stent-engaging element (e.g., stent-engaging element 45), where at least two of the engagements are separated by a period of non-engagement; and, as the stent is distally driven out of the sheath, varying the axial density of the stent within the tubular structure by varying the axial position of the sheath relative to the tubular structure.

Some embodiments of the present stent advancement instruction methods include instructing a person on how to use a stent delivery device (e.g., device 10) that includes a sheath (e.g., outer sheath 20) and a stent (e.g., stent 30) disposed in the sheath. The instructing may include demonstrating the following steps to the person: distally driving the stent out of the sheath and into a tubular structure by repeatedly engaging the stent between its distal and proximal ends with a stent-engaging element (e.g., stent-engaging element 45), where at least two of the engagements are separated by a period of non-engagement; and engaging the stent at its proximal end with a stent-retention element (e.g., stent-retention element 70) that is positioned within the sheath.

The instruction methods may be accomplished in some embodiments by a live demonstration in the presence of the person and in other embodiments by a recorded or simulated demonstration that is played for the person. An example of a recorded

demonstration is one that was carried out by a person and captured on camera. An example of a simulated demonstration is one that did not actually occur, and that instead was generated using a computer system and a graphics program. In the case of a recorded or simulated demonstration, the demonstration may exist in any suitable form—such as a on DVD or in any suitable video file (such as an .mpg, .mov., .qt, .rm, .swf, or .wmv file)—and the instructing may be accomplished by playing the demonstration for the viewer using any suitable computer system. The viewer or viewers may cause the demonstration to play. For example, the viewer may access the recorded or simulated demonstration file using the internet, or any suitable computer system that provides the viewer with access to the file. See FIG. 16.

In embodiments of the present methods that involve stent delivery into an anatomical structure, and the device used to accomplish the method is in a desired location within a patient to start the stent advancement, the movement (e.g, the ratcheting movement) of the stent-engagement element can begin such that the distal end of the stent (which can also be provided with one or more radio opaque markers to enable easier viewing of its position during the procedure) exits the outer sheath of the device, but not to such an extent that it expands to contact the anatomical structure. If the distal end of the stent is proximal of where the operator wants it, and a stent-retention element is used, the stent-retention element can be pulled proximally to resheath the stent and reposition the device; if the stent is distal of where the operator wants it, the entire device can be withdrawn proximally and the deployment process continued.

The different features of the present devices can be made from commercially-available, medical-grade materials. For example, nose cone 150 may be made from a

polyether block amide (such as PEBAX® resin, available from Arkema Inc, Philadelphia, PA). A distal portion of inner element 60 (such as inner sleeve 61) may be made from polyimide and coupled to a more proximal portion made from stainless steel hypotube (such as 304 or 316L stainless steel). Luer fitting 100 coupled to inner element 60 (e.g., outer sleeve 63) may be made from polycarbonate. Outer sheath 20 may be made from a braided polyether block amide (e.g, a braided PEBAX® resin). Device body 90, user-actuatable element 50, block 51, and stopper 120 may be made from ABS (acrylonitrile butadiene styrene) plastic, polycarbonate, or DELRIN® acetal resin (available from DuPont). Stopper 120 may be coupled to a stainless steel spring that biases it as described above. Element 40 may have a shaft formed from polyimide (or, a series of shafts, as in the preferred embodiment, that are made from polyimide or nitinol hypotube), and stent-engaging element 45 may include or be coupled to a short piece of nitinol hypotube (e.g., tube 46) coupled to the polyimide shaft with a suitable adhesive (e.g, LOCTITE® adhesive, which includes cyanoacrylates) and a piece of nitinol hypotube fashioned in the desired shape and welded (e.g, laser welded) to the short piece of nitinol hypotube. Stent-retention element 70 may include an intertwined stainless steel wire (used as proximal portion 72) that is covered with a material such as nylon, FEP (fluorinated ethylene propylene) tubing, or PET (polyester) tubing, and distal portion 71 may be made from stainless steel hypotube. Furthermore, steps may be taken to reduce the friction between the parts that contact or may contact either other during use of the present devices, such as contact between the stent and the outer sheath.

The present devices may be used to deliver self-expending stents that are woven, including stents woven from multiple strands, such as wires. Some examples of weaving

techniques that may be used include those in U.S. Patent Nos. 6,792,979 and 7,048,014, which are incorporated by reference. The strands of a woven stent may terminate in strand ends (e.g, wire ends) that are then joined together using small segments of material, such as nitinol hypotube, when the stent strands are wires made from nitinol. The stent may be passivated through any suitable technique in order to remove the oxide layer from the stent surface that can be formed during any heat treating and annealing, thus improving the surface finish and corrosion resistance of the stent material. Suitable stent creation techniques for stents that may be used with the present devices (including the strand crossings that may be engaged by stent-engaging element 45) are set forth in U.S. Patent Application Serial No. 11/876,666, which is incorporated by reference.

* * *

It should be understood that the present devices and methods are not intended to be limited to the particular forms disclosed. Rather, they are to cover all modifications, equivalents, and alternatives falling within the scope of the claims. For example, while the embodiments of the present devices shown in the figures included a stent-engaging element and a user-actuatable element that moved the same distances in response to operator input, other embodiments of the present devices could include gears or other mechanisms that create a ratio between the distance that the user-actuatable element moves and the resulting distance that the stent-engaging element moves that is not 1:1 (such that the reciprocating element distance can be greater or less than the user-actuatable element distance). Furthermore, still other embodiments may employ other structures for achieving periodic engagement of a stent in order to advance it distally, such as a through a squeeze-trigger mechanism similar to the one shown in U.S. Patent

No. 5,968,052, which is incorporated by reference, or in U.S. Patent No. 6,514,261, which is incorporated by reference, or through a stent-engaging element that rotates rather than translates and that possesses a cam portion configured to engage the stent during part of a given rotation and not engage the stent during another part of that rotation. Furthermore, still other embodiments may employ other forms of reciprocating movement of a stent-engaging element (such as stent-engaging element 45), such as through another form of operator input like a rotational user-actuatable input (rather than a translation input, as is shown in the figures) coupled to the stent-engaging element via a cam.

The claims are not to be interpreted as including means-plus- or step-plus-function limitations, unless such a limitation is explicitly recited in a given claim using the phrase(s) "means for" or "step for," respectively.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that the prior art forms part of the common general knowledge in Australia.

What is claimed is:

1. A device including:

an outer sheath;

a handle coupled to the outer sheath, the outer sheath stationary relative to the handle;

a stent disposed within the outer sheath; and

a stent-engaging element disposed within the outer sheath;

wherein the stent is distally driveable out of the outer sheath through at least two periods of engagement of the stent by the stent-engaging element, each said period of engagement configured to drive the stent distally without a mechanized concomitant withdrawal of the outer sheath and each said period of engagement separated by a period of non-engagement of the stent by the stent-engaging element that is configured to not drive the stent distally.

2. The device of claim 1, wherein the stent has a distal end, a proximal end, and a lumen extending between the distal end and the proximal end, and wherein the stent-engaging element is positioned at least partially within the lumen of the stent.

3. The device as in any one of claims 1-2, further including a user-actuatable element coupled to the handle and coupled to the stent-engaging element by an element having a passageway.

4. The device of claim 3, wherein the element having the passageway is configured to accept a guidewire.

5. The device of claim 3, wherein the user-actuatable element is movable within a slot of the handle.

6. The device as in any one of claims 3-5, further including a stopper having a first position that restricts distal advancement of the user-actuatable element.

7. The device of claim 6, wherein the stopper has a second position that does not restrict distal advancement of the user-actuatable element and wherein the stopper is biased in the first position.

8. The device as in any one of claims 1-7, wherein the stent has a proximal end and wherein the device further includes a stent-retention element engaging the proximal end of the stent.

9. The device as in any one of claims 1-8, wherein the stent includes a plurality of woven wires.

10. The device of claim 9, wherein the stent-engaging element is configured to (a) engage wire intersections during each said period of engagement, and (b) fold inwardly and slide proximally during each said period of non-engagement.

11. The device as in any one of claims 1-10, wherein the handle has a proximal end and wherein a proximal-most point of contact of a user with the device that causes each said period of engagement is located at or distal of the proximal end of the handle.

12. The device as in any one of claims 1-11, wherein the stent-engaging element is shaped like a shovel or scoop.

13. A stent advancement method including:

distally driving a stent disposed within an outer sheath into a tubular structure that is not part of an animal, the outer sheath coupled to a handle and stationary relative to the handle,

wherein distally driving the stent includes engaging the stent by a stent-engaging element disposed within the outer sheath without a mechanized concomitant withdrawal of the outer sheath during at least two periods of engagement, each said period of engagement separated by a period of non-engagement of the stent by the stent-engaging element that does not drive the stent distally.

14. The stent advancement method of claim 13, wherein movement of the stent-engaging element corresponds to movement of a user-actuatable element.

15. The stent advancement method as in any one of claims 13-14, wherein the stent includes a plurality of woven wires and wherein engaging the stent by the stent-engaging element includes engaging wire intersections during said periods of engagement and folding inwardly and sliding proximally during said periods of non-engagement.

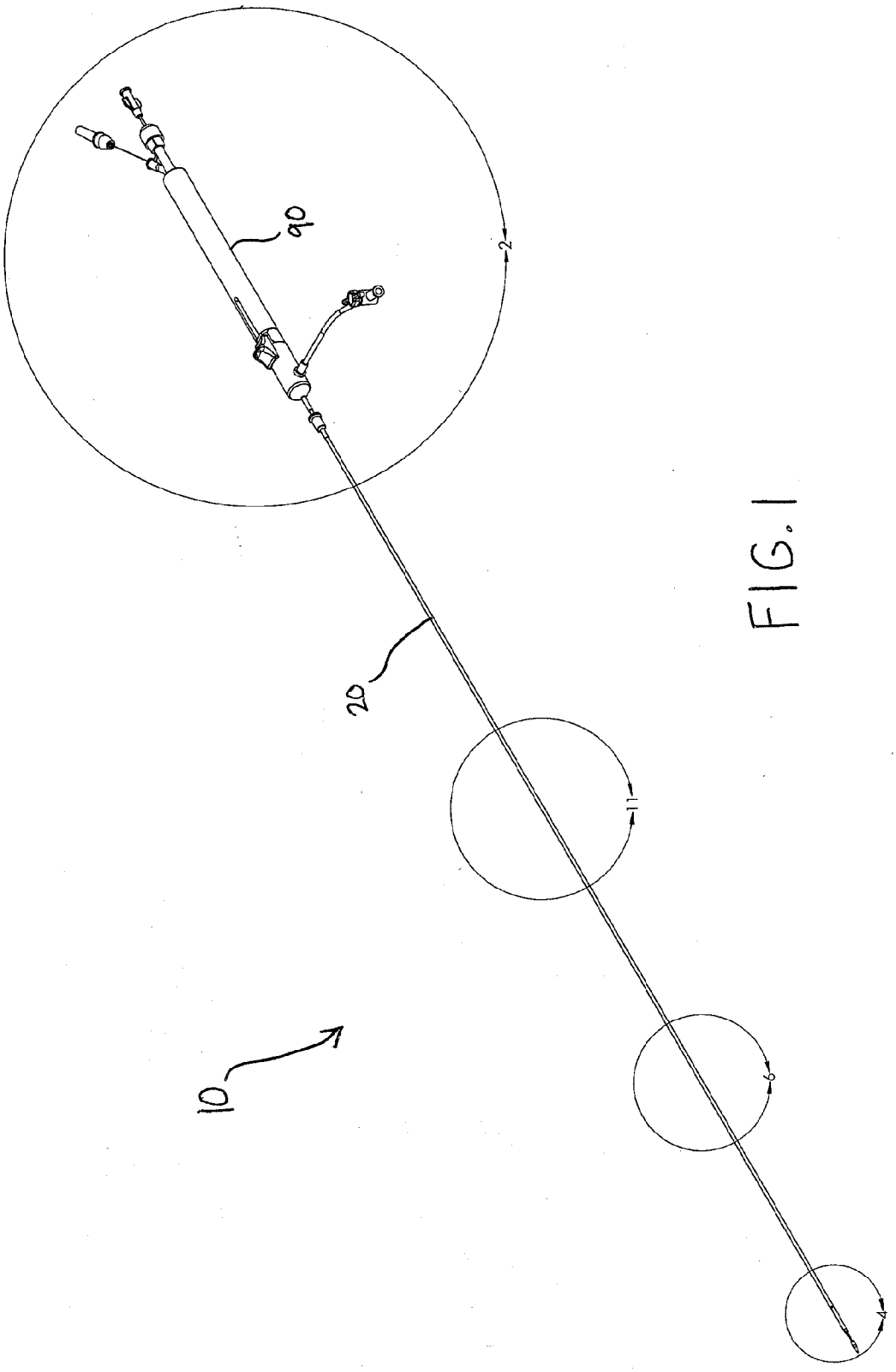


FIG. 1

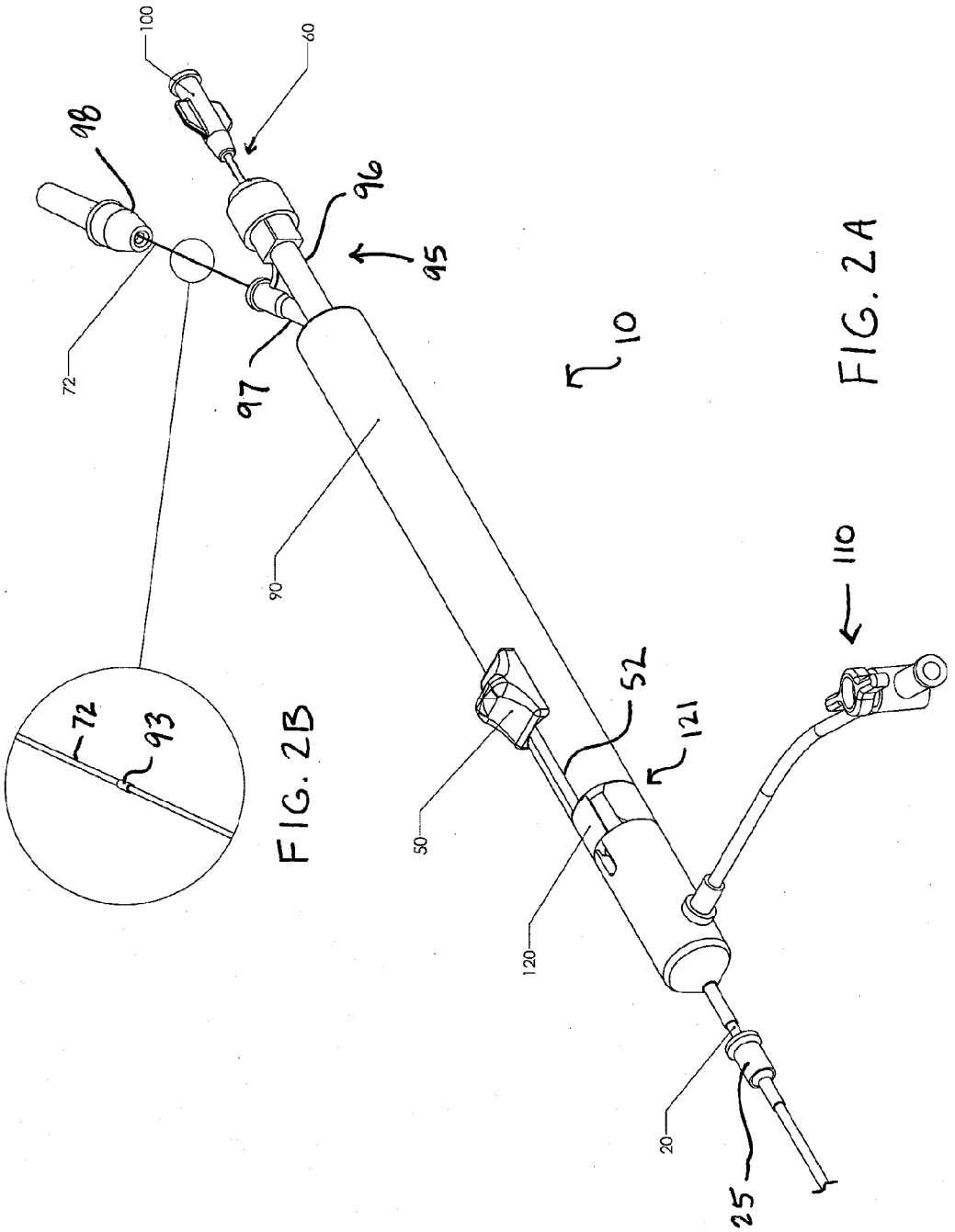


FIG. 2A

FIG. 2B

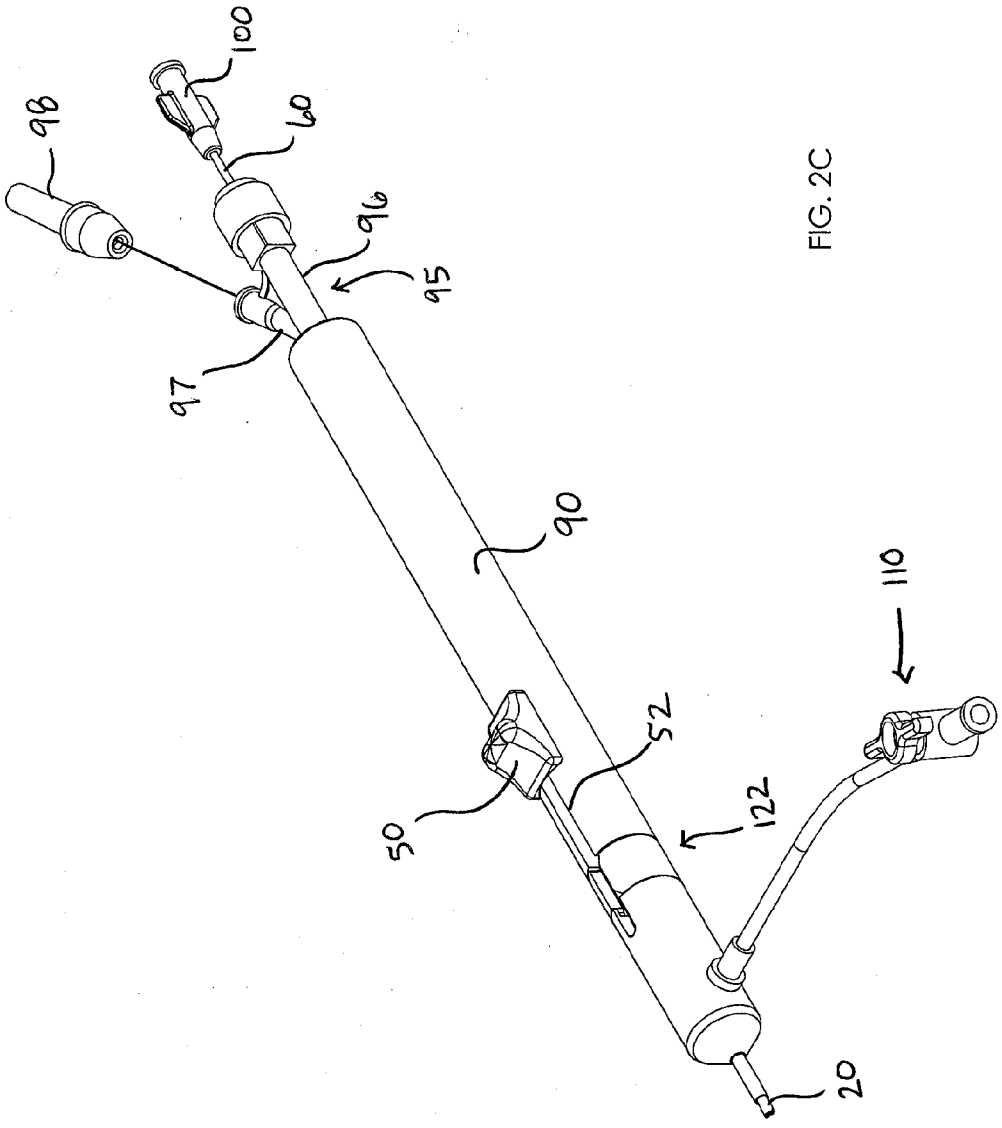


FIG. 2C

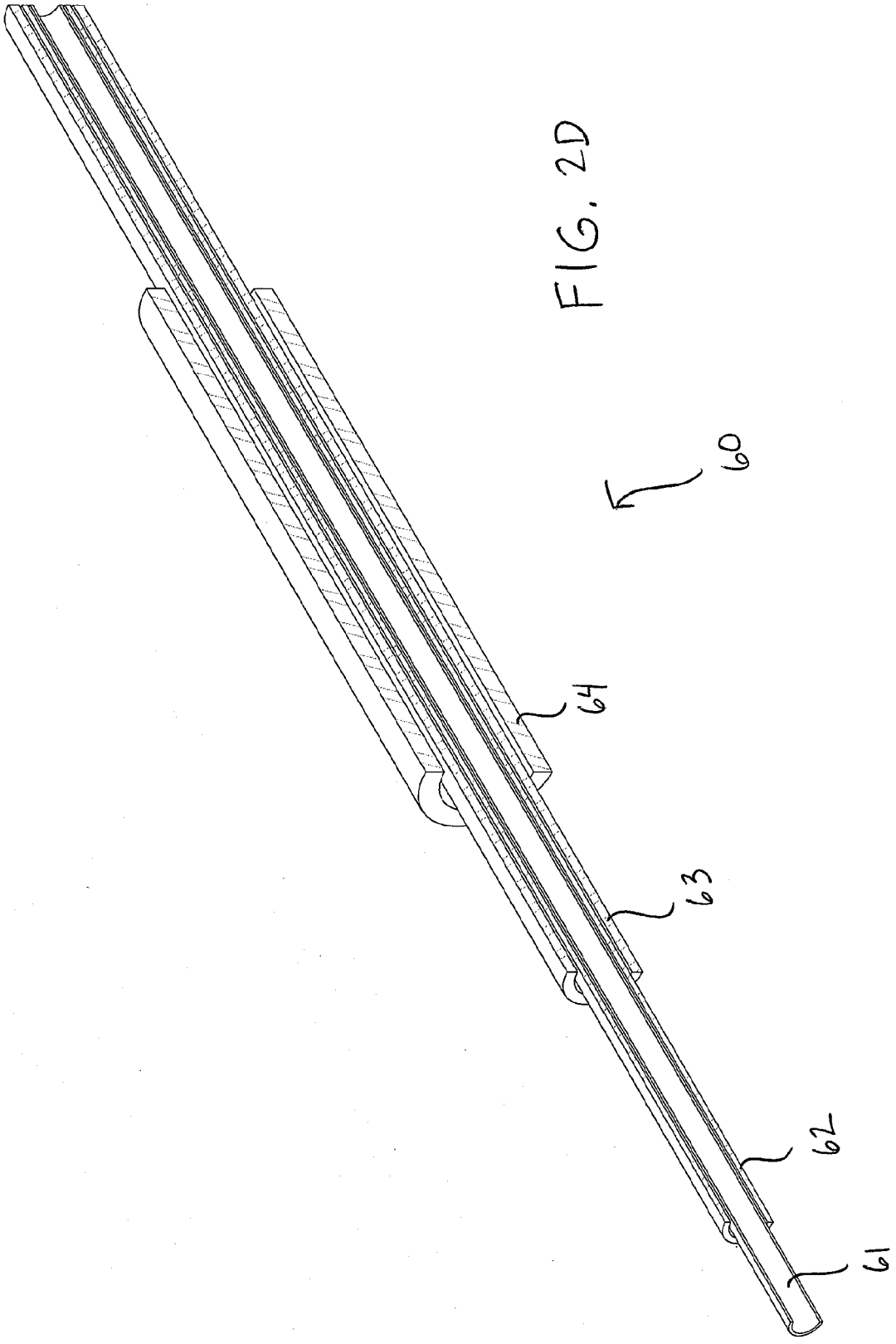


FIG. 2D

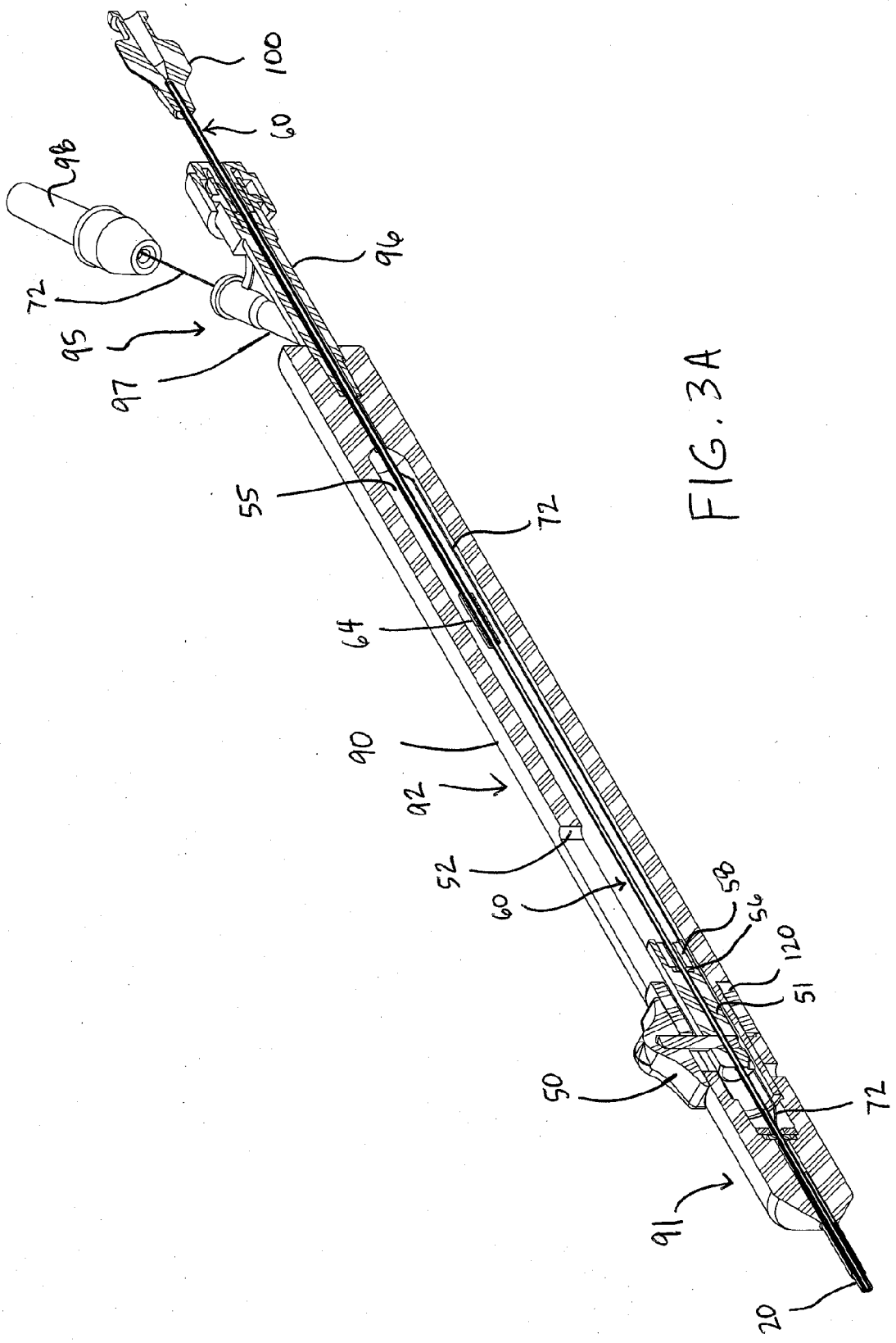


FIG. 3A

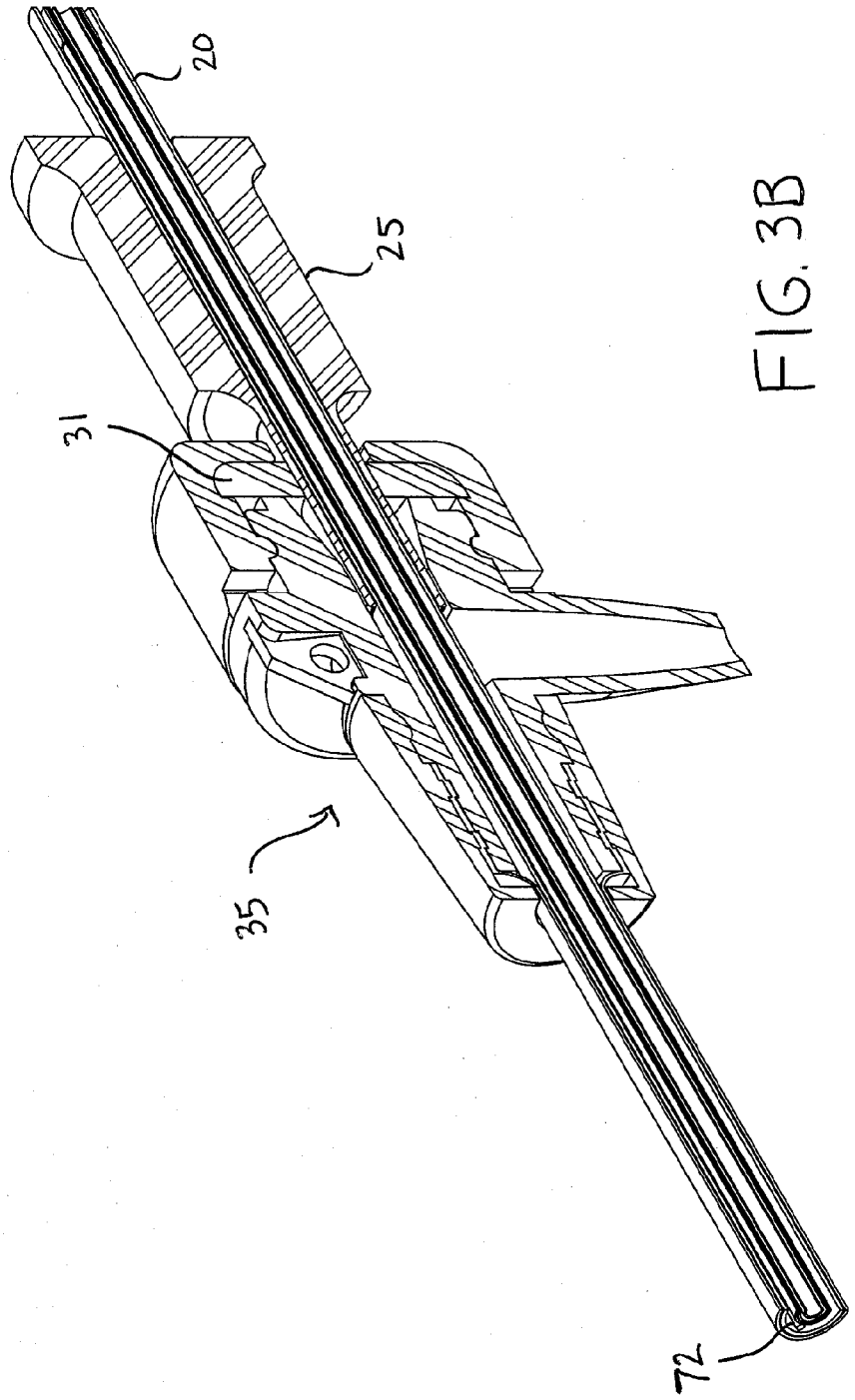


FIG. 3B

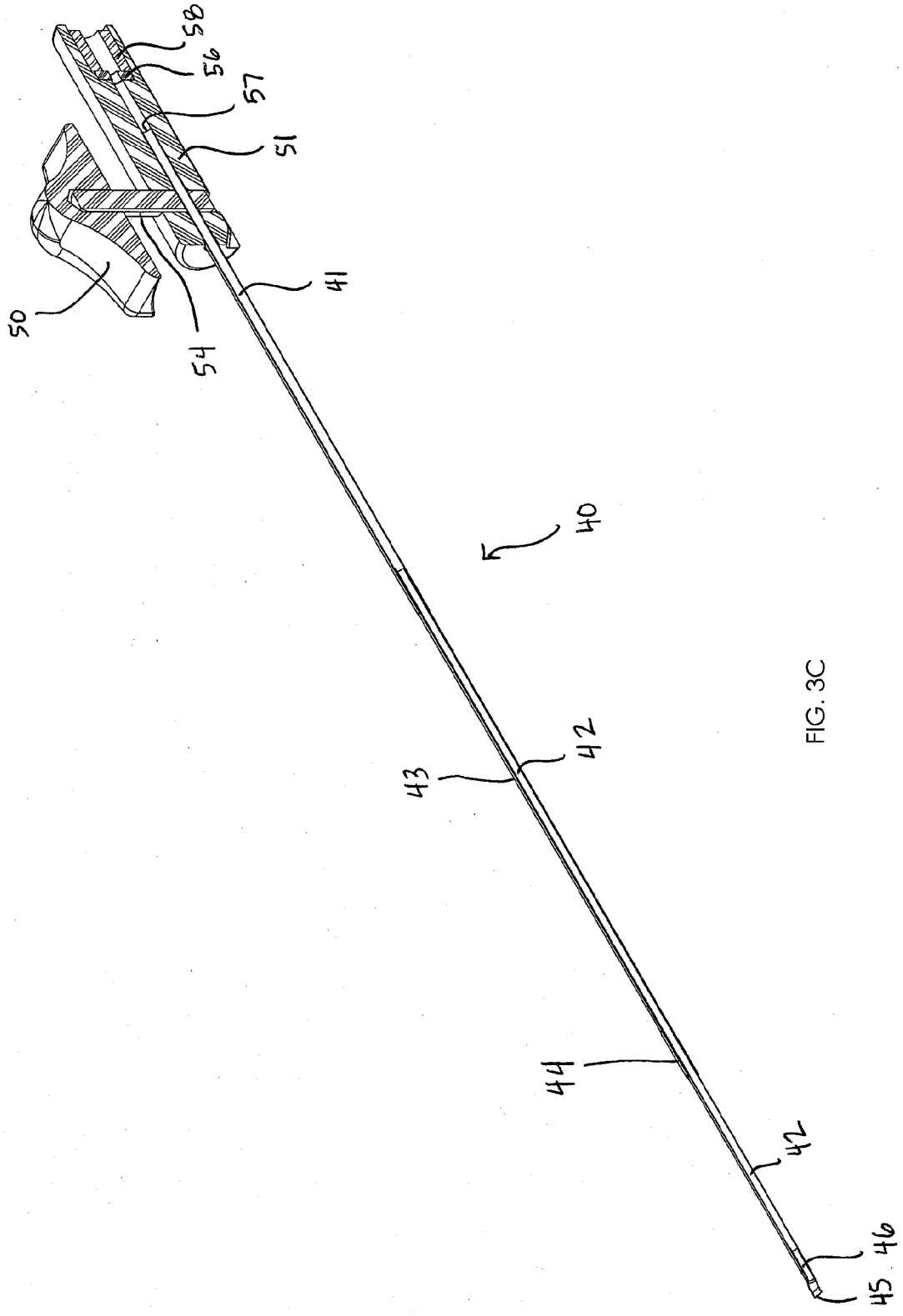


FIG. 3C

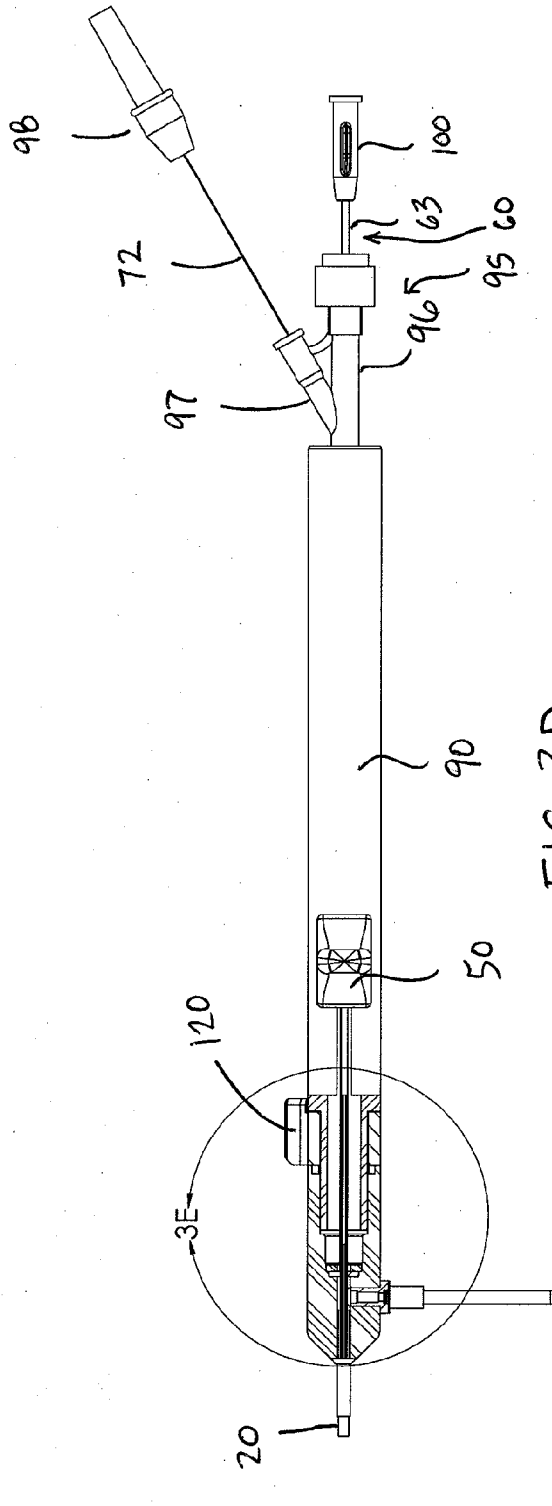


FIG. 3D

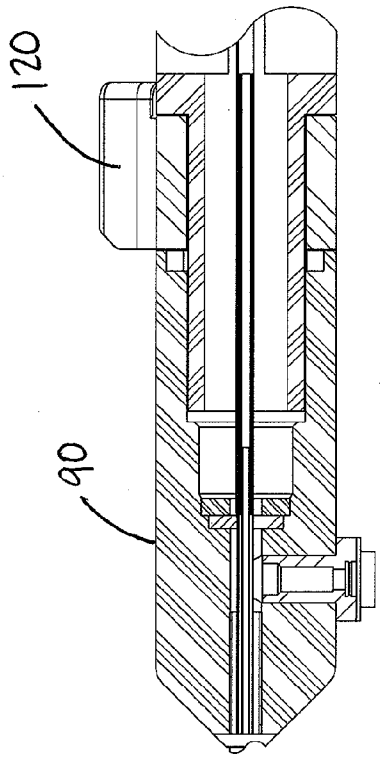


FIG. 3E

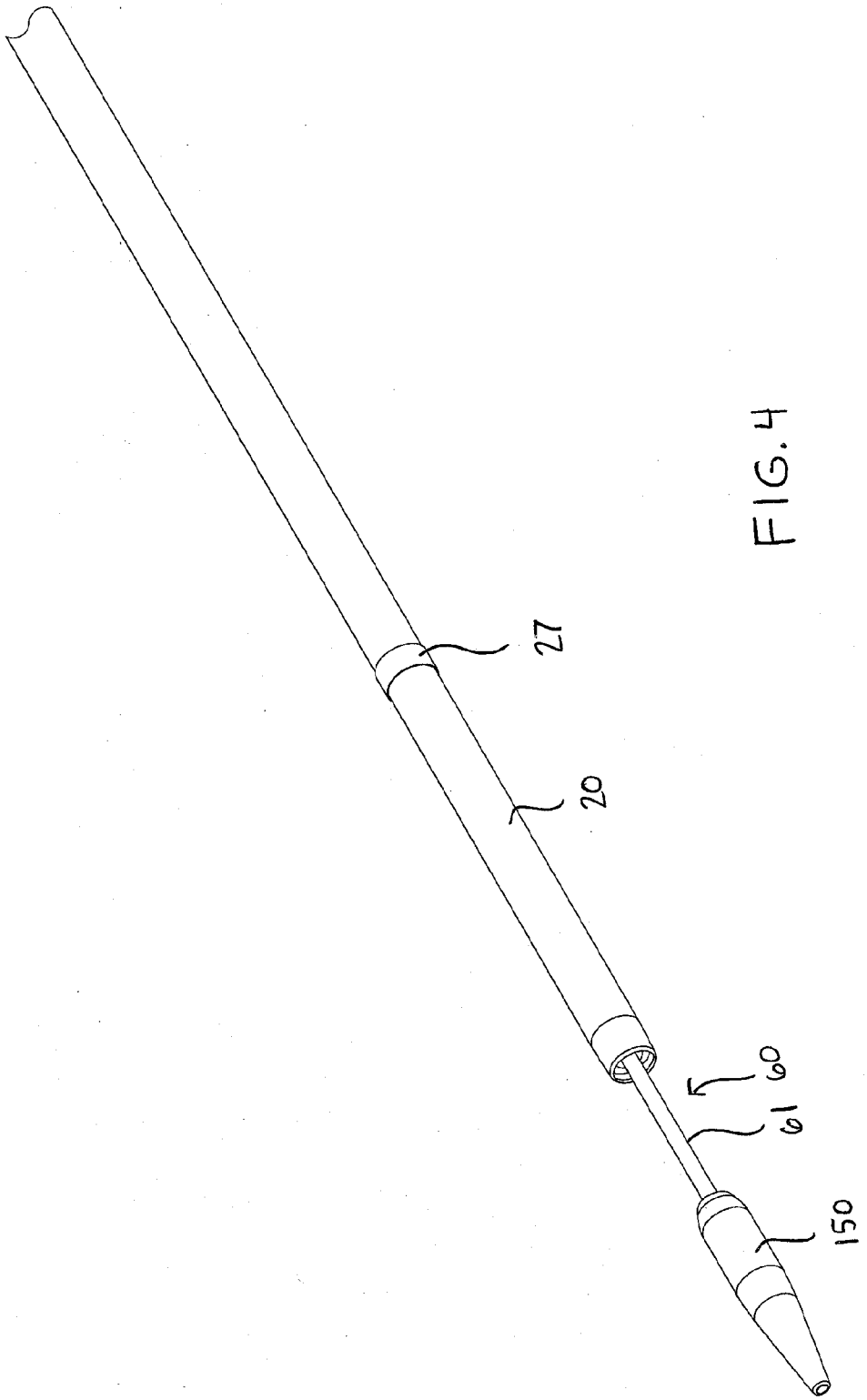


FIG. 4

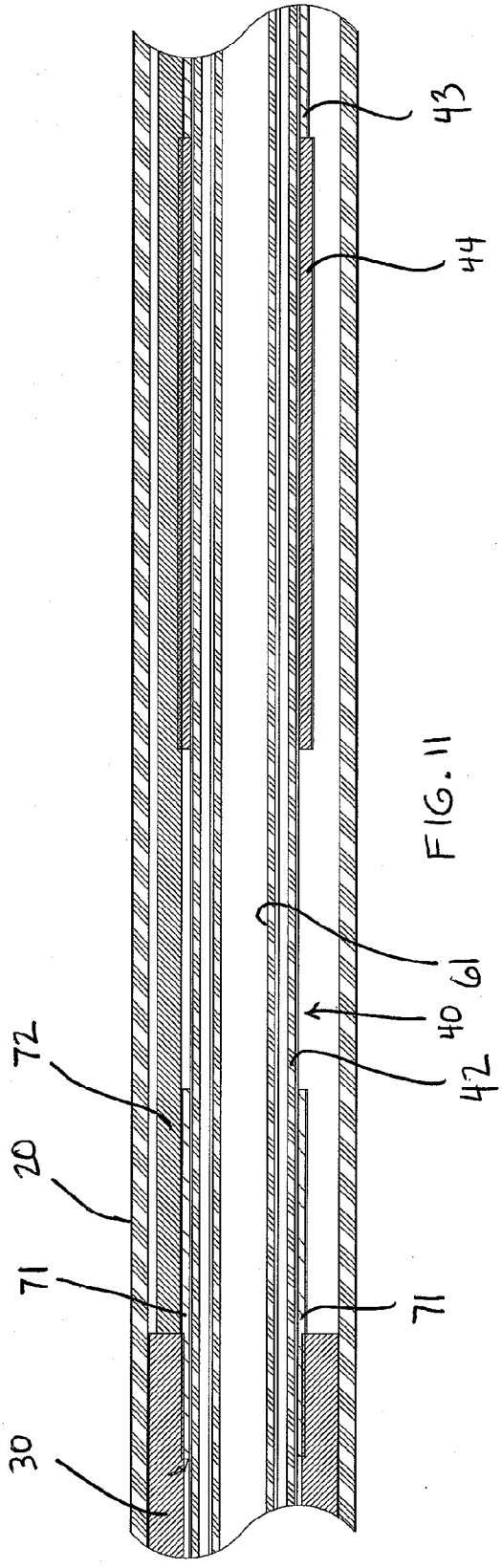


FIG. 11

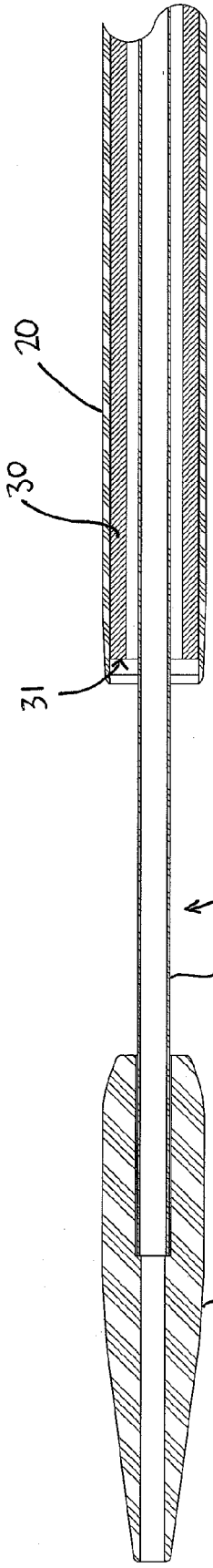


FIG. 5

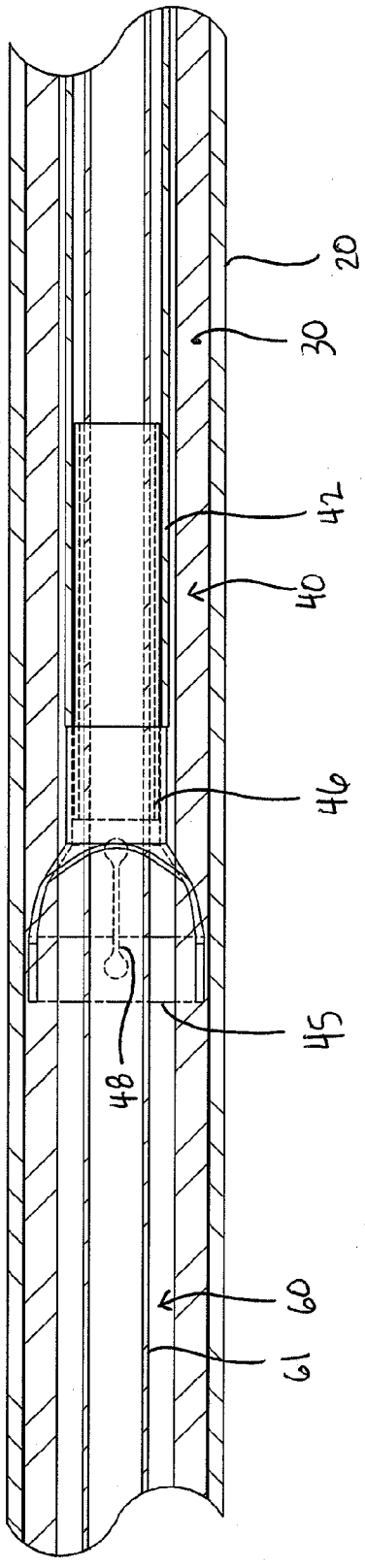


FIG. 6

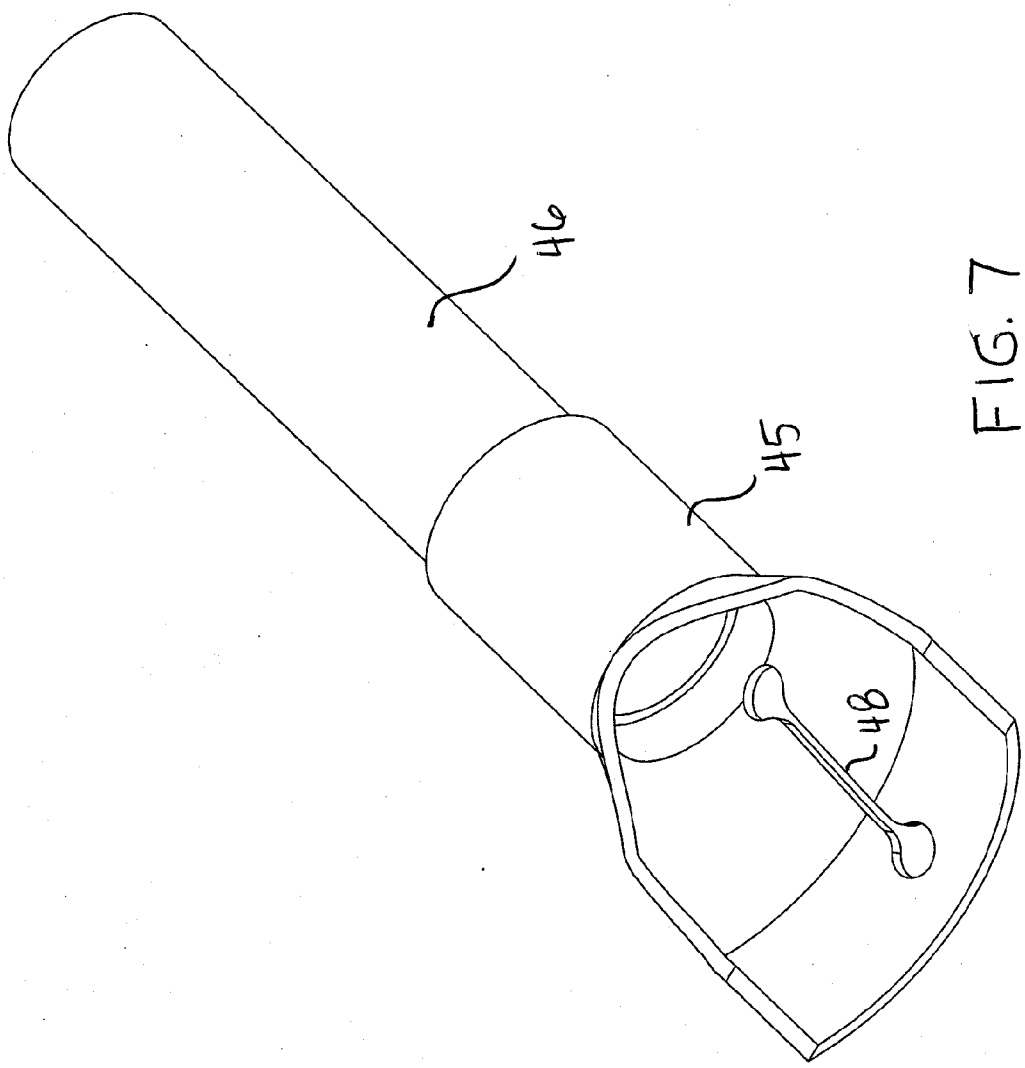


FIG. 7

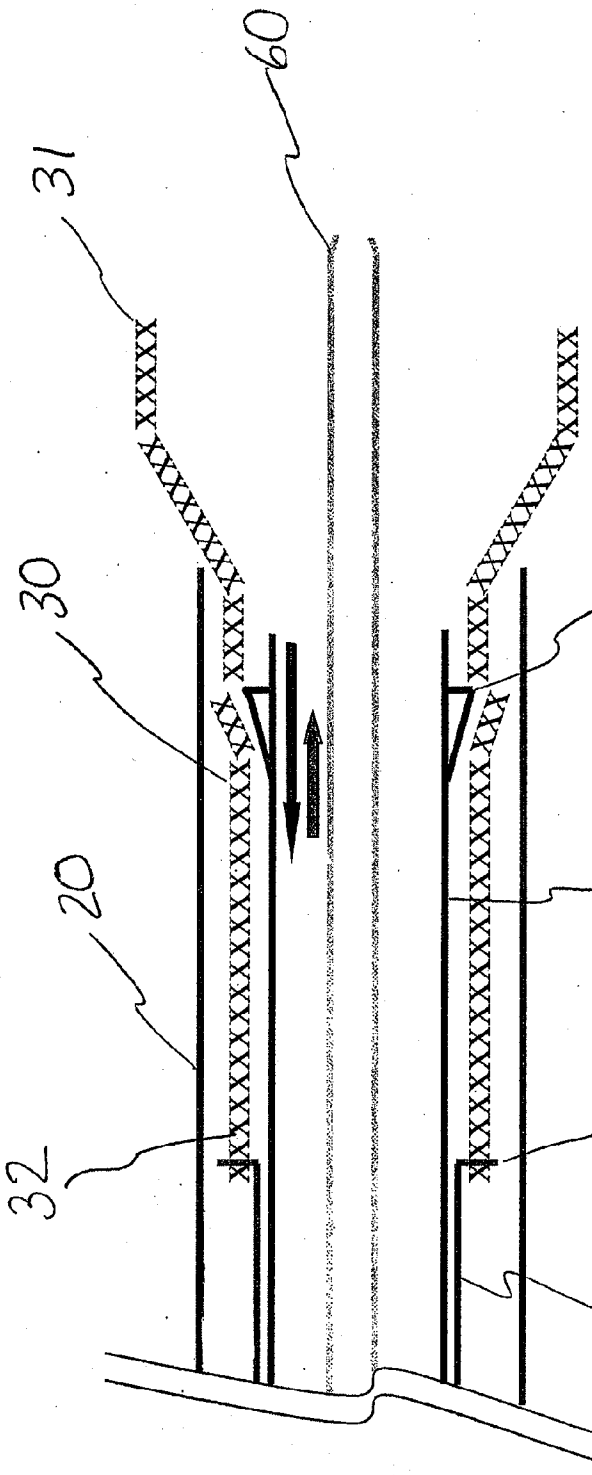


FIG. 8

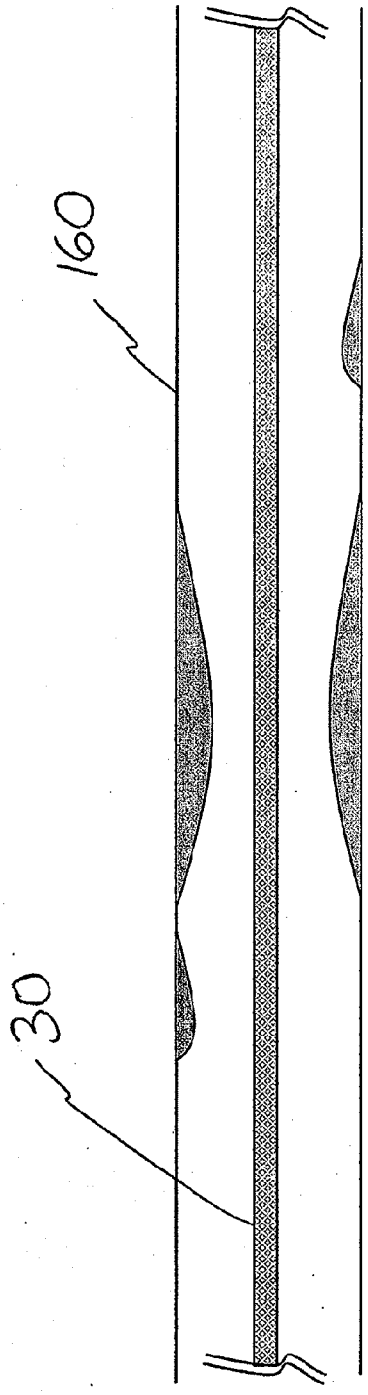


FIG. 9

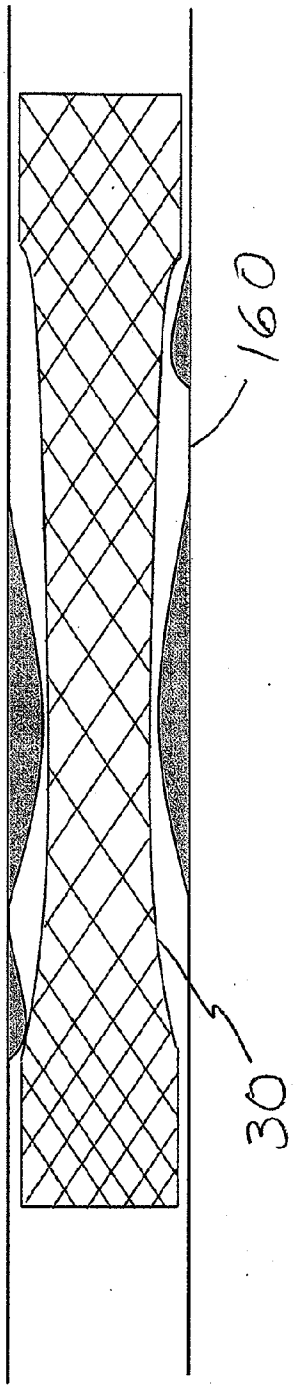


FIG. 10

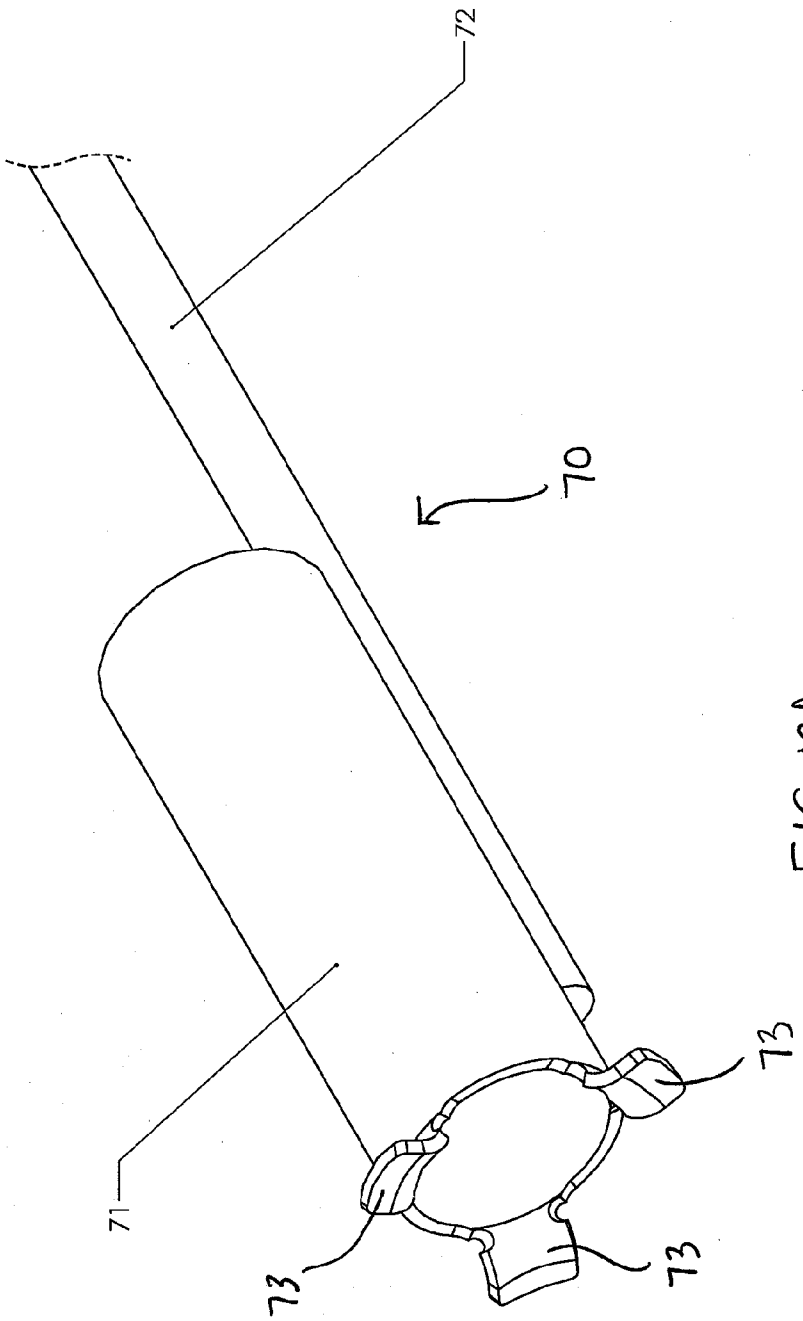


FIG. 12A

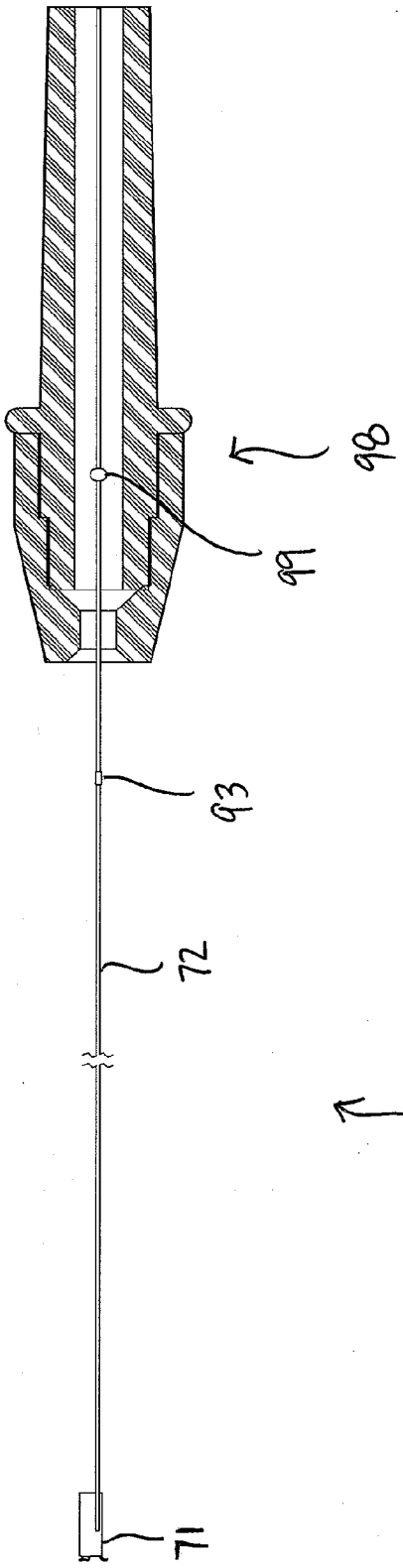


FIG. 12B

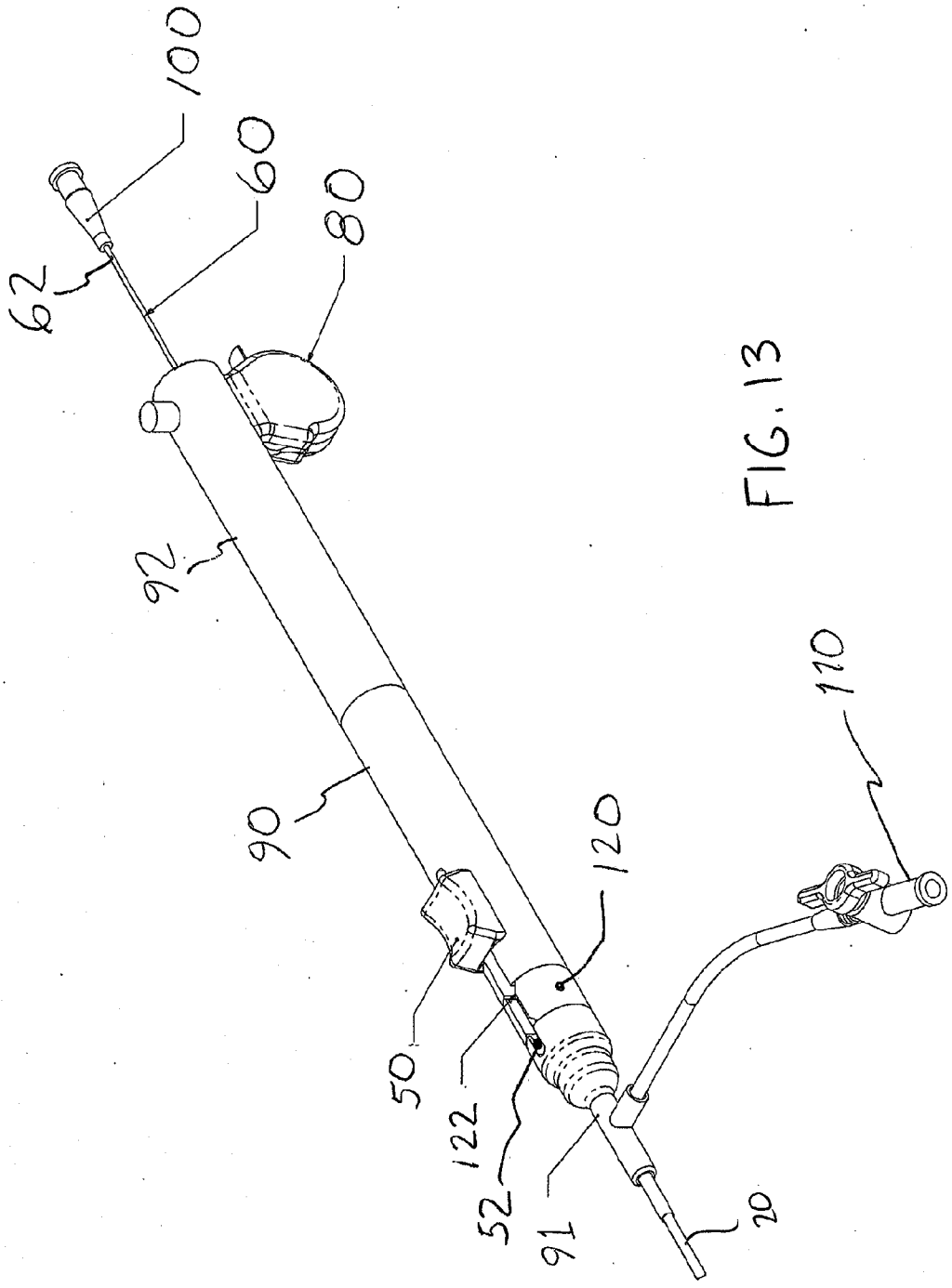


FIG. 13

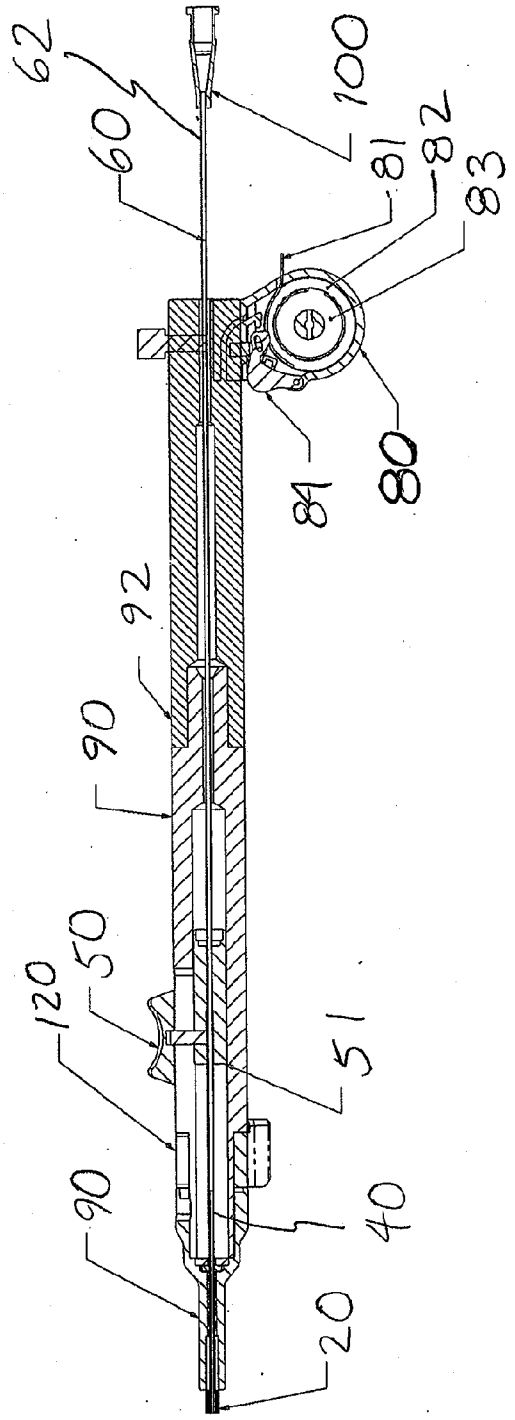


FIG. 14

FIG. 15A

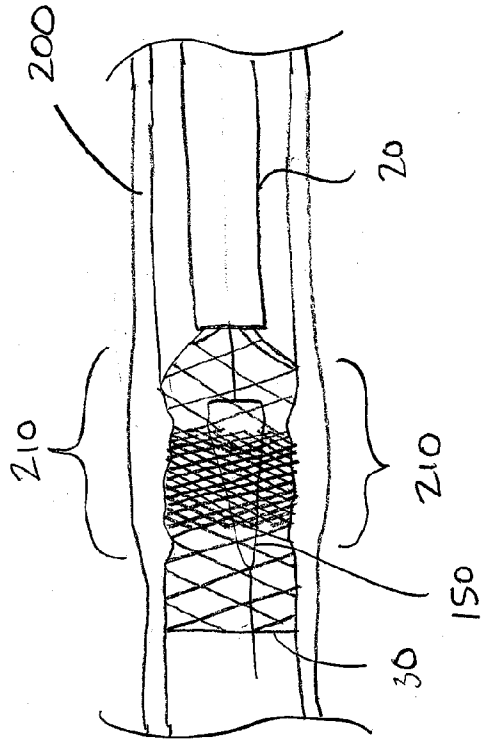
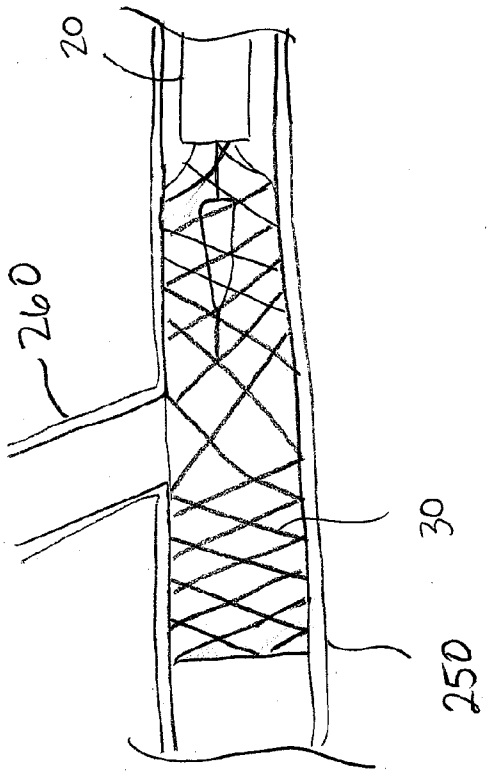


FIG. 15B



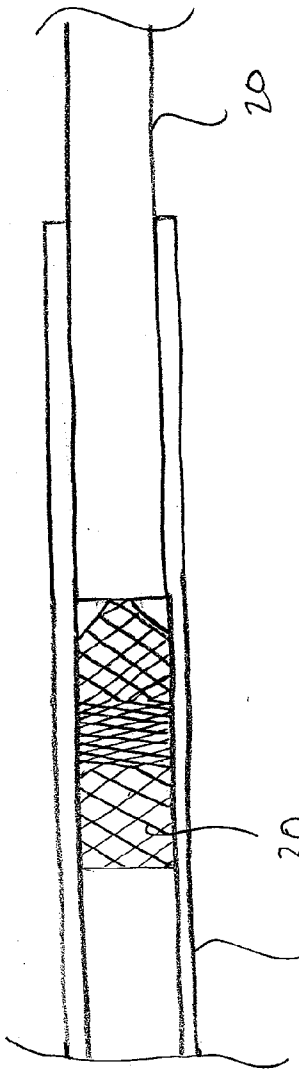


FIG. 15C

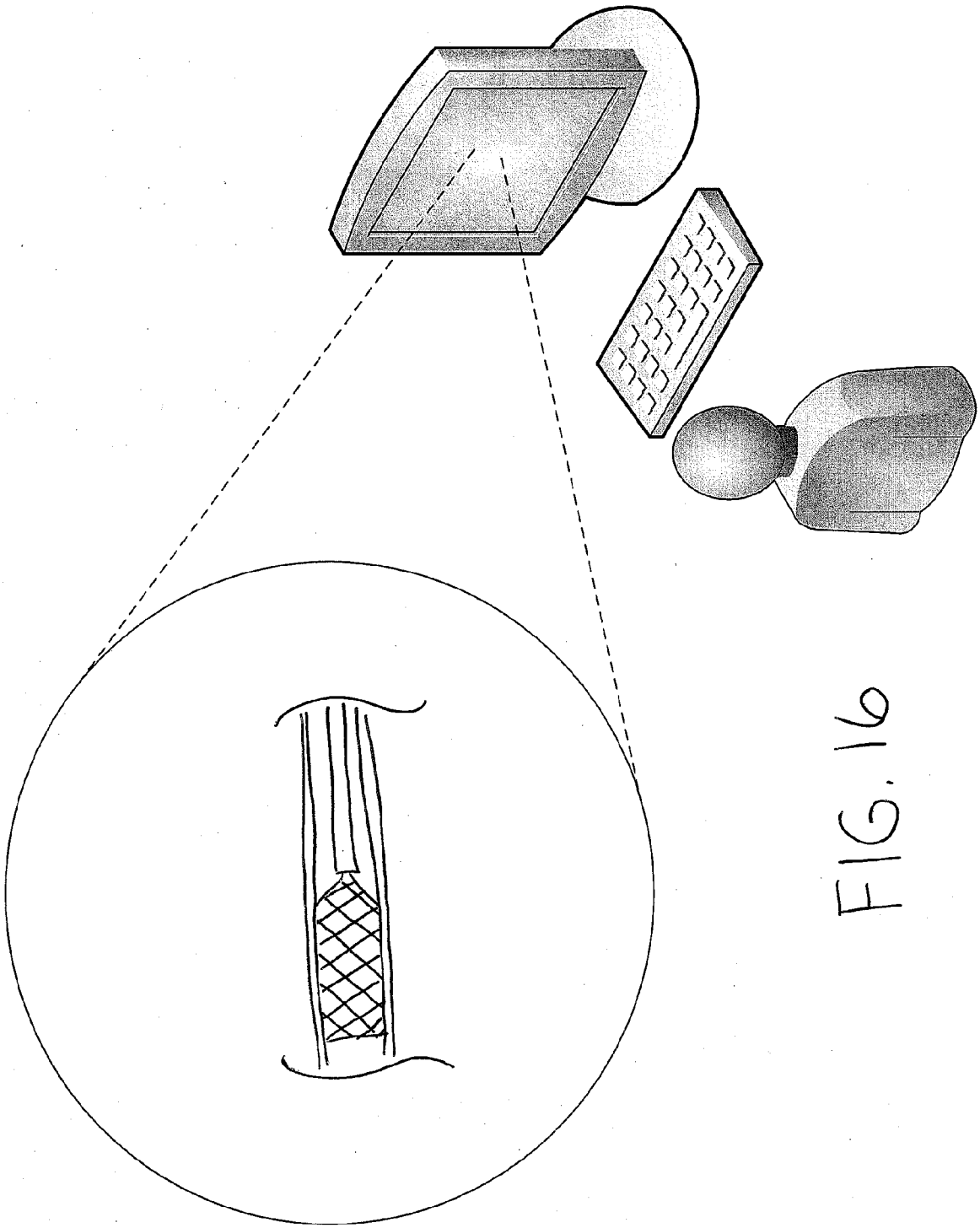


FIG. 16