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(54) SYSTEM FOR INTRODUCING MULTIPLE MEDICAL DEVICES

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Related U.S. Application Data

(60) Provisional application No. 60/491,408, filed on Jul. 31, 2003. Provisional application No. 60/563,968, filed on Apr. 21, 2004. Provisional application No. 60/570,656, filed on May 13, 2004.

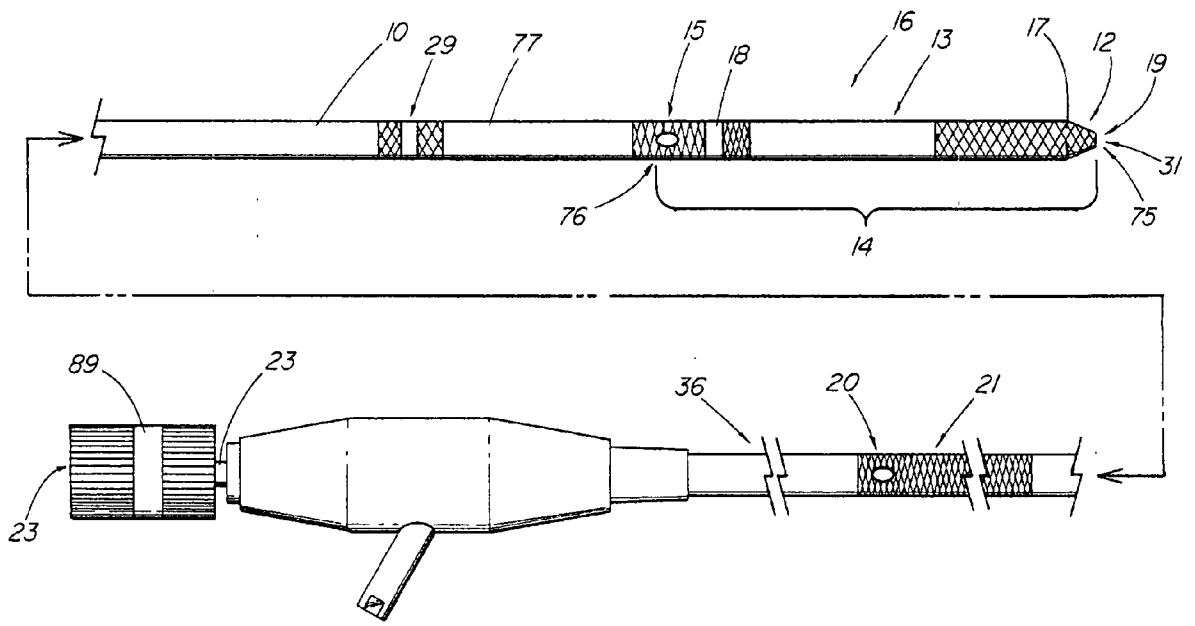
Publication Classification

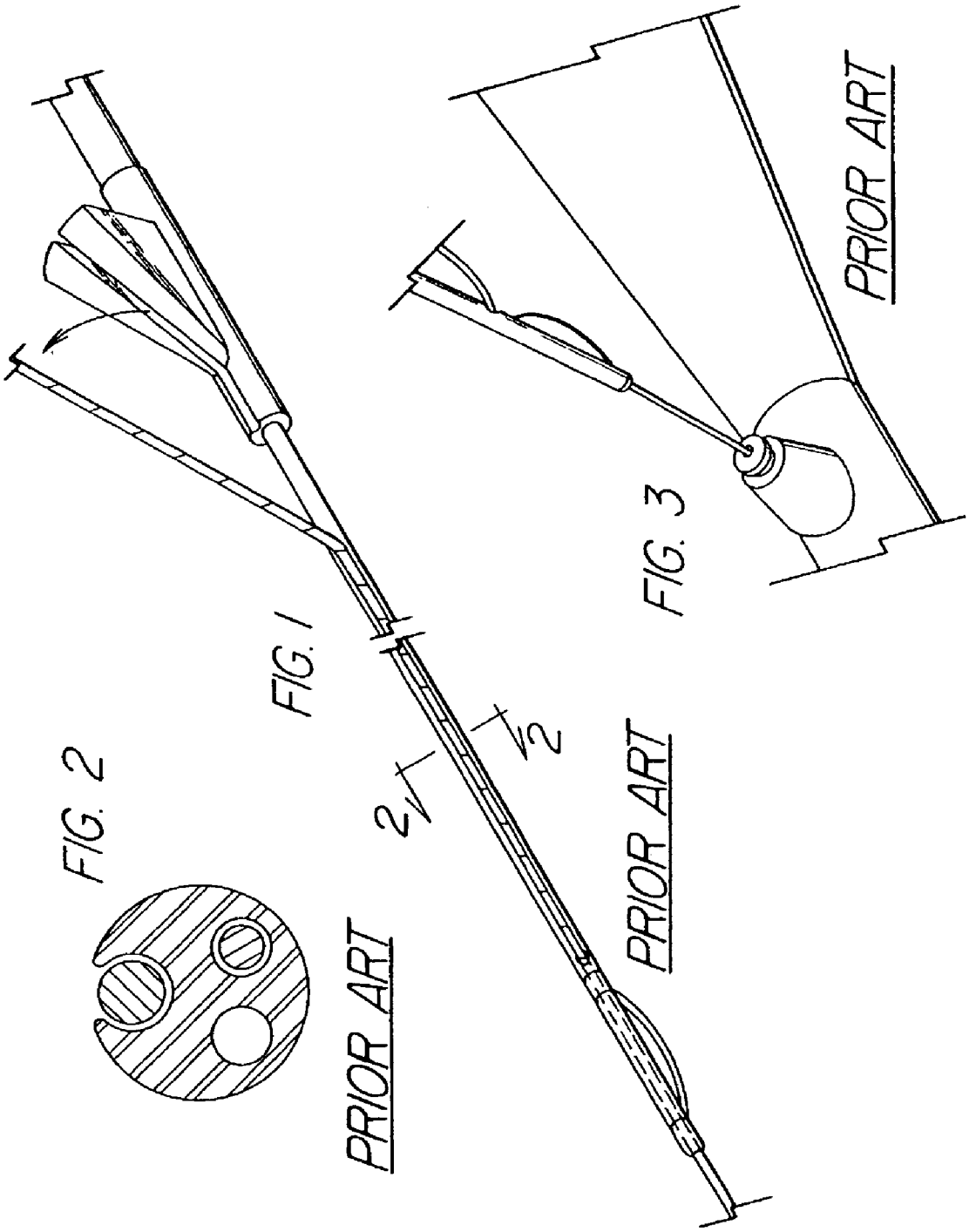
(51) **Int. Cl.**[7] **A61B 6/00**

(52) **U.S. Cl.** **600/434**

(57) **ABSTRACT**

A method and apparatus for introducing a first elongate medical device and short wire guide that are coupled together into a work site and remotely disconnecting them within the work site such that a secondary device comprising a catheter member can be introduced over the wire guide to the work site, and/or a second wire guide can be introduced to the work site via a passageway of the primary access device. A system of indicia, such as radiopaque or viewable markers, permits the operator to monitor the relative alignment of the devices within the work site to determine when uncoupling has occurred. In one example of the method, a wire guide and primary access device (e.g., a sphincterotome) is coupled to the wire guide and introduced via a duodenoscope into the biliary system. After performing a first medical operation, the devices are uncoupled with the wire guide being left within the biliary system such that a secondary access device, such as a balloon, biopsy device, stent delivery catheter, dilator, etc., can be introduced to perform a second medical operation without a traditional over-the-wire exchange being required. In another example of the method, a prosthesis, such as a valve or stent, is placed within the work site coupled to a wire guide which is remotely disconnected within the work site and a secondary device, such as a dilation balloon or second prosthesis, is introduced into the work site after the first delivery system is removed.




FIG. 1
PRIOR ART
FIG. 2
PRIOR ART
FIG. 3
PRIOR ART
2
1
2

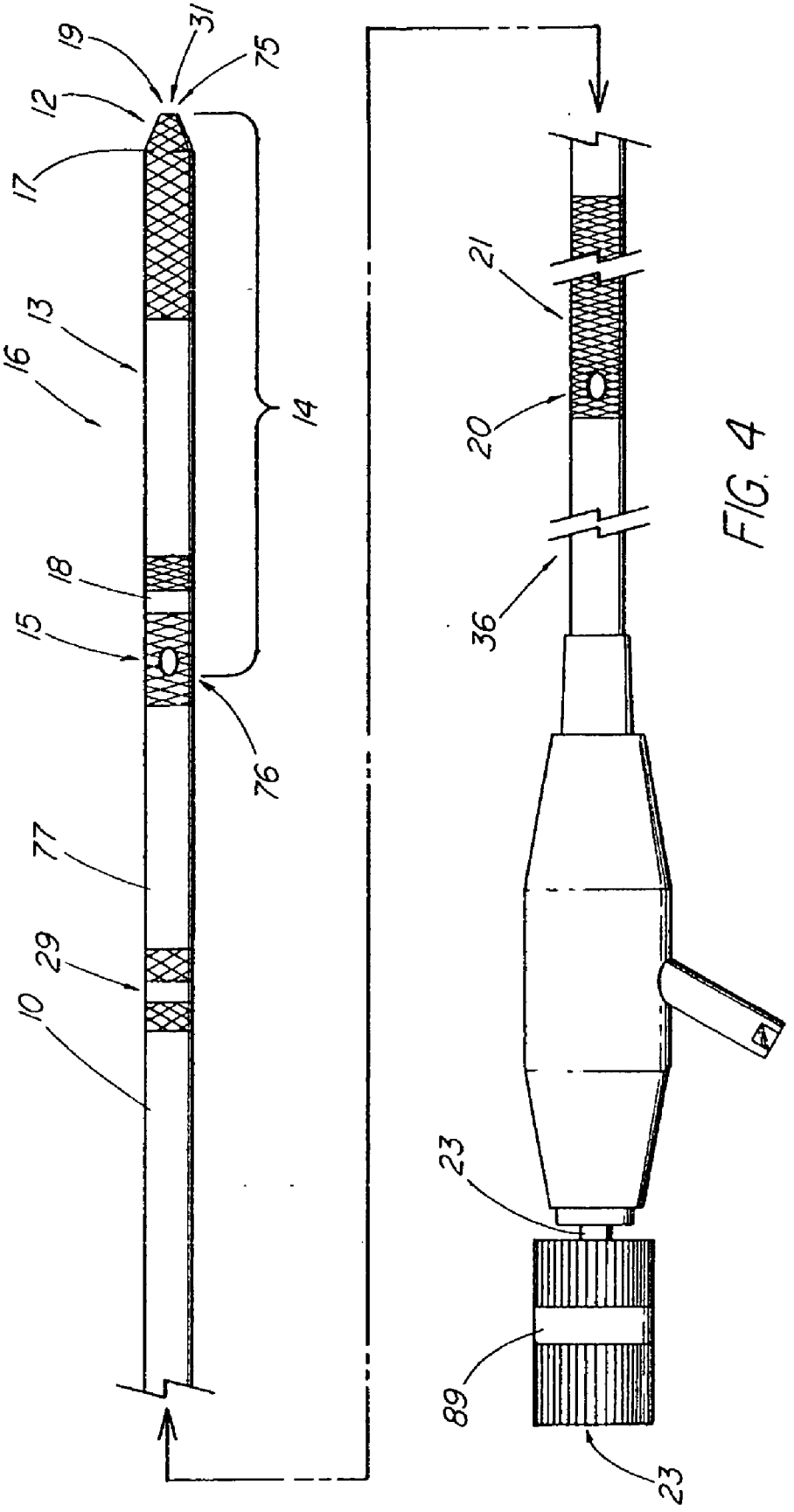


FIG. 4

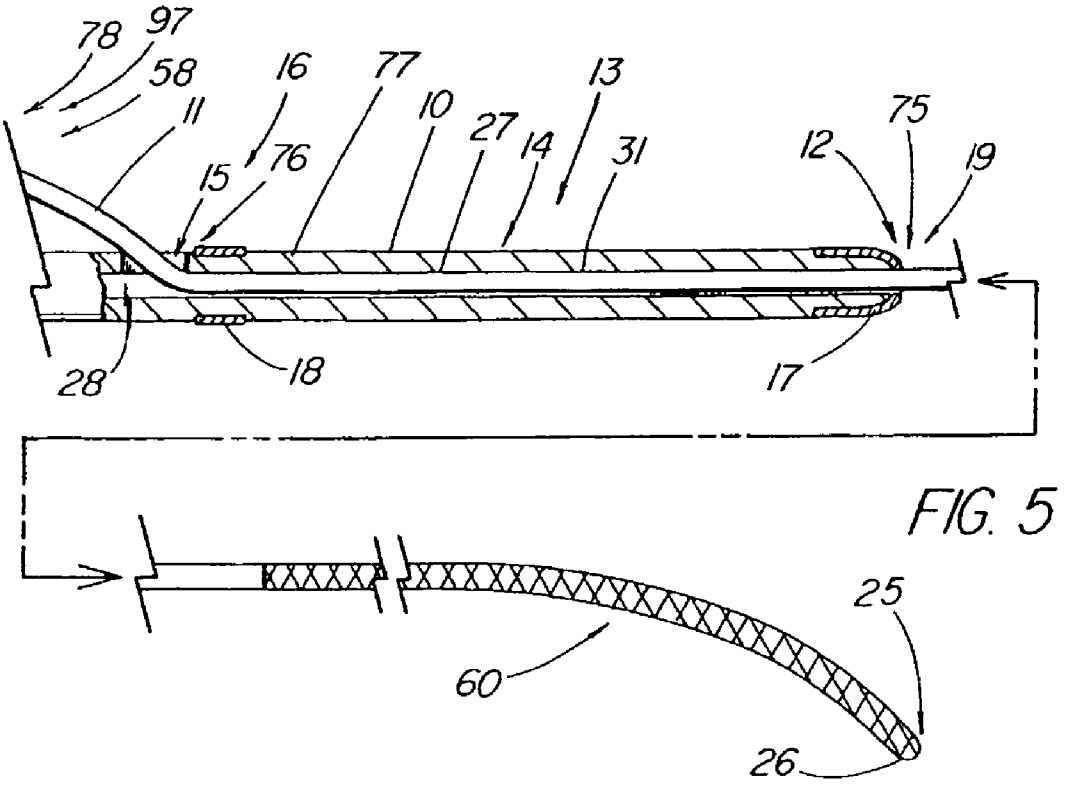


FIG. 5

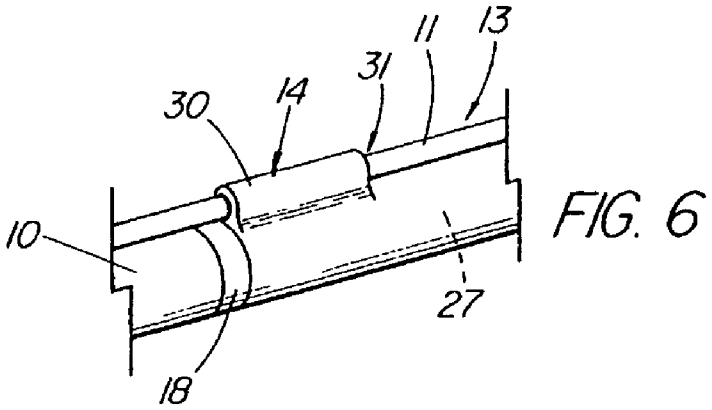


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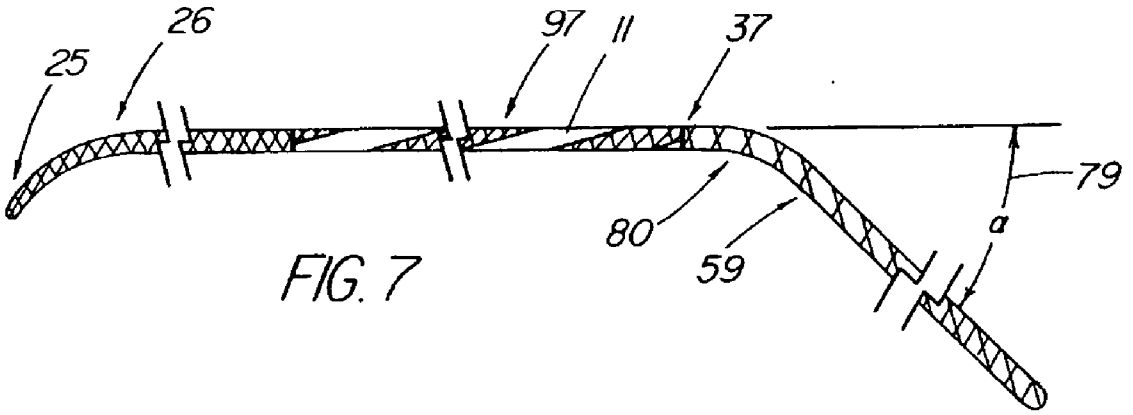


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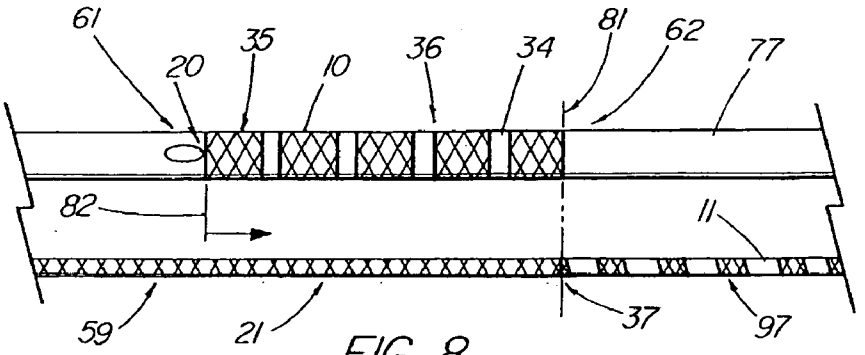


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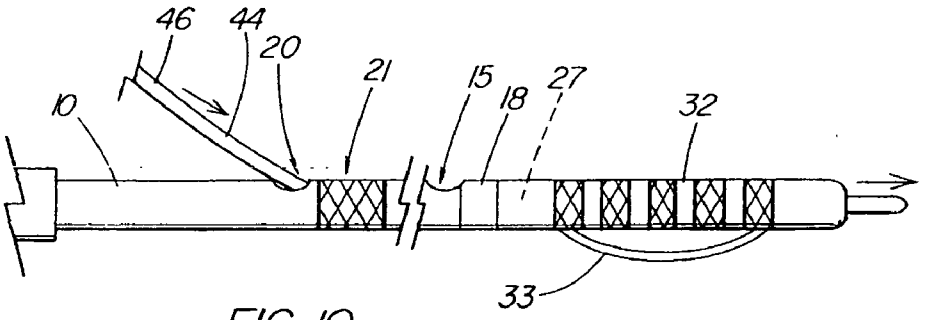


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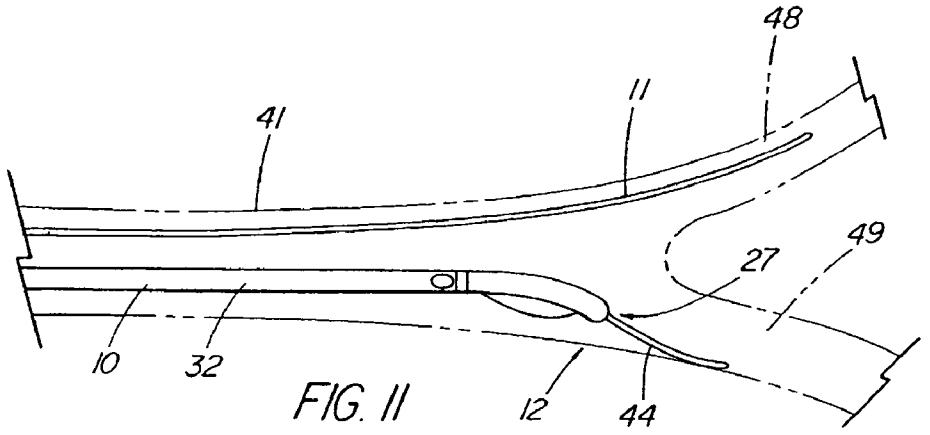


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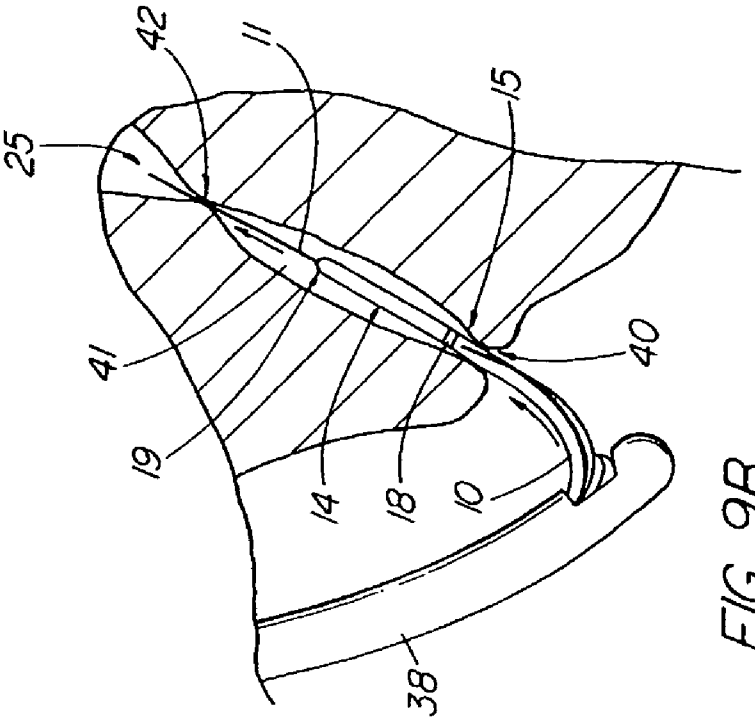


FIG. 9B

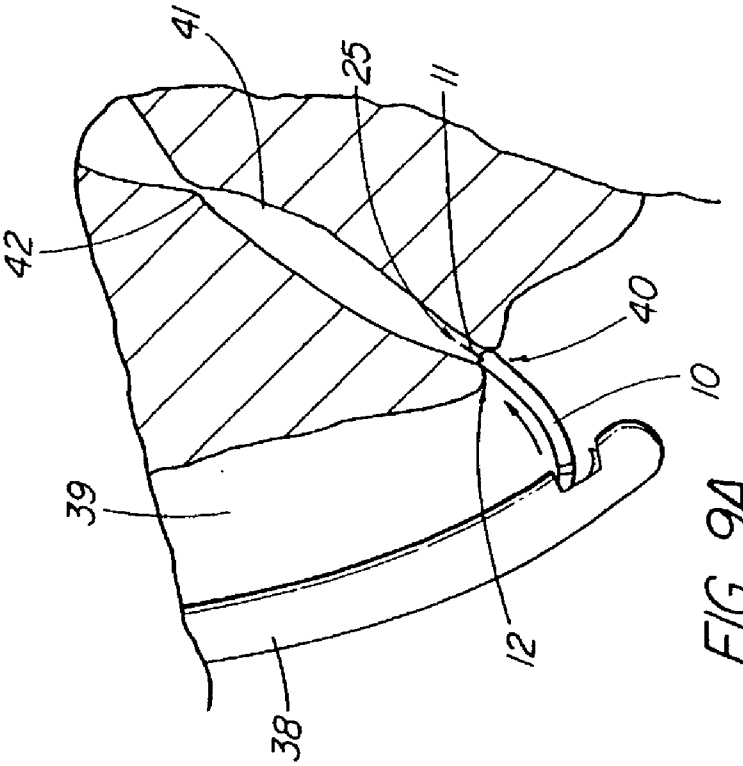


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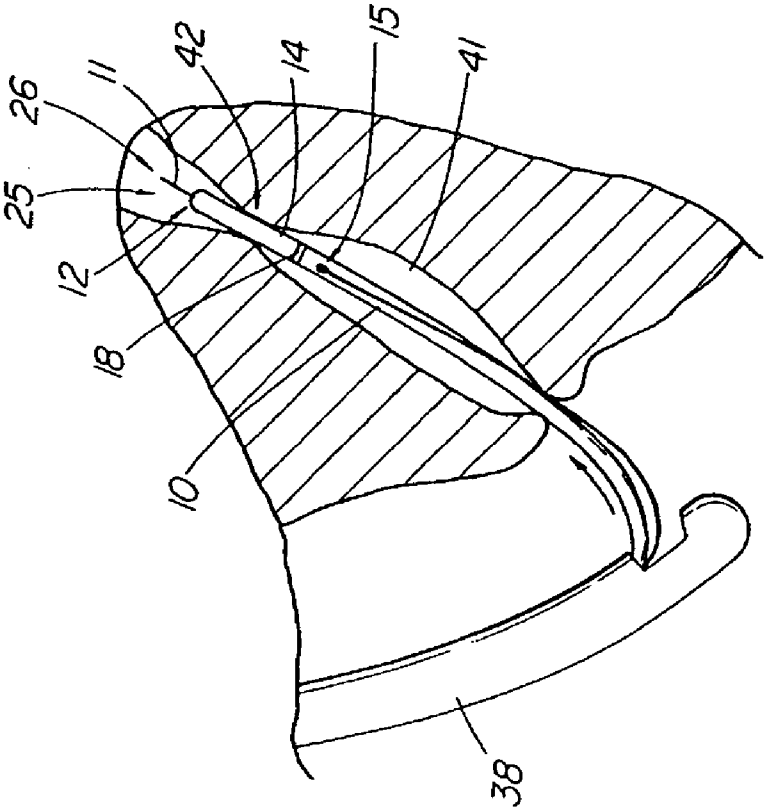


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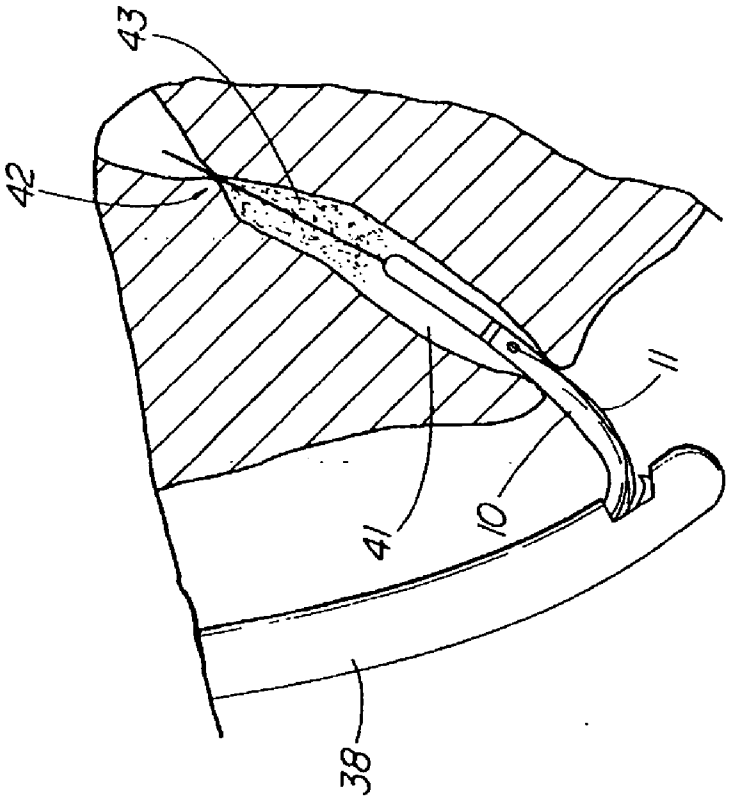


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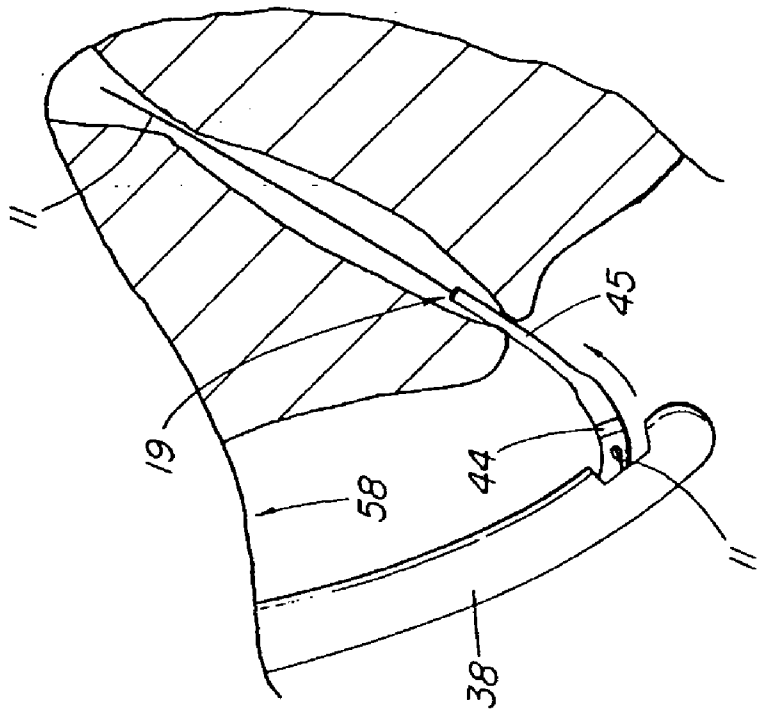


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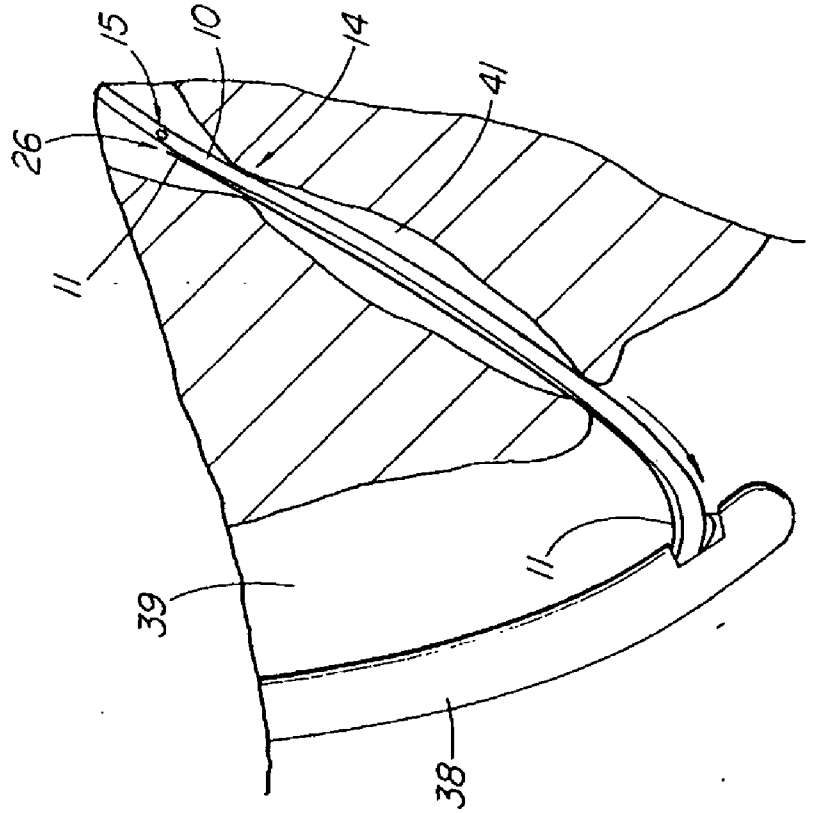


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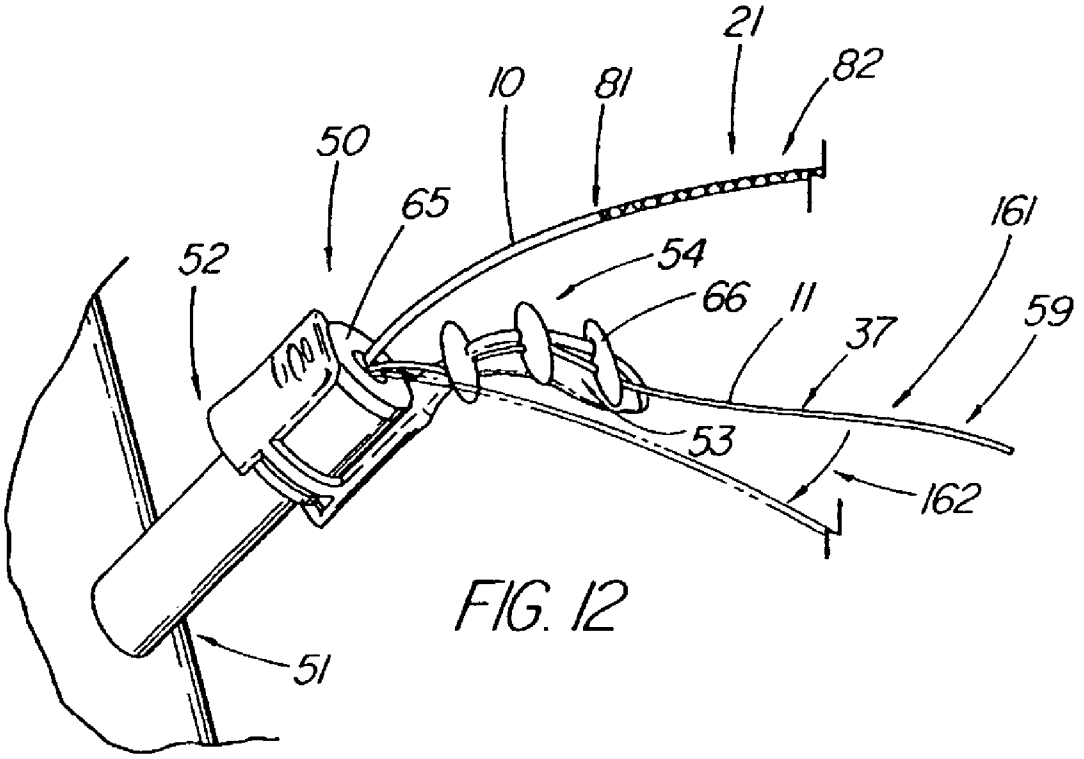


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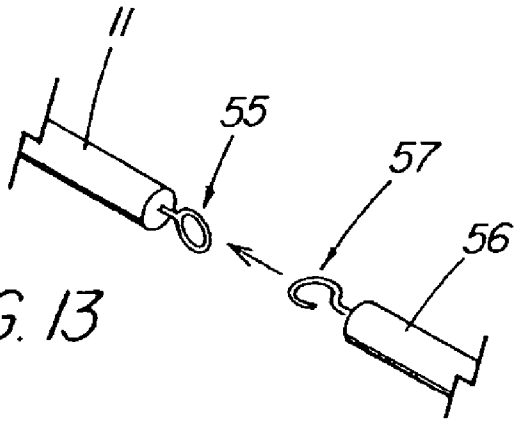


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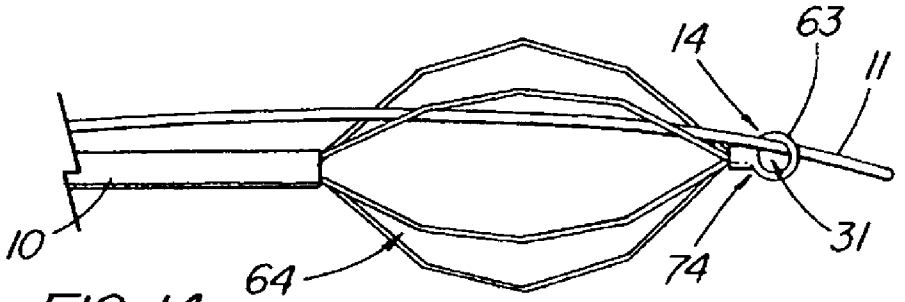


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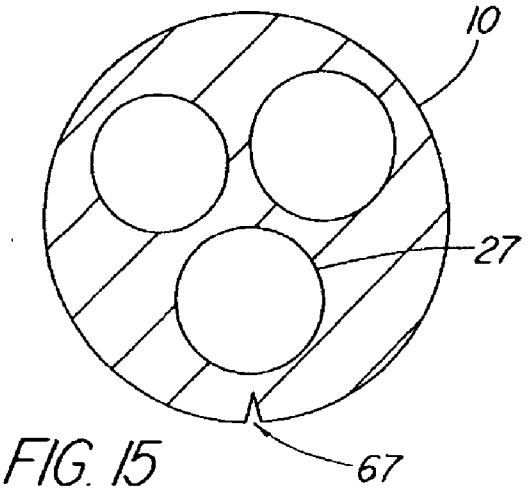


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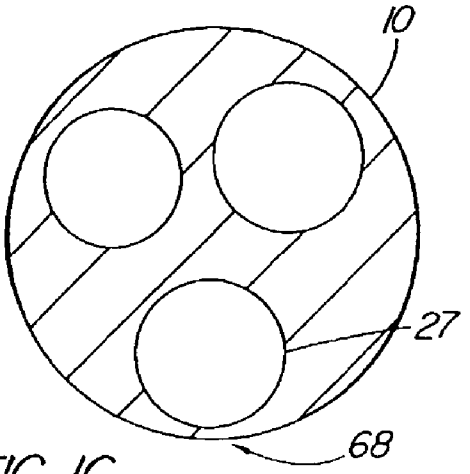


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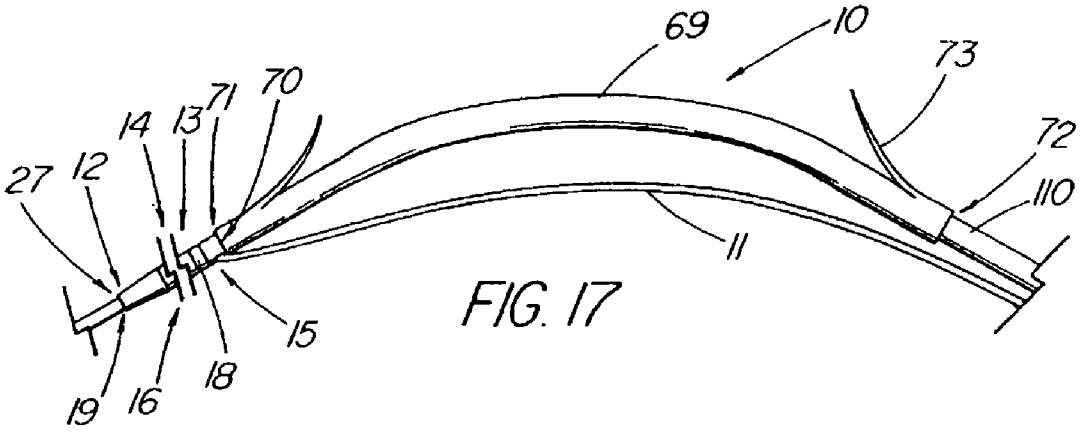


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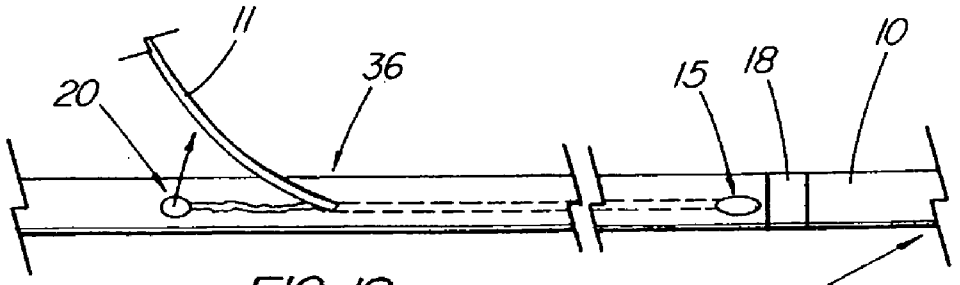


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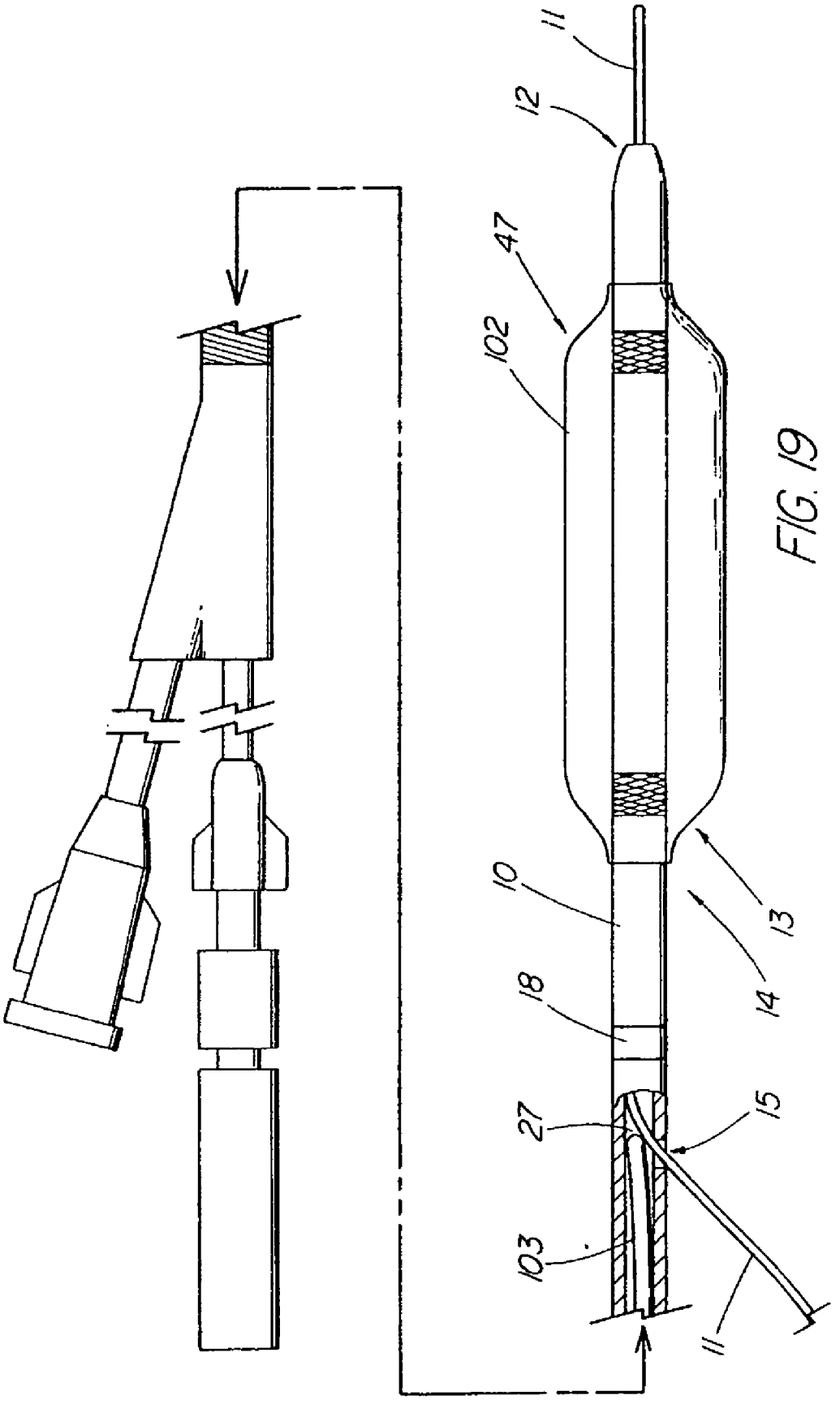


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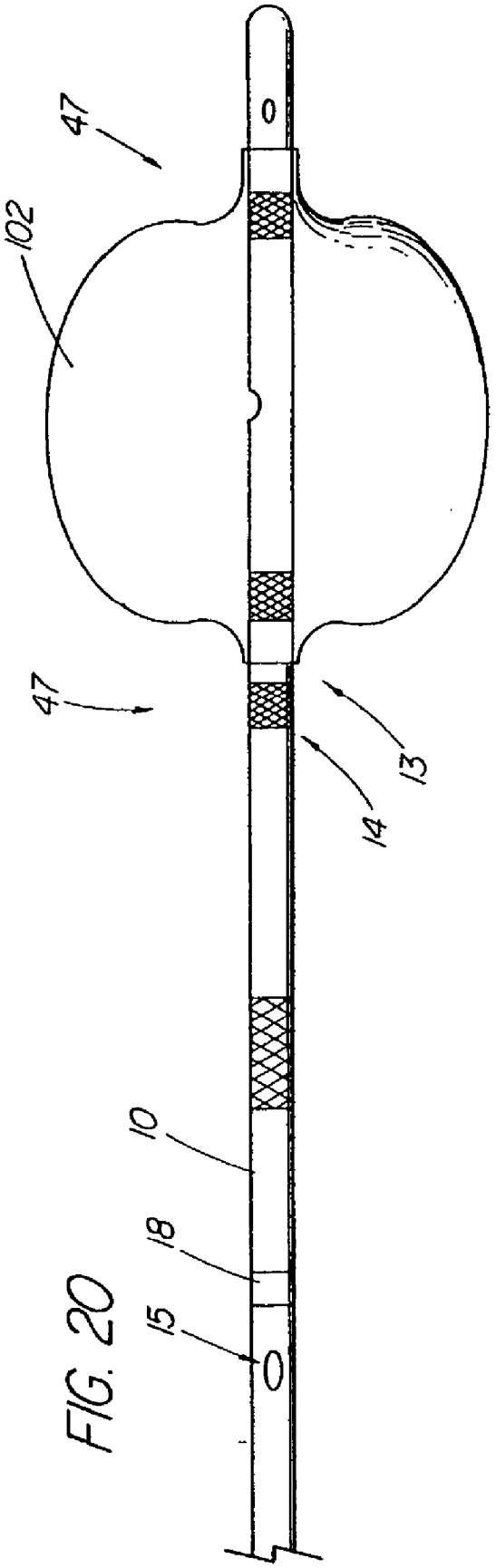


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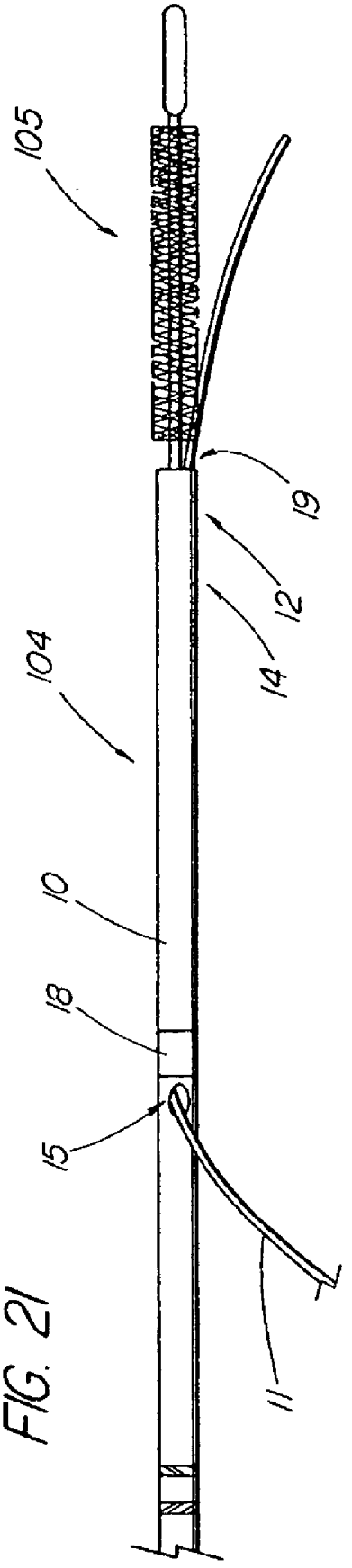


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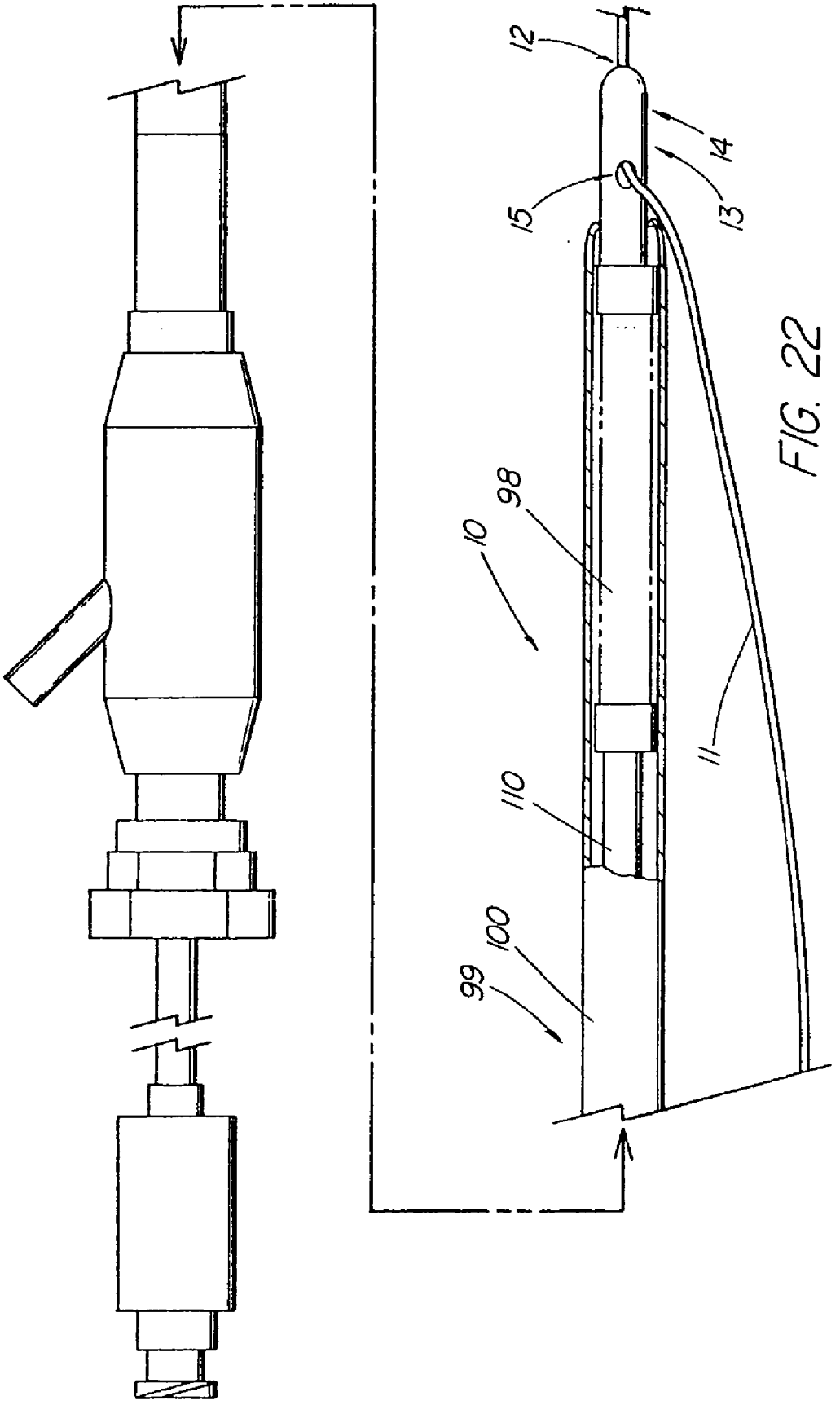


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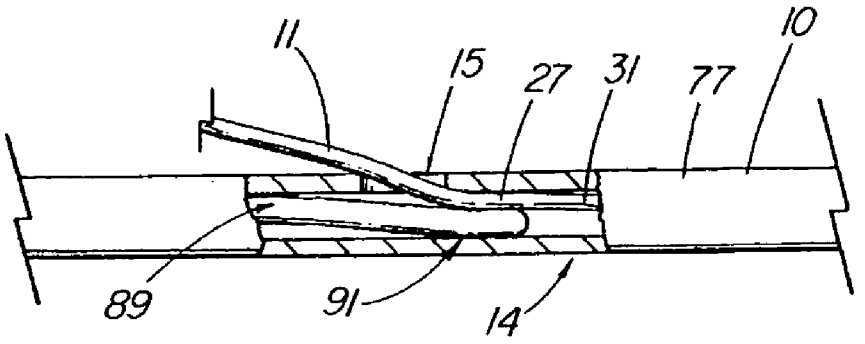


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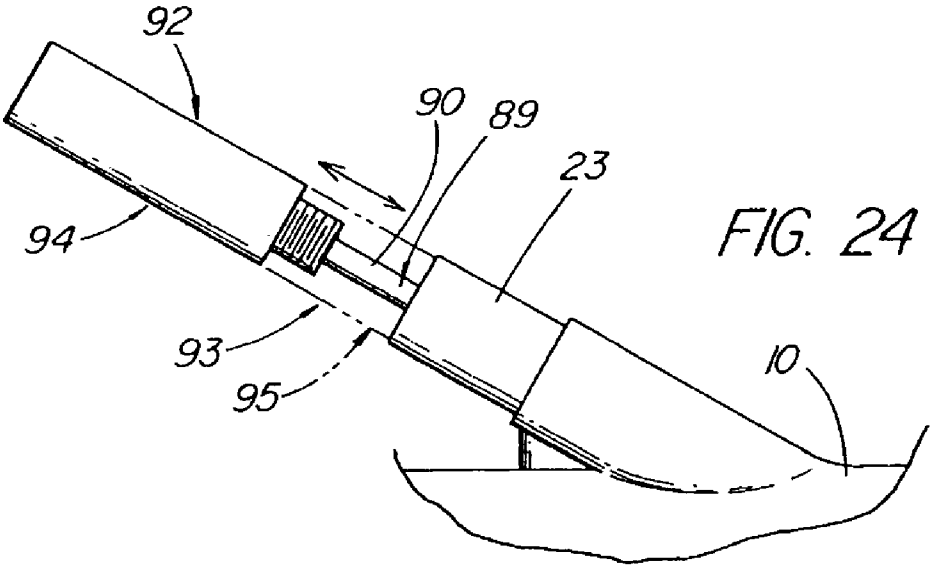


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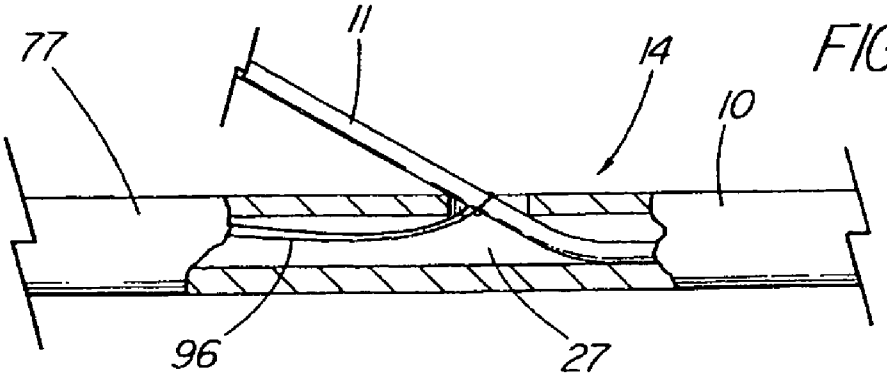


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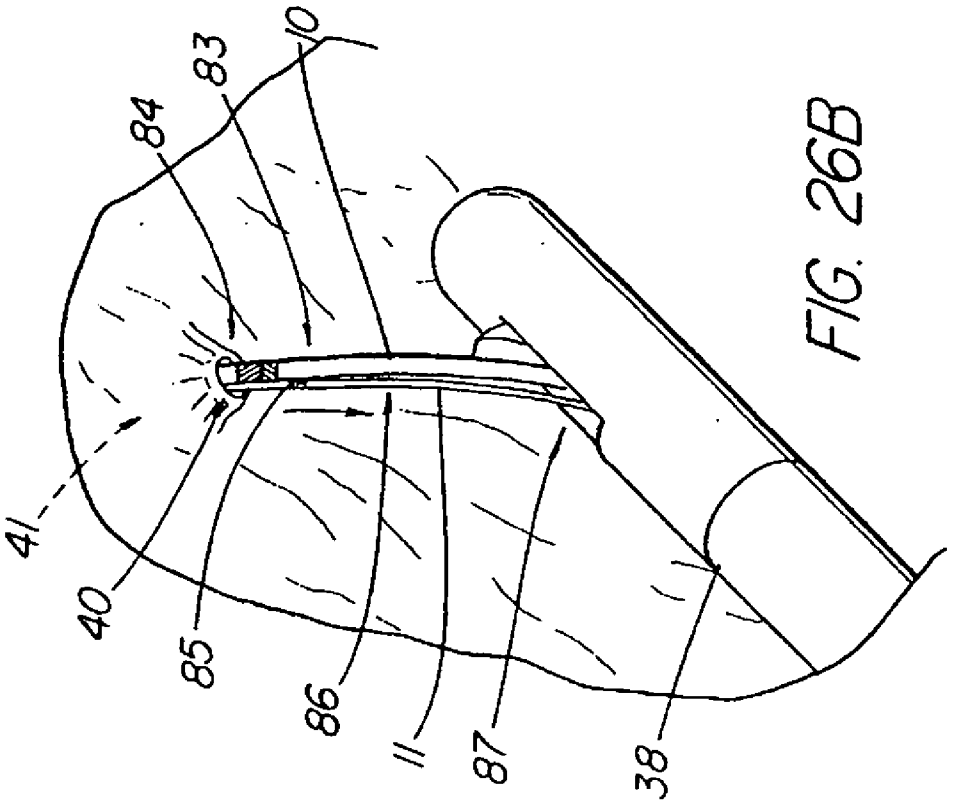


FIG. 26B

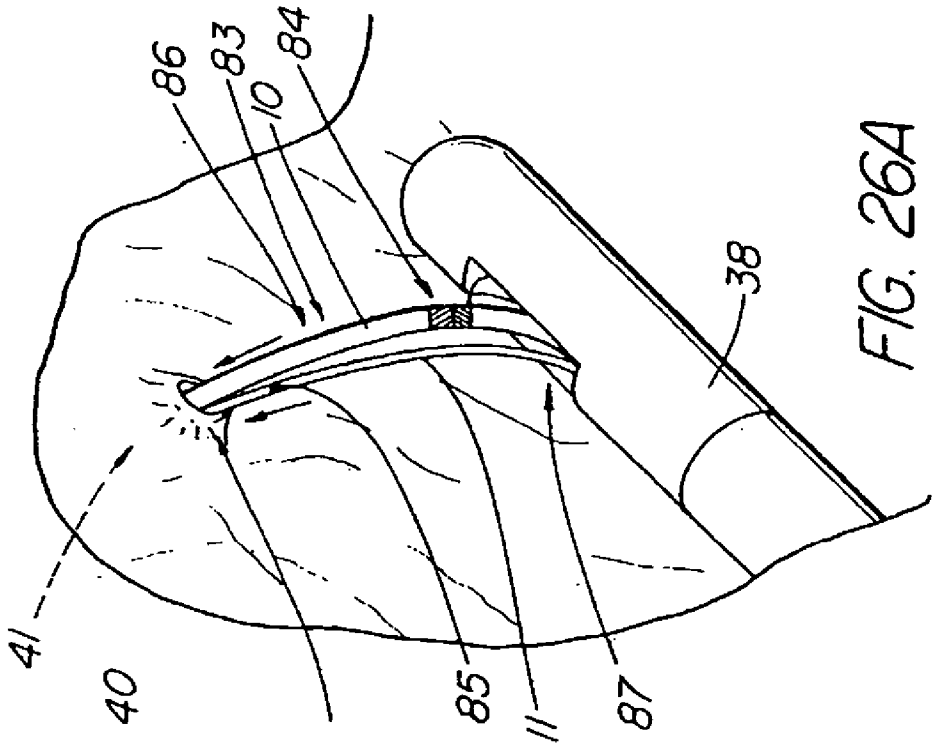


FIG. 26A

FIG. 27

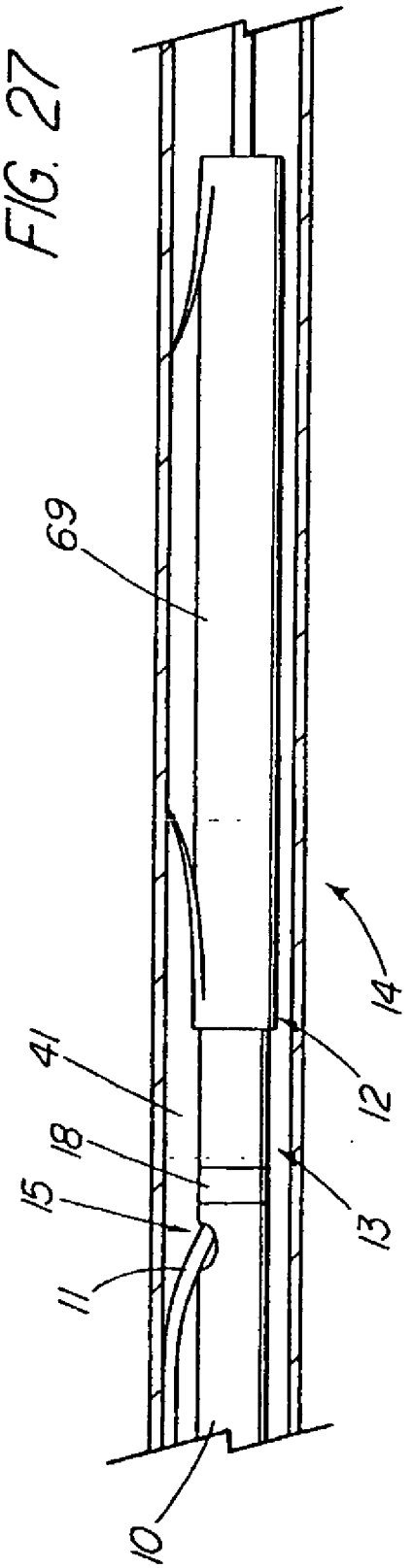
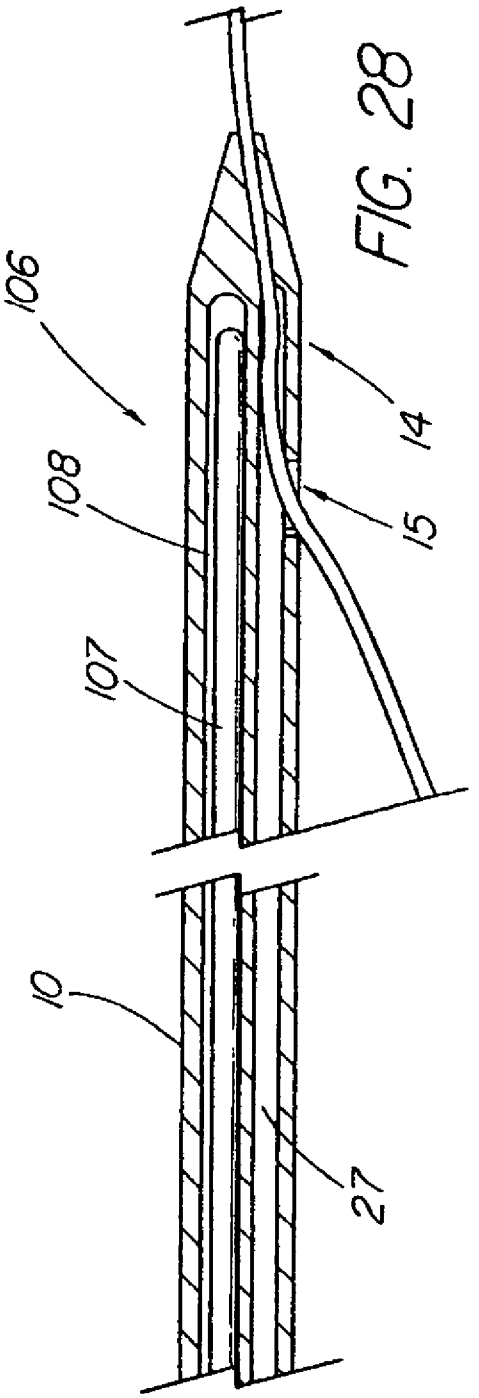


FIG. 28



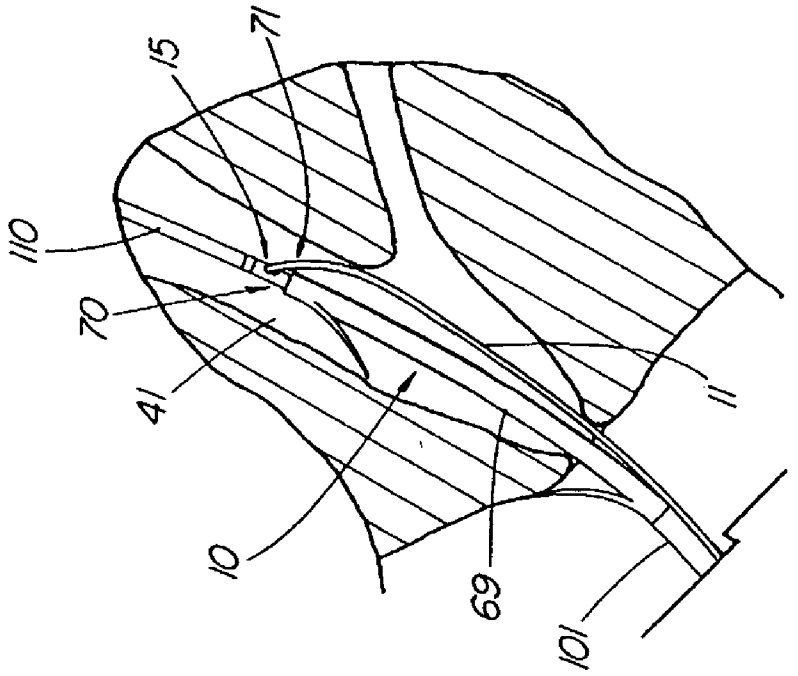


FIG. 29B

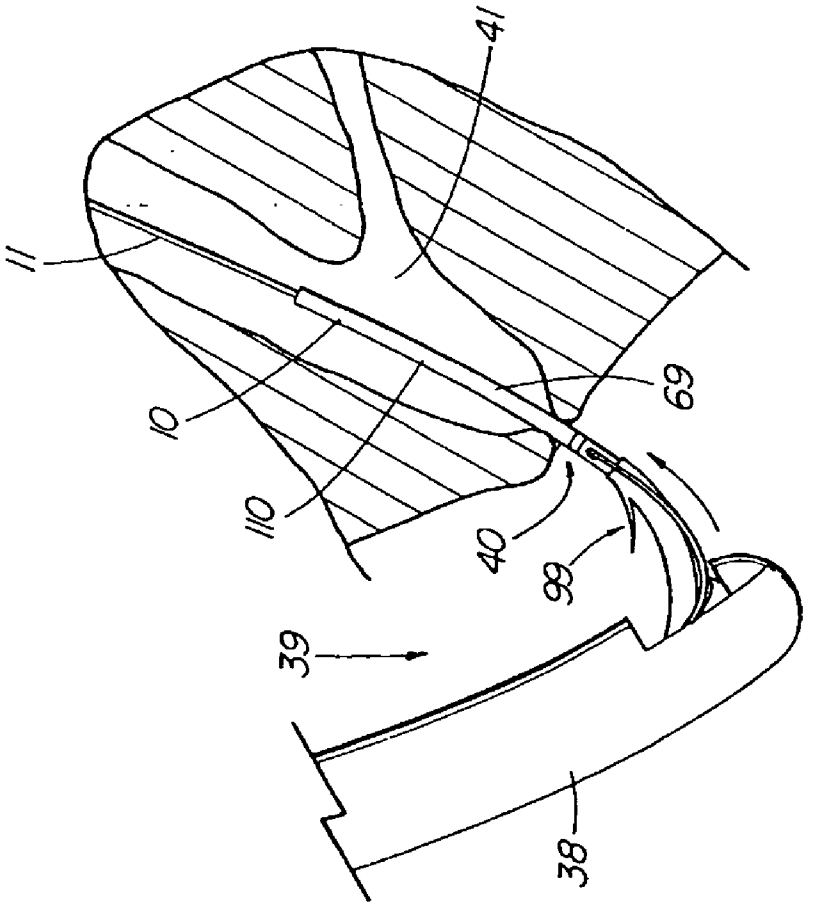


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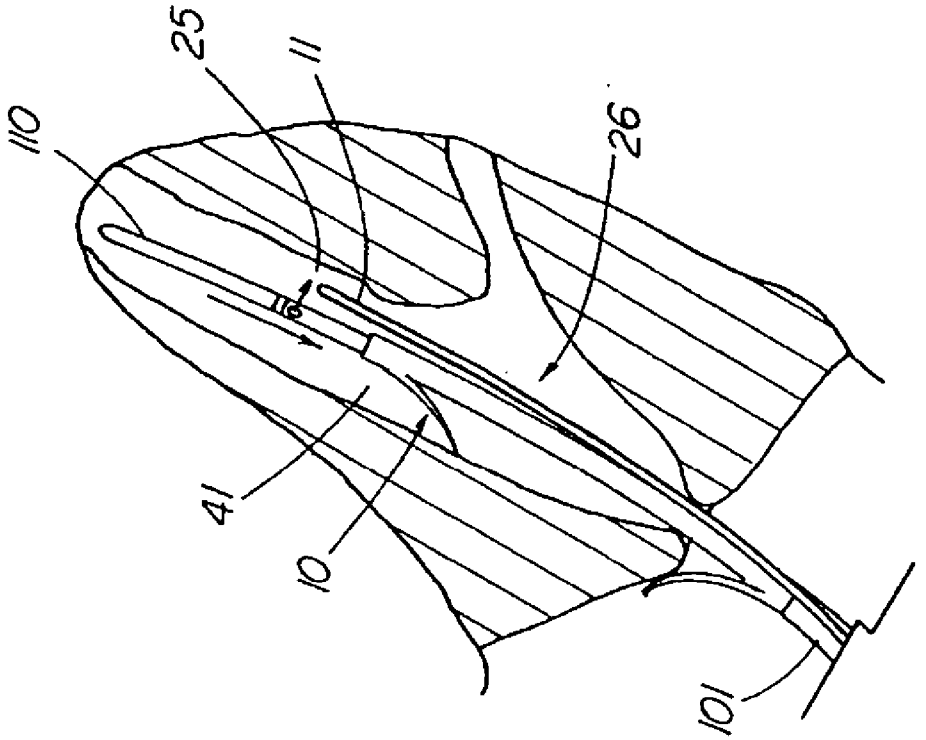


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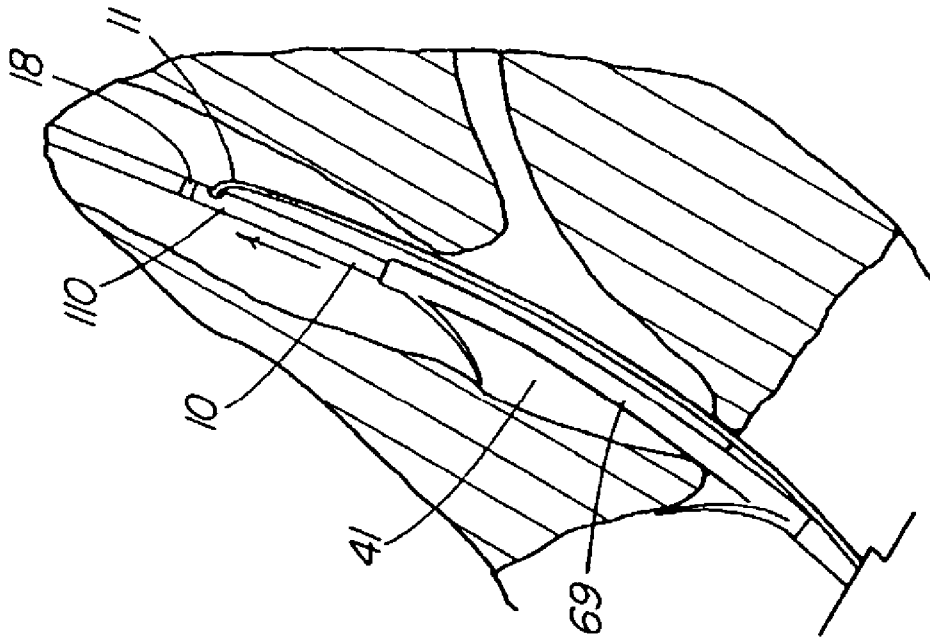


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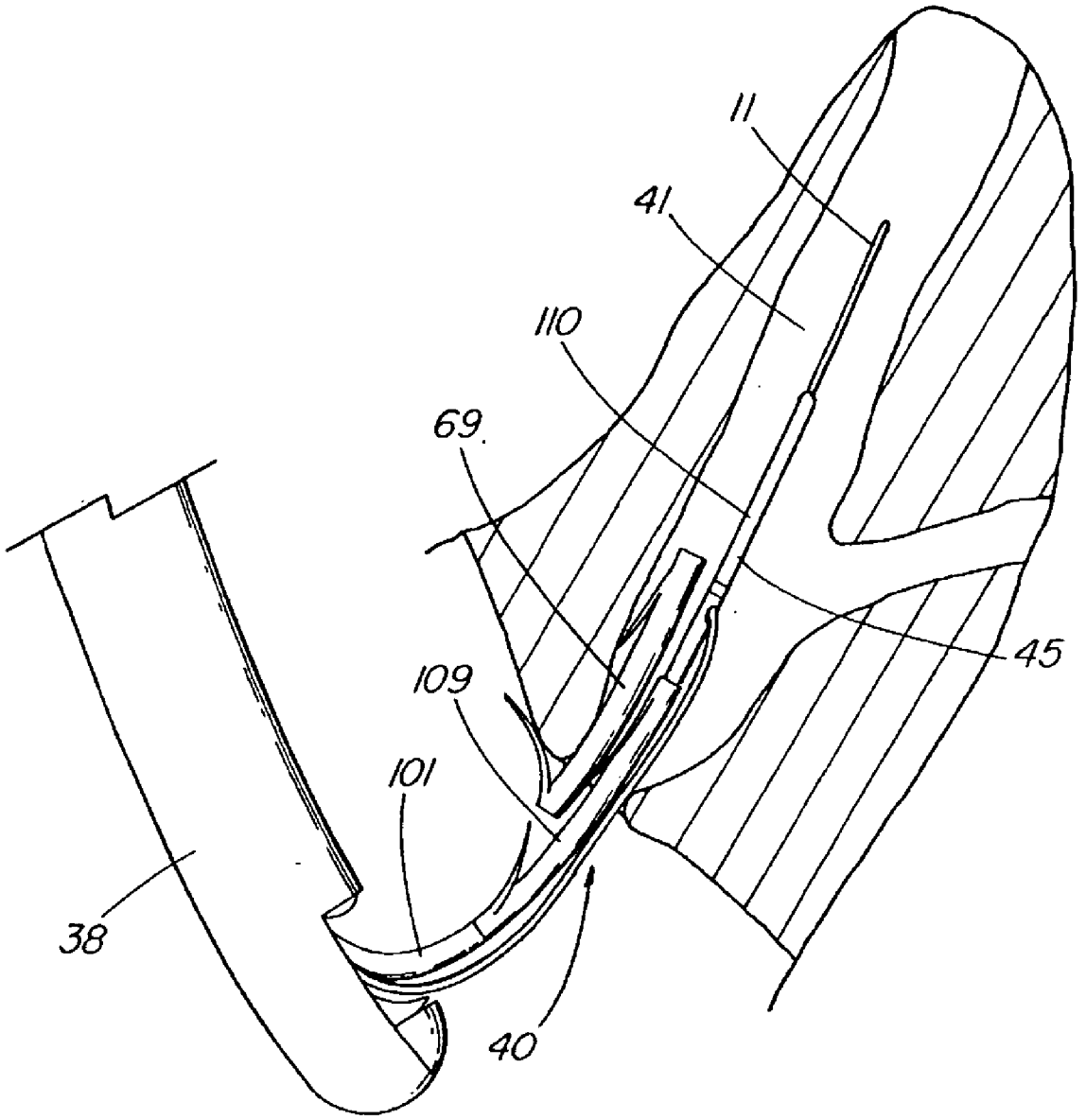


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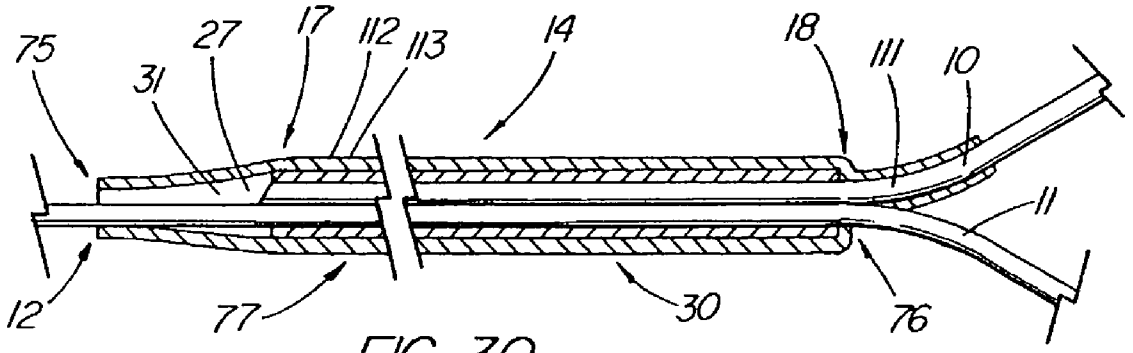


FIG. 30

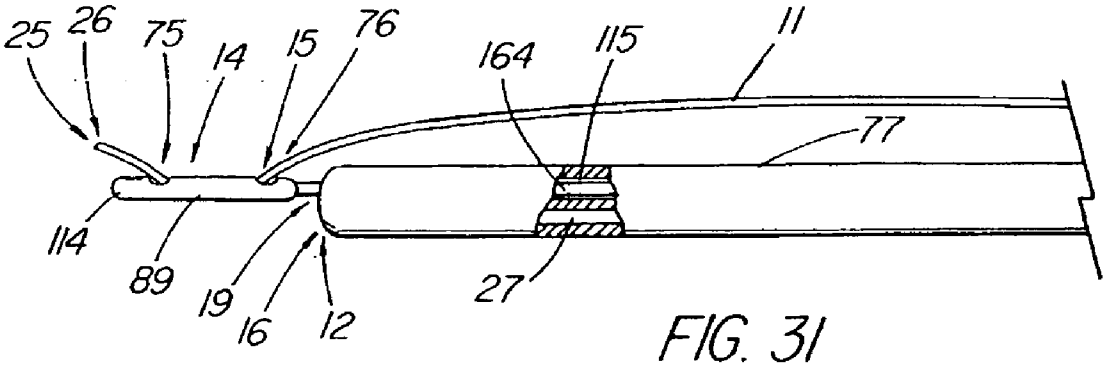


FIG. 31

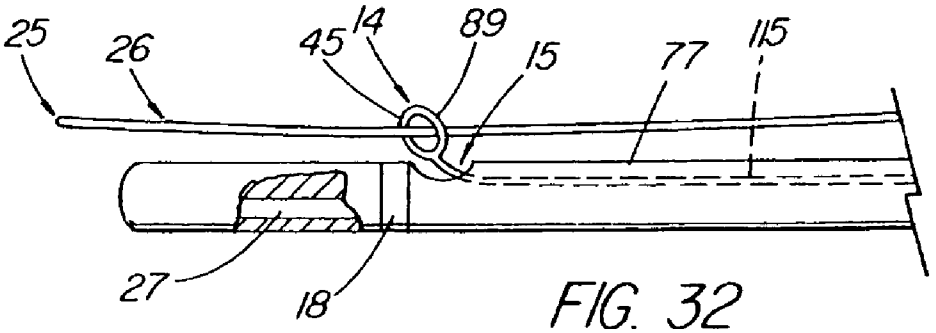


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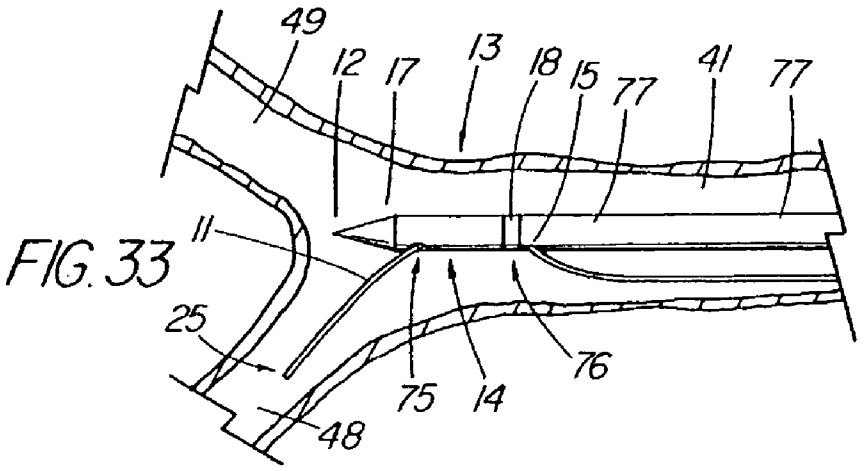


FIG. 33

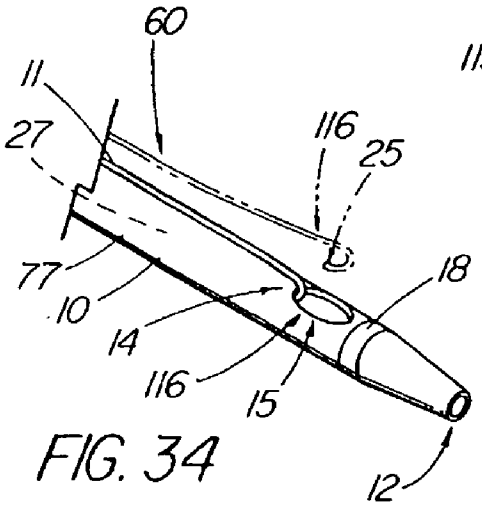


FIG. 34

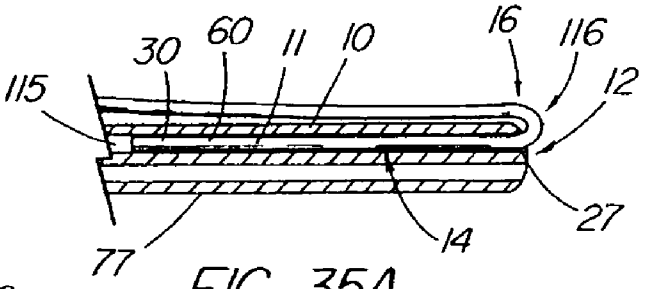


FIG. 35A

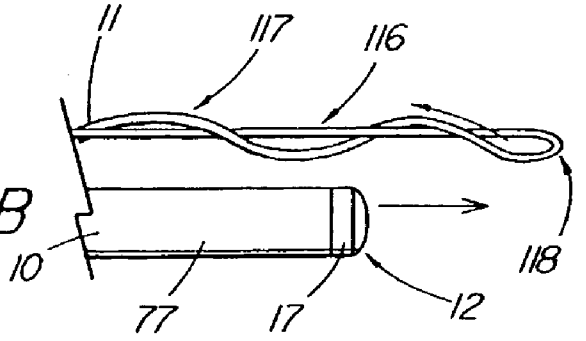


FIG. 35B

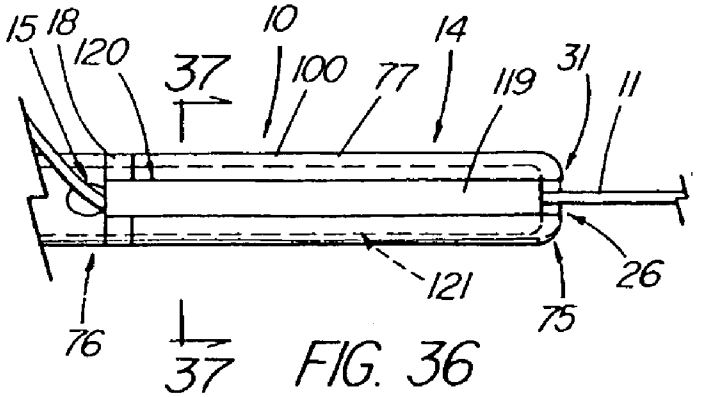


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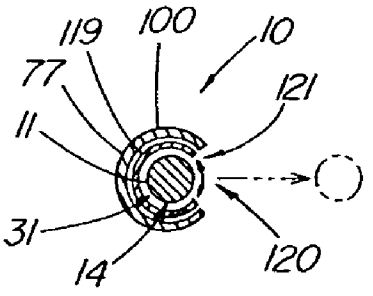


FIG. 37

FIG. 38

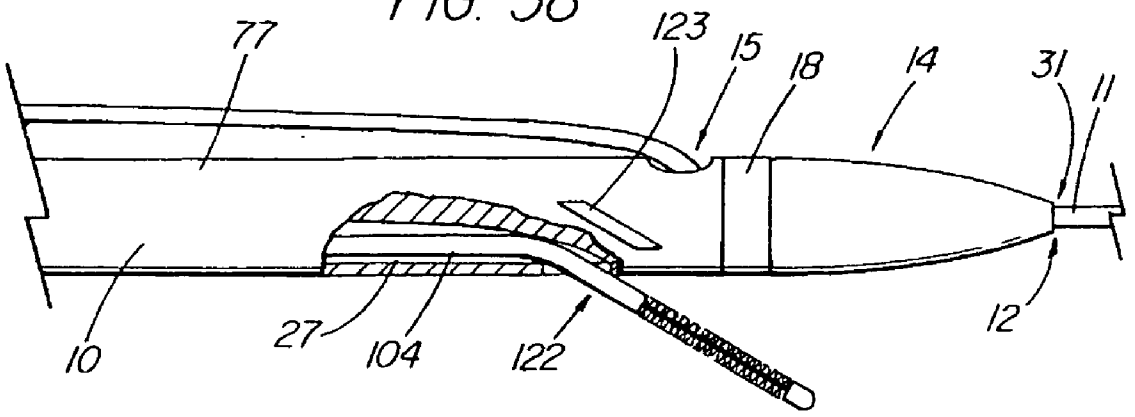
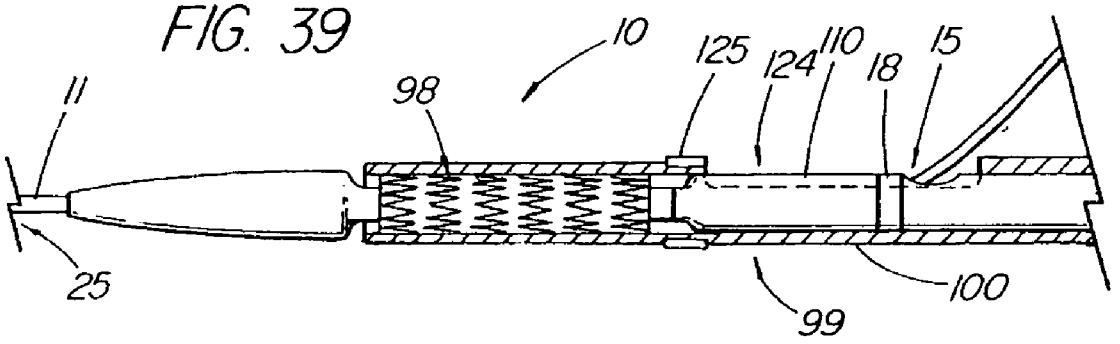


FIG. 39



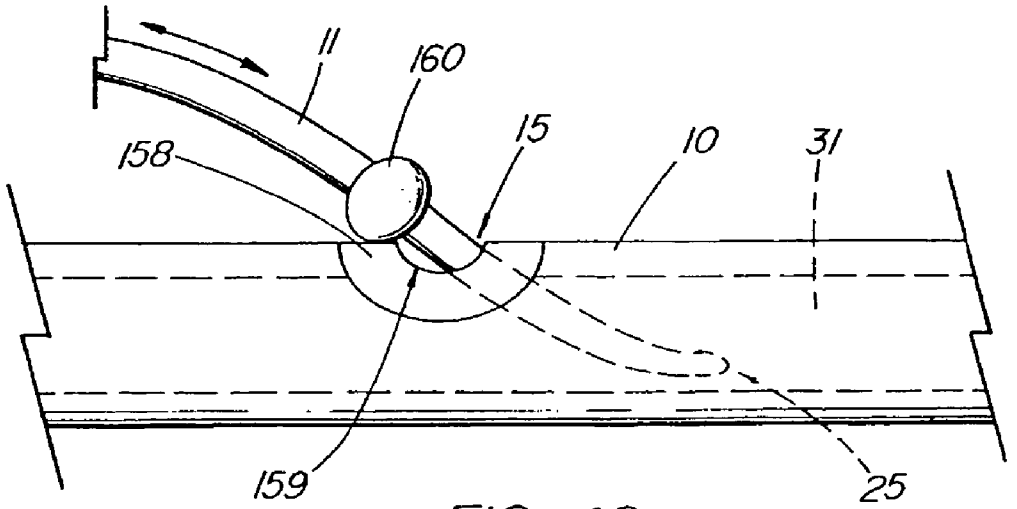


FIG. 40

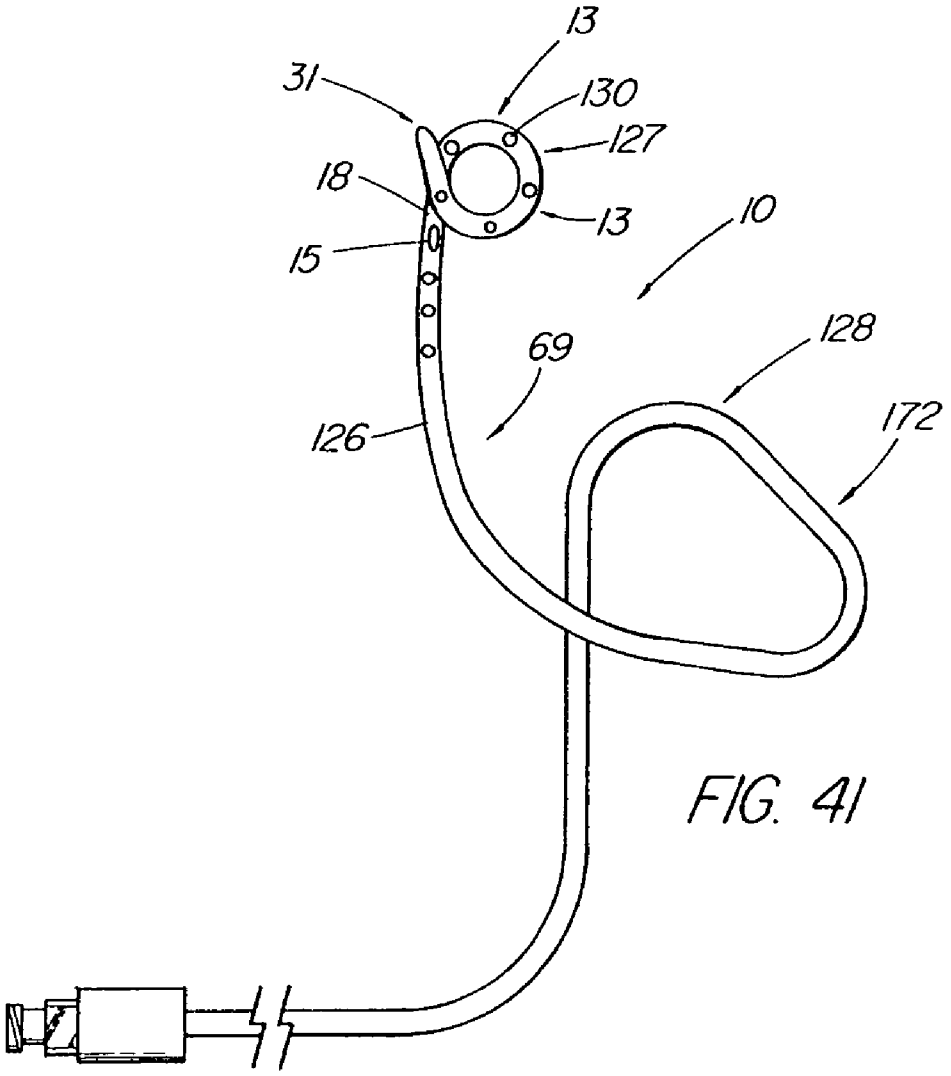


FIG. 41

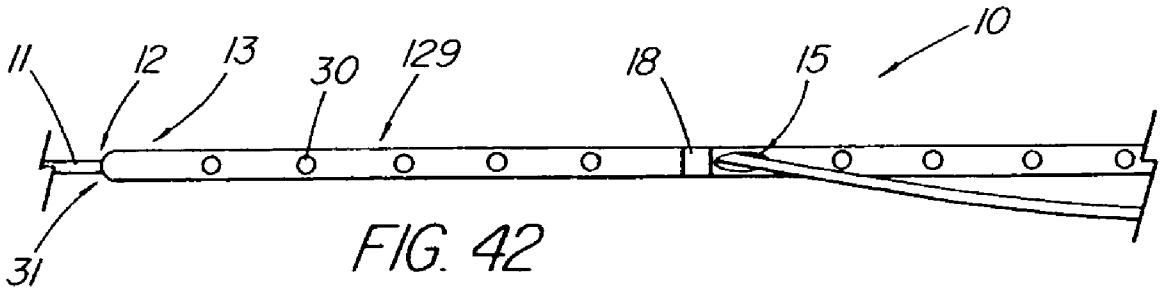


FIG. 42

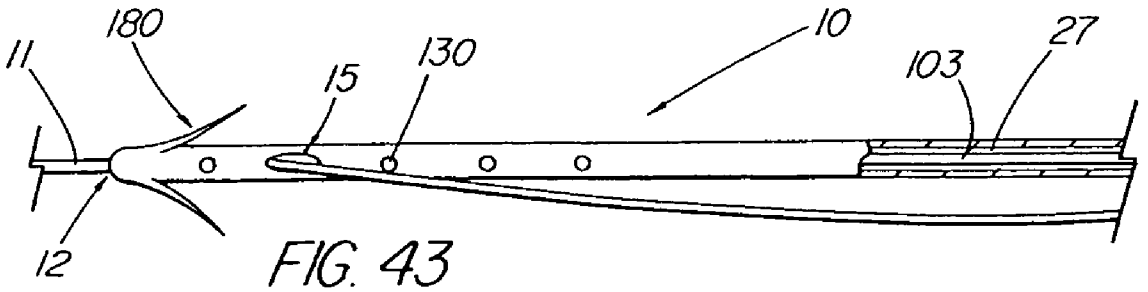


FIG. 43

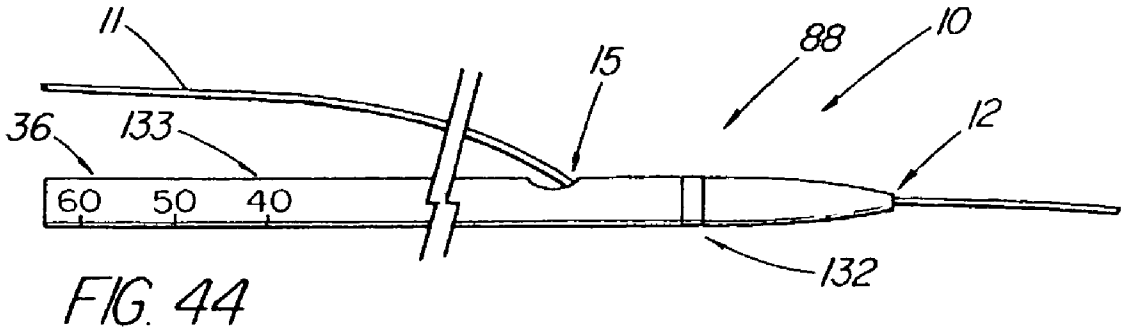


FIG. 44

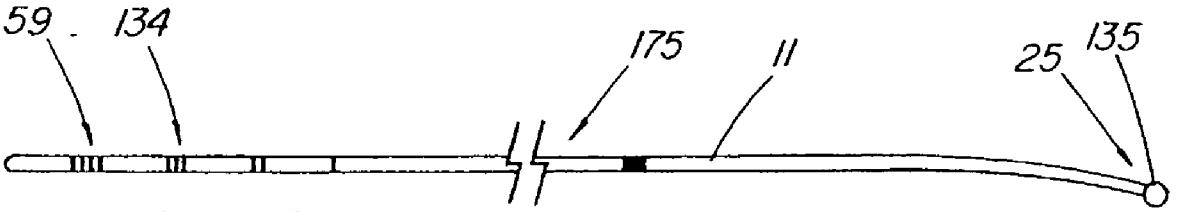


FIG. 45A

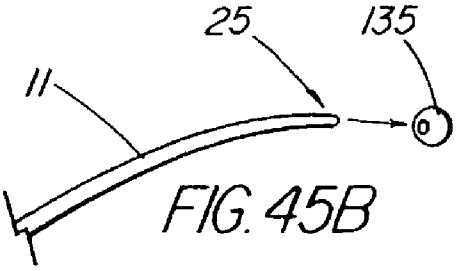


FIG. 45B

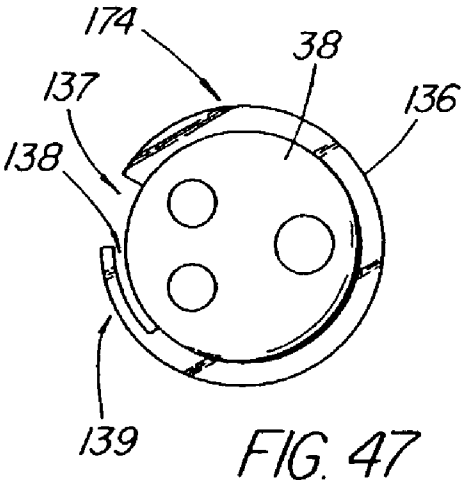


FIG. 47

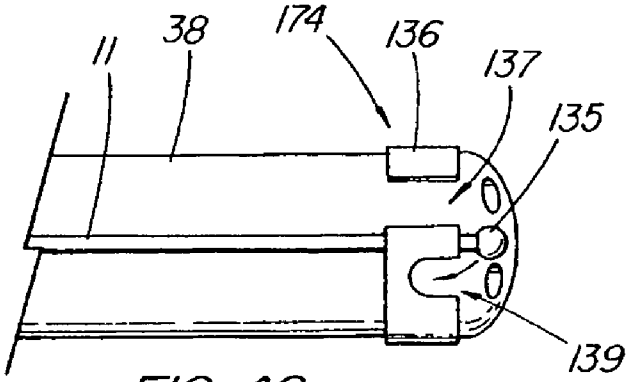


FIG. 46

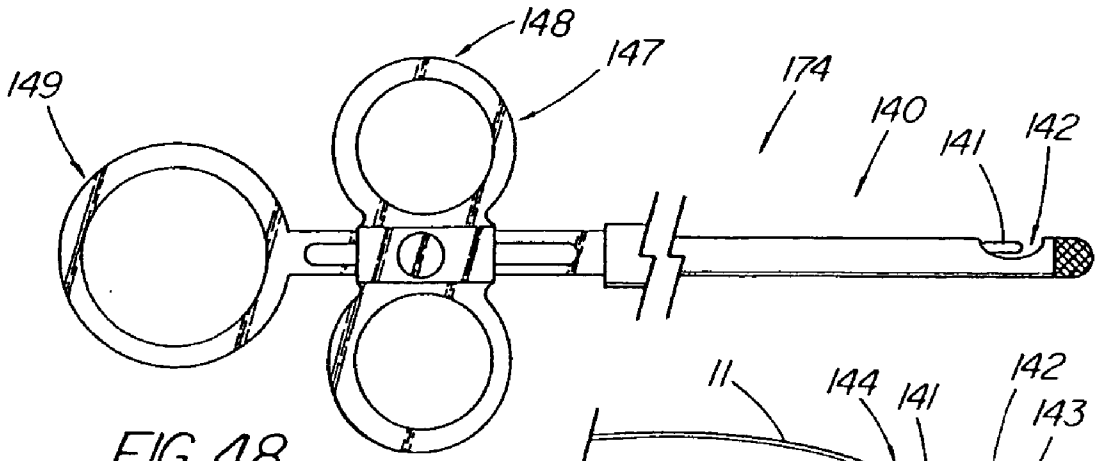


FIG. 48

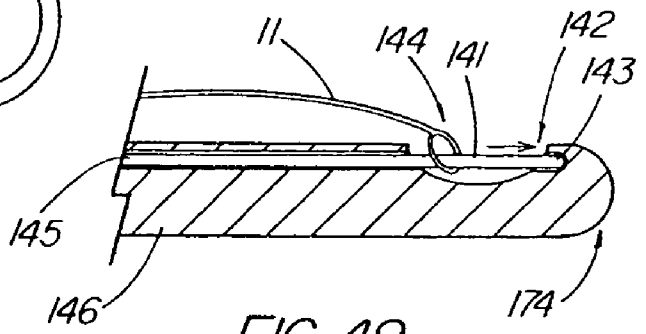
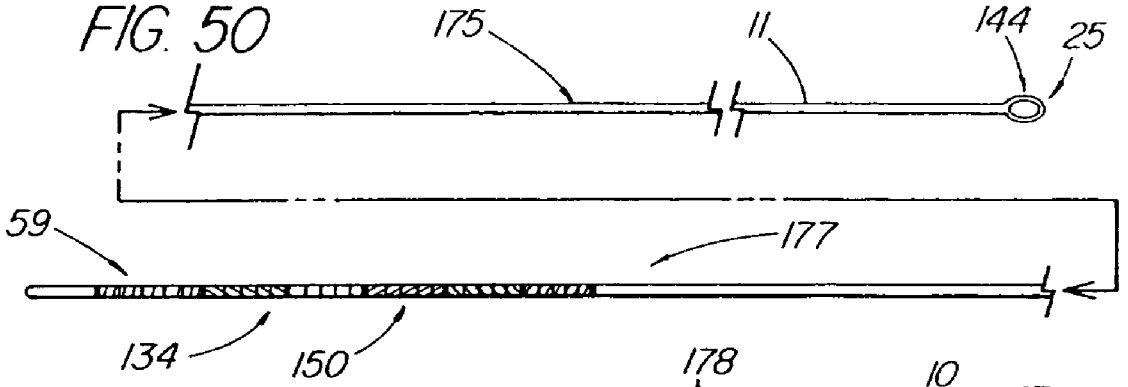


FIG. 49

FIG. 50



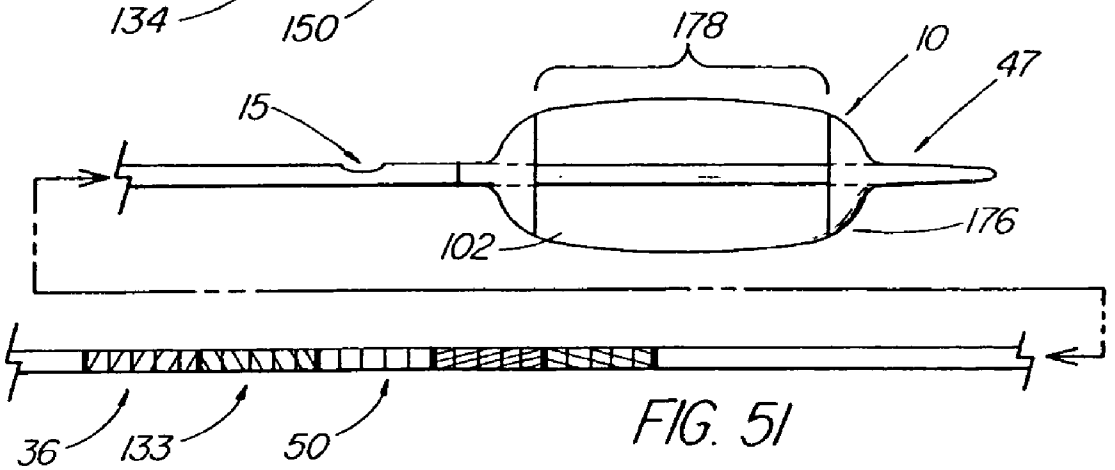


FIG. 51

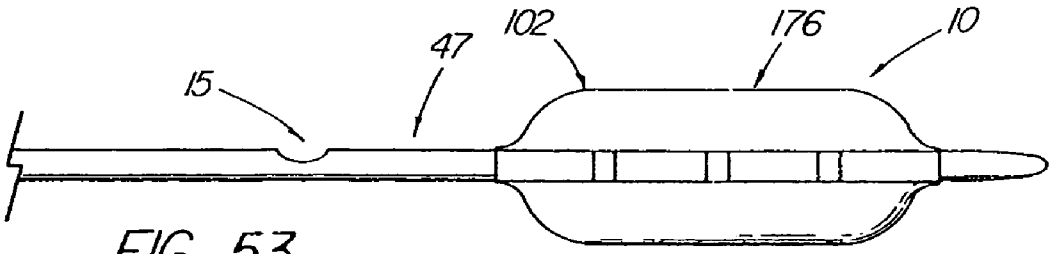


FIG. 53

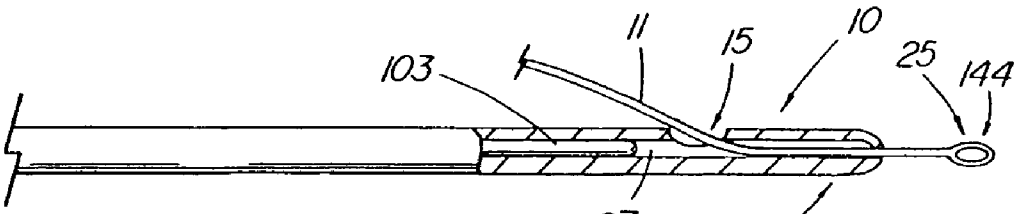


FIG. 54

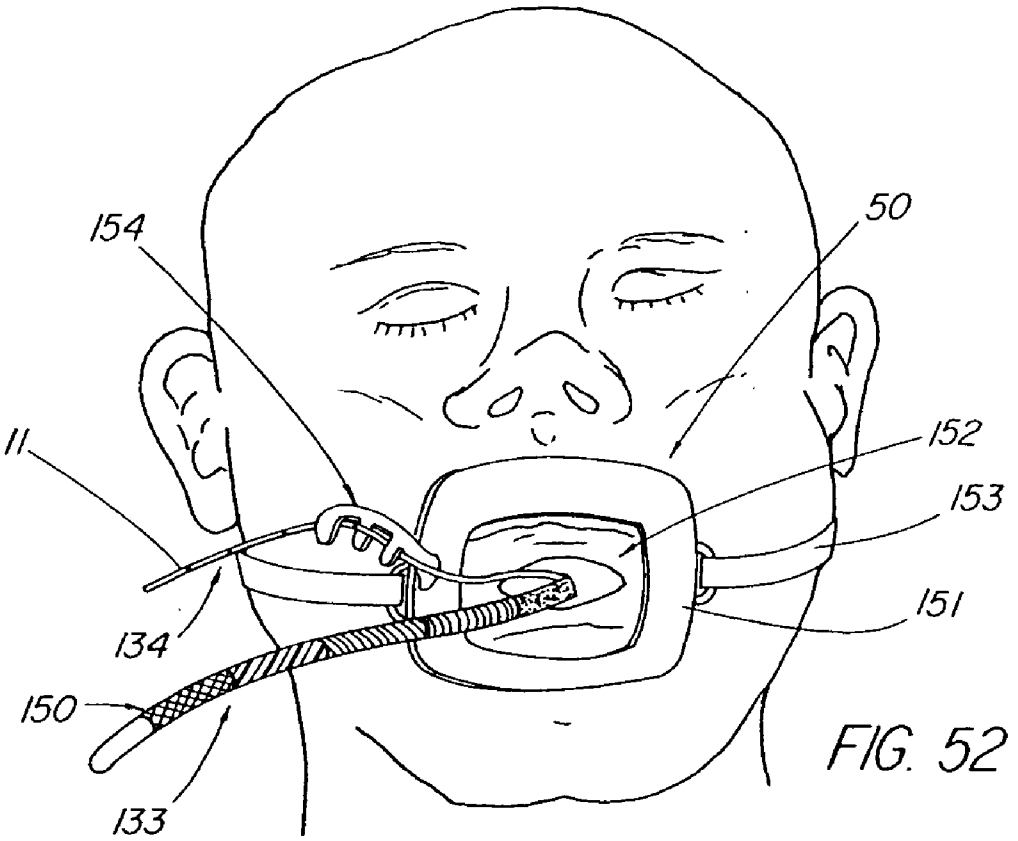


FIG. 52

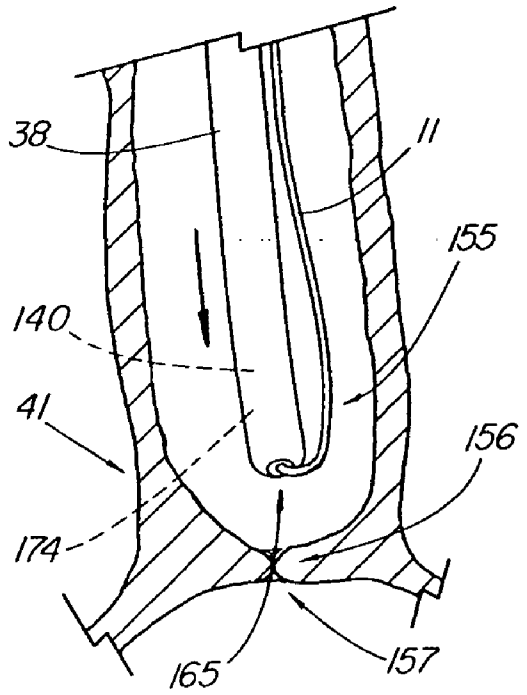


FIG. 55A

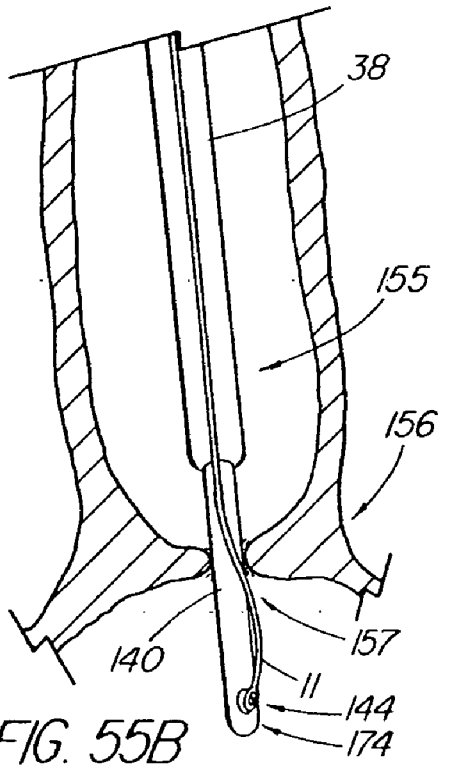


FIG. 55B

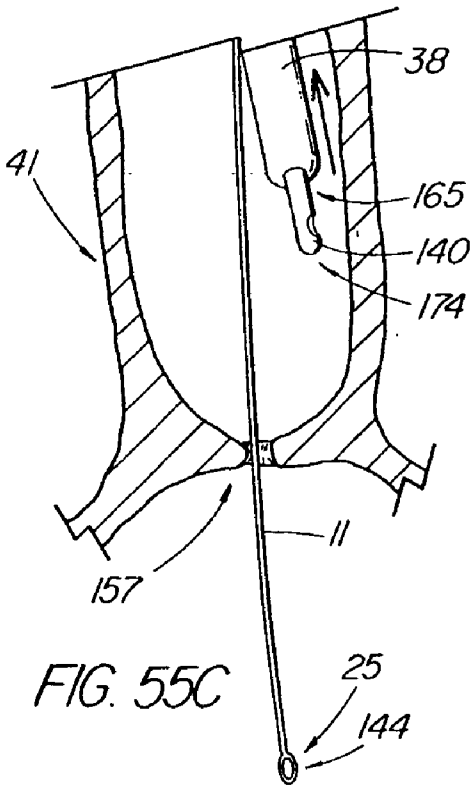


FIG. 55C

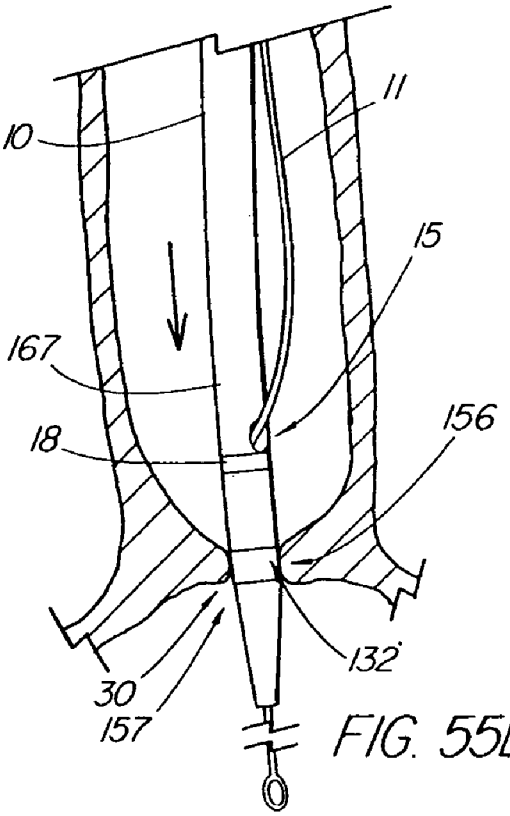


FIG. 55D

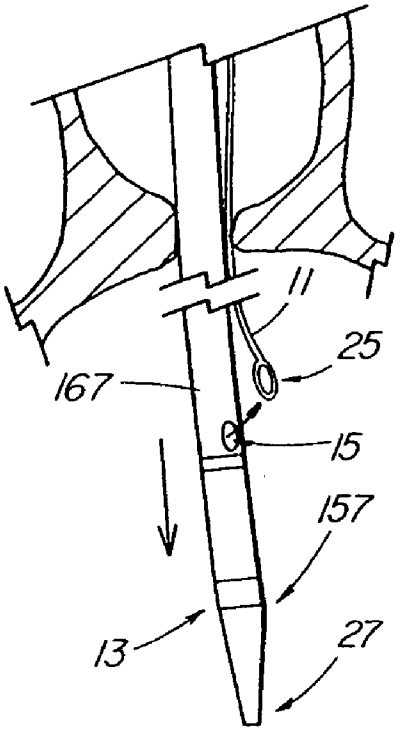


FIG. 55E

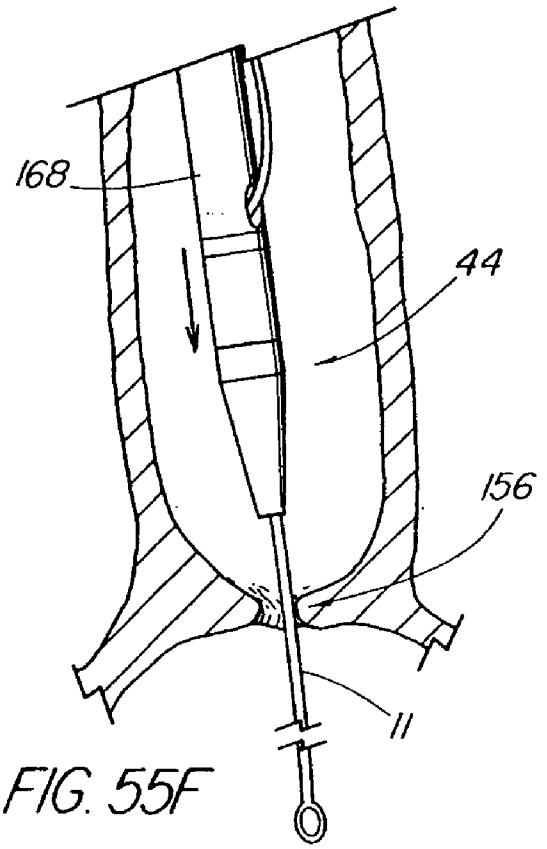


FIG. 55F

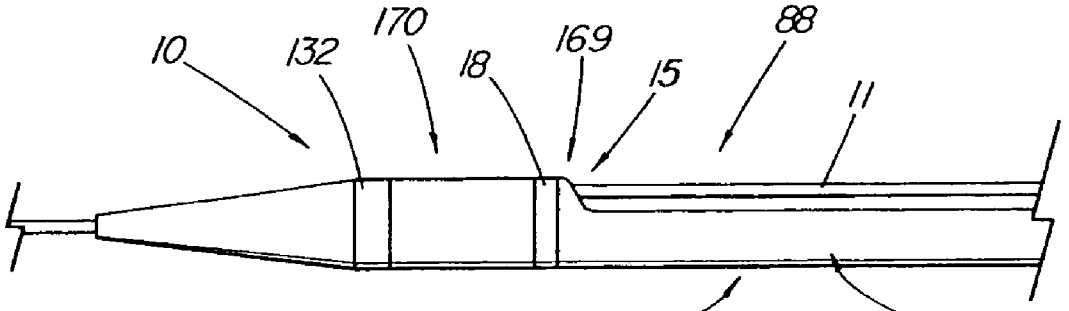


FIG. 56

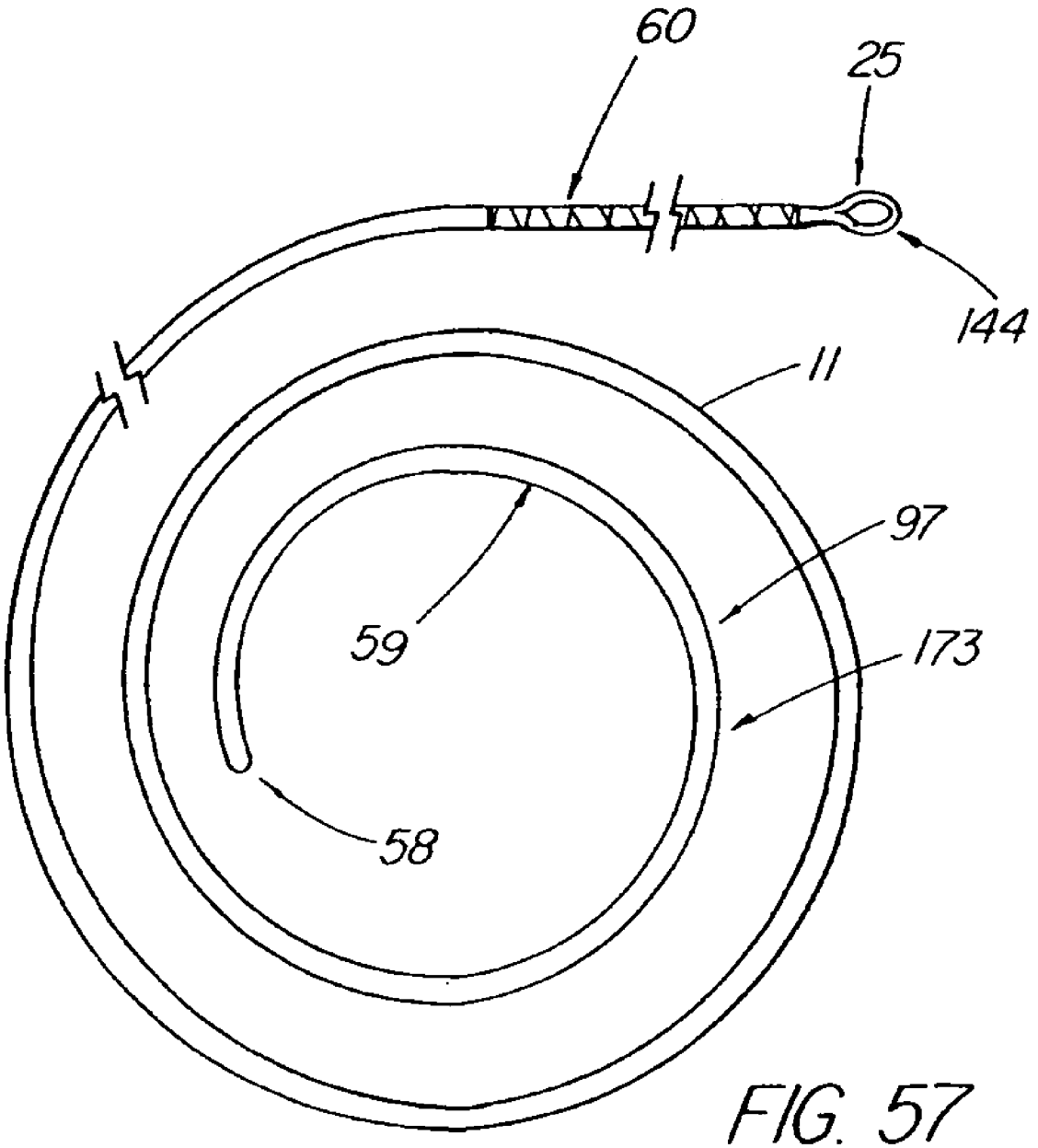


FIG. 57

SYSTEM FOR INTRODUCING MULTIPLE MEDICAL DEVICES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a non-provisional application which claims priority of provisional applications Ser. No. 60/491,408, filed Jul. 31, 2003, Ser. No. 60/563,968, filed Apr. 21, 2004, and Ser. No. 60/570,656, filed May 13, 2004.

TECHNICAL FIELD

[0002] This invention relates to medical devices, more particularly catheters and the like that are introduced into the patient over a wire guide.

BACKGROUND OF THE INVENTION

[0003] Minimally invasive medicine, the practice of gaining access into a blood vessel, duct, or organ using a wire guide to facilitate the subsequent introduction or placement of catheters and other medical devices, has been evolving since the Seldinger technique was first popularized during the late 1950s and 1960s. A significant advance was gaining the ability to exchange medical devices over a single indwelling wire guide without requiring displacement of the wire in the process and loss of access to the site. This 'over the wire' (OTW) exchange technique requires an extra long guide wire so that control over the wire could be maintained at all times during the procedure. To accomplish this, the portion of the wire extending out of the patient must be at least as long as the device itself so that a proximal portion of the wire could be secured at all times maintain longitudinal positioning, typically by an assistant standing well behind the physician. For example, endoscopic catheters that are used to access the biliary system are typically 200 cm or more in length, requiring a wire guide of more than 400 cm (e.g., 480 cm) to be long enough to remain in the duct during the exchange. To remove the catheter over the wire, the physician and an assistant must carefully make a series of well-coordinated, one to one movements between the exchange wire and device. The assistant pushes the wire the same amount as the physician pulls back on the catheter until the device is completely outside of the patient and the physician gains control over the wire at the port of the scope. The assistant then pulls the device off of the wire such that a second device can be fed back over the wire and into the patient to perform a second operation, requiring the same push-pull technique in reverse. This procedure requires a well-trained assistant, who actually is responsible for the advancement of the wire, instead of the physician. In biliary ERCP, this lack of wire guide control can be a disadvantage when cannulating the ampullary orifice because the techniques used are typically highly dependent on good verbal communication between the physician and assistant, and the experience of the latter.

[0004] Although the 'long wire' or OTW technique still remains a commonly used method of exchanging devices in the biliary system, a technique was developed which allowed for a much shorter wire guide and more physician control over the wire. Variously known as the 'rapid exchange,''monorail,' or 'short-wire' technique, it differs from the OTW technique in that instead of the device being introduced over the length of the wire guide, the wire guide is coupled for only a portion of the length of the catheter device. The device is fed over the wire guide, which then exits the passageway or a coupling portion of the catheter at a point between the catheter's distal end and the proximal portion via a port or channel formed in the side of the catheter, typically located within the distal portion of the device. This allows the physician to have control of the proximal or external portion of the wire at all times as it exits the patient or scope and reduces the need for coordinating device movements with an assistant. When the coupled portion exits the patient (or endoscope in the case of gastroenterological or other endoscopic procedures), the physician performs a short exchange (instead of the traditional long-wire exchange, which in biliary procedures, requires the assistant to stand well out of the sterile field in order to assist with the exchange). With certain other devices, the catheter is split or torn away to uncouple it from the wire as the catheter exits the patient. To introduce the device, the coupled portion of the catheter is advanced over the proximal end of the wire guide, while the physician is careful to maintain the wire in position so that its distal end is maintained within the work site and access is not lost.

[0005] Rapid exchange or short wire techniques have proven particularly desirable in coronary and vascular medicine whereby it is common for a sequence of procedures using multiple catheter-based devices to be performed over a single wire, such as stent placement following angioplasty. Another example of where short wire exchange techniques are often used is in endoscopic procedures performed in the pacreatobiliary system. Typically, an ERCP (endoscopic retrograde cholangiopancreatography) procedure is performed by introducing a catheter device from a duodenoscope through the ampullary orifice (Papilla of Vater) and into the biliary tree, which includes the bile duct, pancreatic duct, and hepatic ducts of the liver. The cannulation device, which typically comprises a sphincterotome/papillotome or ECRP catheter, is introduced into the biliary tree to perform a first operation, which could be diagnostic in nature, such as injecting contrast media, or for therapeutic purposes, such as enlarging the ampullary orifice. When a second medical operation is required, such as to remove a stone, open a stricture, sample tissue, etc., a second or peripheral device, e.g., balloon, basket, snare, biopsy brush, dilator, stent delivery catheter, etc., can be introduced over the original wire guide to perform a secondary therapeutic procedure.

[0006] While OTW techniques have permitted the exchange of devices, the development of short wire techniques has found acceptance by physicians who prefer to maintain greater control of the wire guide at the scope. Well-known examples of this rapid exchange technology are the devices comprising the MICROVASIVE RX BILIARY SYSTEM™ (Boston Scientific Corporation, Natwick, Mass.) in which the catheter portion of the devices include an internal lumen extending between a distal opening and a proximal side opening spaced 5-30 cm therefrom, depending on the device, thereby requiring an exchange of that length as the device is being removed over the 260 cm JAGWIRE® Guidewire guide developed for that system. An example of a sphincterotome of this system (AUTOTOME™ Cannulating Sphincterotome) is depicted in **FIG. 1**. Extending proximally from the proximal side opening, the lumen forms a 'C-channel' (shown in **FIG. 2**) that holds the wire guide within the catheter as the catheter portion is introduced into the scope, but allows the wire to be laterally pulled out of the

channel to gain access of the wire at the biopsy port of the scope as the catheter is being removed from the scope (**FIG. 3**), so that a second catheter type device (e.g., balloon, basket, stent delivery catheter, etc.) can be subsequently fed over the proximal end of the wire. As the distal portion of the first device is exiting the scope, a short exchange is required (coordinated push-pull movements between the physician and assistant) that is similar in practice to that used in an OTW procedure, until the physician gains control of the wire and the assistant can pull off the first device without risking loss of access. The proximal end of the wire guide is typically secured to the scope during much of the procedure to prevent loss of access, but it must be disengaged from the scope to allow the exchange and removal of the catheter.

[**0007**] While the Microvasive system has offered modest time savings, more physician control of the wire, and placed less reliance on the skill of the assistant to help perform the exchange, a short exchange procedure is still required in which care must be taken to prevent loss of wire guide access to the duct, particularly since the wire guide cannot be secured to the scope during removal of the catheter. Because the wire guide resides in the channel of the catheter and the coupled devices are constrained together in the accessory channel, uncoupling must take place as the distal portion of the catheter exits the proximal end of the scope. The process is further slowed by the frictional resistance between the wire and catheter, which remains a problem in subsequent exchanges as devices are fed or removed over the wire residing in the catheter lumen or C-channel.

[**0008**] Having a C-channel extending along the catheter can result in certain clinical disadvantages. For example, the split in the catheter provides an entry point for blood and bile, a known source of viruses and bacteria, to enter the catheter lumen and migrate to the proximal end of the device where they typically leak out onto the floor and clothing of those involved in the procedure. The channel also represents a point of potential air leakage, which can compromise the ability to maintain adequate insufflation within the duodenum during the procedure. Another disadvantage of a C-channel is that it degrades the integrity of the catheter, which can be problematic in a cannulating device (such as a deflecting Sphincterotome) when attempting to push through or 'lift' the papilla to straighten the entry pathway into the duct, or when pushing through a stricture.

[**0009**] The current rapid exchange or short wire system also fails to address some of the shortcomings found in the traditional OTW method. For example, recannulation of the papilla is required when placing multiple plastic drainage stents side by side since the delivery system must be removed to disconnect the wire. Furthermore, existing devices do not offer the ability to place a second wire guide after the first one, such as to place stents in multiple ducts, since the catheter, which could otherwise serve as a conduit, must be removed from the patient and work site before it would have a free lumen for a second wire. Another disadvantage of current systems for exchanging biliary devices is the incompatibility between the two systems. Long wire devices lack the side access port for use with a short exchange wire and the MICROVASIVE RX BILIARY SYSTEM™ devices with C-channels are poorly configured for long wire exchange since once the C-channel has been breached during the first exchange, it is difficult to introduce a long wire through the proximal wire guide access port (which includes the open channel) and keep it from slipping from the channel as it is being introduced. Further, the C-channel is typically not compatible with smaller-diameter wire guides (less than 0.035") for the same reason. Incompatibility between systems means that physicians cannot take advantage of all of the choices available when selecting the best device and treatment for a particular patient.

[**0010**] What is needed is an improved short-wire system and technique for efficiently and reliably exchanging devices within a work site which is compatible with long wire exchange method and which addresses the other deficiencies described above.

SUMMARY OF THE INVENTION

[**0011**] The foregoing problems are solved and a technical advance is achieved in an illustrative system and method for introducing and exchanging multiple elongate medical devices, e.g., tubular members such as catheters and the like, over an indwelling guiding member, such as a wire guide, within a patient by remotely uncoupling the first device (primary access device) from the guiding member within the work site (defined as a lumen, duct, organ, vessel, other bodily passage or cavity, or the pathway leading thereto in which wire guide/guiding member access is maintained throughout a particular procedure or series of procedures), thereby facilitating the removal of the device and simplifying introduction of a secondary access device over the indwelling wire without an exchange of devices taking place outside of the patient. While the primary focus of this application is the exchange of devices within the pancreatobiliary system or elsewhere in the gastrointestinal tract, the system and method of remote uncoupling of devices within a work site can be adapted for any part of the body to perform any suitable procedure where the exchange of devices takes place over an indwelling guiding member. Examples include, but are not limited to the introduction and placement of balloons, stents, grafts, occluders, filters, distal protection devices, catheters for ablation, phototherapy, brachytherapy etc., prosthetic valves, or other instrumentation or devices into the vascular system, including the coronary arteries, peripheral arterial system (e.g., carotid or renal arteries), or venous system (e.g., the deep veins of the legs). Other exemplary sites include the genito-urinary system (e.g., bladder, ureters, kidneys, fallopian tubes, etc.), and the bronchial system. Additionally, the present system and method can be used for exchanging devices within body cavities, e.g., the peritoneum, pleural space, pseudocysts, or true cystic structures, via percutaneous placement and exchange through a needle, trocar, or sheath.

[**0012**] The basic system of devices for remote uncoupling comprises a guiding member, typically a wire guide. It should be understood that hereafter, the term 'wire guide' is used in the specification in a generic sense to include any device (e.g., small-diameter catheter, laser fiber, string, plastic beading, stylet, needle etc.) configured to perform the same function, although such a device technically may not be considered a wire guide (or 'guidewire') as the term is most commonly used in the medical arts. Remote uncoupling permits a shorter guiding member/wire guide to be used than for other short wire methods (e.g., rapid exchange), and thus hereafter, the methods described in this specification are referred to collectively as the 'ultra-short wire' technique, or depending on the work site, 'intraductal

exchange' (IDE), 'intravascular exchange' (IVE), etc. The reason that the wire guide can be of a shorter length than traditional rapid exchange wire guides is that there is no exchange outside the patient. In fact, remote uncoupling allows for the exchange wire guide to be shorter than the devices being introduced since the devices are not removed over the wire. For example, the wire guide of the present inventive system of biliary devices (for use in a 145 cm channel duodenoscope) is typically 185 cm (minimum functional length of about 180 cm), as opposed to the 260 cm wire guide typically used for the Microvasive 'rapid exchange' procedures in which a 5 to 30 cm external exchange must be performed each time, depending on the device used. The shorter wire is easier to manipulate by a single operator and helps prevent it from contacting non-sterile surfaces, such as the floor, patient bed, instrument table, imaging unit, etc. The 185 cm length still permits most external changes to be performed, if necessary. To accommodate a longer wire for exchanging a device otherwise not compatible with the system, an optional coupling mechanism on the proximal end of the wire can be included to engage a wire guide extender portion to lengthen the wire (e.g., to 260 or 480 cm) and permit a traditional exchange to take place.

[0013] Coupled to the guiding member/wire guide is a first elongate medical device (the primary access device), typically a tubular member or catheter device, which includes a coupling region, such as a passageway or lumen, external channel, outer ring, or other interface area, located about the distal portion and which is configured to receive a portion of the wire guide such that both devices can comprise a releasably coupled pair while operating within a work site. The coupling region may be an integral part of the elongate medical device or may located about a separate element disposed therewith (e.g., an elongate engagment member), which for purposes of this application is considered part of the elongate medical device. A separate elongate engagement member can provide a primary or secondary means of releasably securing the wire guide and catheter device until they are to be repositioned or uncoupled. The elongate engagement member, typically but not necessarily disposed within the passageway of the tubular member, can further comprise the coupling region as well. Preferably, the primary access devices used with this system have a closed or self-sealing passageway extending to the proximal (external) portion of the device (instead of an open or split channel) such that the system can be readily converted to introduce a long wire if a long wire-compatible device is selected. Further, the devices of this invention are configured for traditional short wire exchange back over the wire, if so desired, or when remote uncoupling becomes problematic (e.g., due to unexpected anatomical constraints).

[0014] In a first aspect of the invention, the system further includes an alignment indicator system, such as a system of indicia (e.g., radiopaque markers, external markings, endoscopic markings, etc.) located about the wire guide and/or first elongate medical device that can be utilized by the operator in locating the position of the distal end or distal portion of the wire guide relative to the proximal end of the coupling region, such as at a side access port or aperture (e.g., scive) through which the wire exits. The alignment indication system advantageously allows the physician to control when the two devices are coupled or uncoupled within the work site and helps provide confirmation that uncoupling has occurred. Without the ability to receive such confirmation, it would be extremely difficult for the physician to attempt, with any confidence, the uncoupling of the catheter from the wire guide (e.g., under fluoroscopic guidance) without knowing when uncoupling has occurred or is about to occur. Depending on the location or work site within the body and the device being delivered, an attempt to 'blindly' uncouple devices can lead to loss of wire guide access, especially if the device is prematurely withdrawn with the wire guide still engaged. Furthermore, the amount of relative movement between the device and the wire guide required to ensure that uncoupling had occurred would generally be much greater than if indicia were utilized, thus increasing risks such as the wire guide being withdrawn too far and access lost or encountering situations where there is insufficient space within the work site left for uncoupling to take place. Typical rapid exchange devices are not configured with the necessary radiographic or other appropriate indicia since the exchange procedure is intended to take place outside of the patient. The external exchange is a slower process and dictates removal of the first catheter before another catheter or wire guide can be advanced to the work site over an existing device (which always must be a wire guide or guiding device in traditional rapid exchange).

[0015] A first series of embodiments of the system of indicia includes radiographic or ultrasonically reflective markings located about one or more of the devices which are used by the operator under an appropriate external guidance system (fluoroscopy, MRI, CT scan, x-ray, ultrasound, etc.) to determine the state of alignment and engagement between the primary or secondary access device and guiding device. A first example comprises radiopaque or high-density bands, markings, etc., located on the distal portions of the wire guide and first elongate medical device. In particular, the distal tip of the wire guide includes a radiopaque portion that typically comprises at least the length of the coupling region of the first elongate medical device, which itself includes a radiopaque marker, such as a band comprising iridium, platinum, or other suitable material, located about the proximal end of the coupling region (e.g., at, or just distal to the side access port), thus allowing the operator to know when the distal tip of the wire is nearing or has exited the point of the catheter at which the devices become uncoupled or separate within the work site. Additionally, other radiopaque markers may be present that are generally not used to assist in remote uncoupling, such as at the distal end of the catheter or indicia used for stent or balloon placement.

[0016] A second series of embodiments of the system indicia comprises directly viewable indicia located about the proximal portions of the wire guide and the tubular member to which it is coupled during the procedure. In one example, the wire guide comprises a visually distinctive alignment point, such as a single mark (e.g., colored band) or a transition point between different colored and/or patterned regions of the wire guide outer coating, which when aligned with a specified first marking on the proximal portion of the elongate medical device, indicates that the distal ends of the wire guide and tubular member are in alignment with respect to one another. The catheter further includes a second mark that represents the disengagement point, that when aligned with the designated alignment marking of the wire guide, is indicative that the two devices are about to or have uncoupled or disengaged with the distal tip of the wire guide having exited the coupling region. Preferably, the first

(distal) and second (proximal) markings on the proximal portion of the catheter are located within a region that remains external of the patient or scope during a procedure and are spaced apart by the same distance as the length of the coupling region. For very short coupling regions (e.g., rings), a single mark on the catheter may be preferable to indicate disengagement, if proximal indicia are to be used.

[0017] A third series of embodiments of the system of indicia include markings that are configured to be viewable by a fiberoptic endoscope or videoendoscope (e.g., duodenoscope, gastroscope, bronchoscope, ureteroscope, etc.). In devices configured for accessing the pancreatobiliary system, the indicia comprise a marking located on both the wire guide and elongate medical device disposed within an intermediate portion of each, which is typically located distal to the viewing lens or video chip of the scope, but proximal to the ampullary orifice during a typical procedure, such that they can be aligned by using the video monitor (or viewing port) to ascertain that uncoupling within the duct has occurred. The device may include other endoscopic indicia useful during the remote uncoupling procedure. For example, a biliary catheter may include a depth marking at a designated distance from the catheter tip (e.g., 10 cm) which when buried within the papilla, indicates that IDE can be performed safely within the duct without risking loss of wire guide access. Furthermore, the distal portion of the wire guide can be distinctive in appearance (e.g., black) as a visual cue to warn the physician if the tip is in danger of pulling completely out of the duct, which would require recannulation of the papilla. The second and third system of indicia do not require external imaging, thus the physician can advantageously limit the time that the patient is exposed to fluoroscopy. For example, fluoroscopy can be used only at selected, critical times during the procedure with at least one of the other types or indicia being used elsewhere for alignment guidance.

[0018] In addition to the use of visual indicia to confirm whether the wire guide and first elongate medical device (and subsequent devices) are engaged or uncoupled, the present invention includes other types of alignment indication systems, such as a tactile system that includes one or more protuberances and/or indentations along one or more of the devices or the endoscope accessory channel port to allow the physician to 'feel' or sense the point where disengagement has occurred or is imminent due to the discrete point(s) of increased resistance between the device as they move relative to one another. Magnets can be a part of a tactile system as well. Other embodiments of the alignment indicator system include sensor-based systems in which a sensor located within the system, such as along the catheter or endoscope channel/port, detects a calibrated location elsewhere in the system (e.g., the wire guide or catheter) and emits or provides a signal or cue (e.g., electrical signal) that is relayed to the operator in the form of an audio or visual alert that warns the operator that the devices have or are about to become uncoupled. The alignment system can comprise a single system or means for alignment, or any combination of visual and non-visual indicators.

[0019] In a second aspect of the invention, a method is provided for uncoupling the first elongate medical device from the wire guide while both are still dwelling within the work site (i.e., the basic ultra-short wire technique). Both devices are introduced into the work site, using a standard introduction method and introducer member such as an endoscope, introducer sheath, etc., with the wire guide engaged through the coupling region of the medical device being introduced. In one embodiment for use in the pancreatobiliary system, the coupling region comprises a passageway within the distal portion of the catheter, such as the distal 6 cm thereof, with the wire guide exiting at that point through a side access port (e.g., scive) such that the wire guide coextends along the outside of the proximal portion of the catheter as both reside side by side along the introduction pathway, which in the biliary embodiment comprises the channel of the duodenoscope. For example, a wire guide or primary access device, such as a sphincterotome, needle knife, ERCP catheter, etc., may be introduced first to cannulate the duct, with the primary access device being subsequently advanced over the wire to perform a first medical operation that is diagnostic and/or therapeutic in nature. During this time, the wire guide is preferably secured in place by attaching the proximal portion to the endoscope via a locking device, clip, other means located about wire guide entry port (biopsy port), thus fixing its position longitudinally to assist with maintaining access to the work site. Once the first device has performed its intended operation (inject contrast media, ablate the sphincter, etc.), the operator preferably uses the radiographic, endoscopic, and/or proximal system of indica to provide visual guidance during repositioning of the devices to permit disengagement. One technique (referred to herein as 'device IDE') includes advancing the primary access device over the stationary wire guide until uncoupling has occurred. A second technique (referred to herein as 'wire guide IDE') includes withdrawing the wire guide while maintaining the primary access device in a stationary position until the alignment indicia indicates that uncoupling has occurred. A third technique would involve a combination of the device and wire guide IDE. Also, there typically is a characteristic 'whipping' action of the radiopaque wire guide tip portion upon exit from the passageway that is viewable under fluoroscopy which also provides a visually distinctive indicator of uncoupling.

[0020] When the physician, using at least one component of the alignment indicator system, has determined that the tip of the wire guide has disengaged from the coupling region of the primary access device, the first device can be easily removed by merely pulling it back out of the endoscope accessory channel (or introducer sheath in the case of vascular or certain other non-endoscopic applications). Removal is greatly facilitated by the elimination of friction which would have otherwise existed between the wire guide and catheter if the wire resided within the channel or lumen. Although some of the aforementioned MICROVASIVE RX™ biliary devices (e.g., the AUTOTOME™ sphincterotome) include a side port within the distal portion, all of the devices lack the combination of indicia that make a remote or intraductal exchange clinically practical or even possible. Furthermore, those devices that include an open channel extending proximally of the side access port cannot be uncoupled within the duct or work site regardless of the lack of indicia since the proximal portion of the wire guide tends to 'seek' and reenter the channel when both devices are residing within the accessory channel of the scope. Thus, remote disconnection is rendered impossible without some means to releasably disengage the wire from the channel.

[0021] After the catheter and wire guide are uncoupled, the proximal end of the wire is available for a third elongate medical device (e.g., a secondary access device or a second device that is the same as the first) to be advanced thereover to the work site. In one example of the method, the proximal end of the indwelling wire is fed through the distal opening and out of the side access port of the secondary device, which is then advanced to the work site. If after the second medical operation using the secondary device, another secondary device is required for another operation, the first secondary device (third medical device) is removed from the wire guide and the patient, and the wire guide is available to provide access for a fourth device in the same manner as the first two.

[0022] In a variation of the present method, the primary access device may be left in place at the work site after disengagement with the wire guide to serve as an introduction pathway or conduit for a second wire guide, such as for a procedure where two branches of a duct or vessel are to be cannulated. An example of such a procedure is when a stent must be placed in two different ducts draining separate lobes of the liver. The second wire guide is typically introduced through a proximal wire guide port or hub of the first device, typically disposed about the handle portion, the port communicating with the passageway. This technique typically requires a long-wire exchange of the catheter. A second option is to introduce the wire through a proximal side access port (e.g., a scive) formed through the wall of the tubular member so that full control of the wire is maintained. In this embodiment, the catheter walls are configured to be splittable between the proximal and side access ports, or include an open or self-sealing channel through which the wire guide can be stripped out toward the distal portion of the device such that a long exchange is not required. Removing or stripping the wire guide laterally from the passageway can be done by any well-known means, such as scoring or structurally weakening a wall of the catheter, using a splittable, isotropically oriented catheter wall material (e.g., PTFE), incorporating a sealable or locking seam therealong, or by thinning the wall and/or using a material that allows the wire guide to split the wall and form its own exit pathway when sufficient force is supplied. Alternatively, a wire guide that includes a coupling region, such as an attached sleeve, can be used to couple to a standard wire guide that is already indwelling, or both wires can be coupled together and advanced through the passageway of the elongate tubular member.

[0023] After gaining access to the passageway by one of the aforementioned routes, the wire guide is guided under external imaging, such as fluoroscopy, into the desired location. Optionally, if the first device is a sphincterotome or other type of deflectable catheter, the operator can manipulate the shape and orientation of the catheter tip portion to help guide the tip of the second wire guide into the opposite (or side) branch of the duct or vessel. Orientation within the work site can be facilitated with a rotatable handle to direct the tip. Furthermore, it has been demonstrated that certain shorter wire guides, such as the illustrative 185 cm biliary wire guide of the present invention, are sufficiently torqueable such that an operator can simply rotate the wire with his or her fingers to achieve similar results in most instances.

[0024] In another aspect of the invention, primary access devices further include an elongate engagement member configured to releasably engage with the wire guide within or about the coupling region (e.g., the distal passageway of the tubular member). Embodiments include using a flexible wire stop (e.g., a nylon stylet) configured to wedge the wire guide within the passageway when in the fully advanced position, and a thread-like member (e.g., suture) that ensnares the wire guide and provides tension to maintain it in a longitudinally secure position relative to the tubular member. When an elongate engagement member is not used during introduction, such as when secondary access devices are being introduced over the already indwelling wire guide, a stiffening stylet may be optionally maintained in the passageway of the tubular member to add rigidity to the device during introduction and/or for advantageously traversing scives in the tubular member, such as the side access port, to prevent kinking thereabout.

[0025] In still another aspect of the invention, the system of devices adapted for remote uncoupling or ultra-short wire techniques includes a delivery catheter for plastic tubular drainage stents and a technique for deployment that allows for placing multiple stents side by side within the bile duct using a single cannulation procedure. By placing the side access port on the inner carrying member (over which the stent is mounted) at a point distal to the stent, the wire guide can be uncoupled within the duct and the stent deployed without having to withdraw the entire system, including the wire, in the process. The junction between the inner carrying member and wire guide can be advantageously used to 'catch' the stent when the inner member is pulled back, thus allowing the entire delivery system, including the stent, to be pulled back within the duct. This feature, which is not present in other stent delivery systems, is especially important to address situations when the stent is advanced too far into the duct and needs to be repositioned. After the stent is in the correct position for deployment, the inner carrying member is advanced and/or the wire guide withdrawn to uncouple the two, allowing the inner carrying member to be withdrawn through the stent and from the duct while the wire guide remains behind for a second stent delivery catheter (and additional stents) to be advanced into the duct and placed along side the first stent. Pigtail stents and others that include shaped distal portions for anchoring can be temporarily straightened during delivery by the wire guide which traverses the coupling region.

[0026] In still another aspect of the invention, the wire guide can be placed through the mouth by dragging or carrying the wire down using a endoscope and guide wire carrying mechanism that either resides in the channel of the scope and engages the wire guide about the scope tip, or attaches to (or co-extends with) the scope and engages the wire guide alongside. The treatment site, such as the gastroesophageal (GE) junction, is visualized and the distance to the mouth is measured using scale indicia located on the proximal portion of the scope. The wire guide, still coupled to the wire guide carrying mechanism, is then advanced a known distance (e.g., 10 cm) past the treatment site and into the stomach where uncoupling takes place following treatment. The wire guide includes a reference marking (e.g., at 10 cm) which lies at a known reference point relevant to treatment, such as the GE junction. The proximal portion of the wire guide preferably includes scale indicia, such as different colored bands or interverals (e.g., 5 cm) having different numbers or types of markings that reference a particular distance (typically using non-numerical indicia) to

the reference mark at the GE junction. With the wire guide in position, the operator advances a primary access device, such as a dilator, PDT balloon, achalasia balloon etc., using corresponding indicia on the proximal portion thereof that align with that of the wire guide to guide placement of the device to the desired treatment site, such as the GE junction. If a secondary access device is required, such as a larger dilator, the first device is advanced into the stomach over the wire and uncoupled so that the wire becomes available for the next device to be fed thereover. Carrying the wire outside of the scope to a treatment site, which may also include the jejunum or other portions of the gastrointestinal tract, adventageously provides a means for placing devices larger than scope accessory channel, while still retaining the benefit of endoscopic navigation within the patient.

BRIEF DESCRIPTION OF THE DRAWING

[0027] Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings, in which:

[0028] **FIG. 1** depicts a perspective view of a prior art sphincterotome adapted for short-wire exchange;

[0029] **FIG. 2** depicts a cross-sectional view taken along line **2-2** of **FIG. 1**;

[0030] **FIG. 3** depicts the device of **FIG. 1** being used with an endoscope;

[0031] **FIG. 4** depicts a side view of an illustrative catheter configured for use in the illustrative system and method;

[0032] **FIG. 5** depicts a cross-sectional view of the distal portion of the embodiment of **FIG. 4** and illustrative wire guide coupled thereto;

[0033] **FIG. 6** depicts a side view of an embodiment of the present invention wherein the coupling region comprises an external channel;

[0034] **FIG. 7** depicts a side view of a wire guide in which the proximal portion is oriented at an angle relative to the distal and intermediate portions;

[0035] **FIG. 8** depicts a side view of an embodiment of proximal system of indicia located on the first elongate medical device and wire guide;

[0036] **FIGS. 9***a-f* depict the steps of an example of the present method in which multiple catheter devices are exchanged over a guide wire within the common bile duct;

[0037] **FIG. 10** depicts a side view of an embodiment of the present invention wherein the first elongate medical device comprises a balloon catheter;

[0038] **FIG. 11** depicts a view in situ of a sphincterotome of the present invention being used to introduce a second wire guide into a branch of a passageway;

[0039] **FIG. 12** depicts a perspective view of an illustrative wire guide holding device of the present system and method;

[0040] **FIG. 13** depicts a side view of a wire guide having a coupling mechanism for attaching a second wire guide to the proximal end thereof;

[0041] **FIG. 14** depicts a side view of a retrieval basket of the present invention that includes a coupling ring to engage the wire guide;

[0042] **FIGS. 15-16** depict cross-sectional views of sphincterotome catheters comprising a splittable wire guide passageway;

[0043] **FIG. 17** depicts a side view of a biliary stent and delivery catheter of the present invention;

[0044] **FIG. 18** depicts a side view of an embodiment of the present invention comprising a splittable region in the tubular member;

[0045] **FIG. 19** depicts a side view of a dilation balloon of the present invention;

[0046] **FIG. 20** depicts a side view of an extraction balloon of the present invention;

[0047] **FIG. 21** depicts a side view of a biopsy device of the present invention;

[0048] **FIG. 22** depicts a side view of a self-expanding prosthesis delivery apparatus of the present invention;

[0049] **FIG. 23** depicts a partially sectioned side view of a first embodiment of an elongate engagement member (distal portion) comprising a wire stop member;

[0050] **FIG. 24** depicts a side view of the proximal portion of the embodiment of **FIG. 23**;

[0051] **FIG. 25** depicts a partially sectioned side view of a second embodiment of the elongate engagement member comprising a thread-like member;

[0052] **FIGS. 26***a-b* depict a third system of indicia located on the intermediate, viewable portion of the coupled devices of the present invention;

[0053] **FIG. 27** depicts a cross-sectional view of a stent and pusher apparatus of the present invention;

[0054] **FIG. 28** depicts a cross-sectional view of radioactive seed delivery apparatus of the present invention;

[0055] **FIGS. 29***a-e* depict a method of delivering multiple stents within the common bile duct using the system embodied in **FIG. 17**.

[0056] **FIG. 30** depicts a partially sectioned view of a wire-guided wire of the present invention;

[0057] **FIGS. 31-32** depict partially sectioned views of embodiment of the present invention in which the coupling region is located on a separate member;

[0058] **FIG. 33** depicts a side view of an embodiment of the present invention have two distal side access ports;

[0059] **FIG. 34** depicts perspective view of an embodiment of the present invention in which the wire guide hooks into the side access port;

[0060] **FIGS. 35***a-b* depicts side views of a hooked wire guide before and after uncoupling;

[0061] **FIG. 36** depicts a side view of an embodiment of the present invention comprising a pair of slotted coaxial members.

[0062] **FIG. 37** depicts a cross-sectional view of the embodiment of **FIG. 36** taken along line **37-37**;

[0063] **FIG. 38** depicts a partially sectioned view of an introducer member of the present invention;

[0064] **FIG. 39** depicts a partially sectioned view of a delivery catheter of the present invention;

[0065] **FIG. 40** depicts a side view of and embodiment of the present invention comprising a tactile alignment indication system;

[0066] **FIG. 41** depicts a side view of a pigtail drainage catheter of the present invention in its deployed configuration;

[0067] **FIG. 42** depicts a partially sectioned view of the embodiment of **FIG. 41** coupled to a wire guide;

[0068] **FIG. 43** depicts a side view of an alternate embodiment of a drainage catheter having anchoring flaps;

[0069] **FIG. 44** depicts a side view of a dilator catheter of the present invention;

[0070] **FIG. 45** depicts a side view of a wire guide of the present invention adapted for being carried by an endoscope to a work site;

[0071] **FIG. 46** depicts a side view of device attached to an endoscope which for carrying the wire guide of **FIG. 45**;

[0072] **FIG. 47** depicts an end view of the embodiment of **FIG. 46**;

[0073] **FIG. 48** depicts a side view of a wire guide carrying mechanism of the present invention;

[0074] **FIG. 49** depicts a cross-sectional view of the distal portion of embodiment of **FIG. 48** engaging a loop tip wire guide;

[0075] **FIG. 50** depicts a side view of the loop tip wire guide of **FIG. 49**;

[0076] **FIG. 51** depicts a side view of a photodynamic therapy balloon of the present invention;

[0077] **FIG. 52** depicts a plan view of a the devices of **FIG. 50** and **51** being introduced through a bite block/wire guide holder of the present invention;

[0078] **FIG. 53** depicts a side view of an achalasia balloon of the present balloon;

[0079] **FIG. 54** depicts a partially sectioned view of a naso-enteric tube of the present invention including a stiffening stylet;

[0080] **FIG. 55***a-f* depicts steps of esophageal dilation using the present method;

[0081] **FIG. 56** depicts a side view of an dilator having a reduced diameter portion proximal to the side access port; and

[0082] **FIG. 57** depicts a wire guide of the present invention that includes a lubricious intermediate portion.

DETAILED DESCRIPTION

[0083] An illustrative system and method for introducing a series of medical devices over a wire guide into a patient by remotely uncoupling the first device from the wire guide inside of the patient without utilizing a long wire or standard short wire exchange procedure is embodied in **FIGS. 4-57**. A first exemplary embodiment of the system is depicted in **FIGS. 4-5**, which comprises a first elongate medical device **10**, such as the illustrative tubular member **77** or catheter that includes features similar to the GLO-TIP II® E.R.C.P. Catheter (Wilson-Cook Medical, Inc.), the catheter further including a coupling region **14** having a first, distal end **75** (oriented toward the distal end of the device), a second, proximal end **76**, and an interconnecting passageway **31** sized and configured to receive a standard-diameter exchange wire guide **11** (e.g., METRO® Wire Guide; Wilson-Cook Medical, Inc.) or other guiding device suitable for coupling to the first elongate medical device **10**. The coupling region **14**, generally located about the distal portion **13** of the tubular member **77** (first elongate medical device **10**), may be coincident with the distal portion of the main passageway **27** (as depicted) or separate therefrom. The distal portions **13**,**60** of the fist elongate medical device **10** and the wire guide **11**, to which the former is coupled via the coupling region **14**, are generally defined as the portion of each that are disposed within the work site during the medical operation and the subsequent uncoupling of the two devices. For purposes of this disclosure, the work site is defined as the lumen, duct, organ, vessel, other bodily passage/cavity, or the pathway leading thereto, in which wire guide access is maintained to perform a particular medical procedure/operation or series of procedures. For example, in a procedure involving the biliary system, the work site is considered the common bile duct, including the pancreatic duct and the ducts extending into the lobes of the liver.

[0084] The coupling region is configured to permit the first elongate medical device **10** to be co-introduced over the wire guide (either sequentially or together) into the work site in a coupled state (e.g., with the wire guide **11** traversing the passageway **27** of the first device **10**) such that the proximal portion **59** of the wire guide exits the passageway and is external to the tubular member **77** as the wire guide **11** and tubular member exit the patient or scope. Like traditional forms of short wire or rapid exchange, this gives the physician more control over the wire at that point. In the illustrative coupling region **14** of **FIGS. 4-5**, the first end **75** thereof comprises a distal opening **19** in the tubular member **77**, and the second end **76** comprises a side access port **15** or scive traversing the side wall of the tubular member **77** and located approximately 6 cm from the distal end **12** of the tubular member. The illustrative coupling region **14** is located within the distal portion **13** of the first elongate medical device **10** with the coupling region passageway **31** comprising the distal portion of the main wire guide passageway **27**. The range of lengths of the coupling region **14** or the distance of the side access port **15** (or second end **76**) from the distal end **12** of the elongate member **10** can vary according to the device and application as long as the disconnect point is sufficiently close to the distal end of the device to allow for remote uncoupling within the work site. It has been determined that 6 cm is an advantageous coupling region length for many biliary devices of the present invention in that it provides a sufficient length to prevent accidental uncoupling, while still allowing for the anatomical constraints of the duct such that, in most instances, there remains sufficient room for the relative movement required for uncoupling.

[0085] For biliary applications, the length of coupling region could range from less than 1 cm (e.g., a ring) to at

least 15 cm. A more preferred range for most devices would be approximately 3-10 cm with the most preferred range being approximately 5-7 cm. For devices intended for the pancreatic duct, the ideal distance of the side access port **15** to the distal end **12** would be 2-5 cm, given the shorter available distance in which to work. In devices intended for use in body cavities where space is even tighter, the side access port **15** may need to be placed closely adjacent to or at the tip **12** of the device in order for an exchange to be successfully accomplished. On the other hand, procedures in which loss of wire guide access in not particularly of concern, such as in certain vascular procedures and when working in long passageways, such as in the intestinal tract, there may be more options as to where the side access port **15** and coupling region **14** can be located.

[**0086**] The illustrative side access port **15** comprises a semicircular opening (in a cross-sectional view or ovoid shape from a top view) that typically comprises approximately ¼ to ⅓ of the width of the catheter; however, any opening size or shape that permits passage of the wire guide therethrough is possible. It may be advantageous to reinforce the side access port **15** area with one or more wires, sheaths, bands, braiding, or other means which traverse, are bonded to, embedded within, or otherwise reinforce the tubular member at least within the area about the wire guide exit port (side access port) to prevent kinking at that location. The wire guide **11** extends proximally from the distal opening **19** of the first device **10** and exits the passageway **31** and coupling region **14** proximally through the side access port **15**, thereby giving the physician access to the proximal end of the wire such that it can be manipulated and locked or otherwise secured during the procedure, if so desired. As noted above, a relatively short distance of the coupling region **14** advantageously allows the coupled devices to be moved relative to each another by a sufficient distance to disengage or uncouple one from the other by advancing the catheter **10** toward the distal tip **25** of the stationary wire guide **11**, withdrawing the wire guide until it pulls through the catheter and exits the side access port **15**/coupling region **14**, or a combination of forward catheter movement and wire guide withdrawal, all preferably in such a manner that the wire guide still remains within the work site (e.g., the duct) to facilitate access by subsequent devices over the indwelling wire.

[**0087**] Insomuch that no external exchange is required with the present invention, it is only necessary to size the length of the wire guide **11** to account for the furthest point the distal portion **60** is to be advanced into the work site (e.g., for uncoupling to take place), the intermediate portion **97** extending from work site, to the outside of the patient or scope, and the proximal portion **59** (**FIG. 7**) extending therefrom for a length sufficient to be manipulated by the operator, such as to lock the wire guide in place. In the illustrative biliary embodiment, the wire guide **11** is 185 cm in length so as to provide a minimal, but adequate extension of the wire from the scope accessory channel; however, other procedures might necessitate a shorter or longer length. Although the length of the wire guide **11** need only be of sufficient length to manipulate or lock or secure in place, if necessary, the proximal portion **59** preferably should be sized to accommodate a traditional short wire exchange procedure, using the appropriately configured devices, if one is required (such as when remote uncoupling may not be possible or desirable for some reason). The wire guide **11** is preferably sized to slidably and releasably reside within the coupling region with minimal friction, although a mechanism is contemplated as part of the present invention in which the catheter (or coextending ancillary device) releasably engages and locks with the wire at a particular point therealong. The coupling region **14** of **FIG. 5** comprises the distal portion of the passageway **27** (passageway **31**), with the proximal portion **28** of the passageway providing a continuation of the lumen that extends proximally from the point of the side access port **15**. Alternatively, the proximal passageway **28** can be at least partially blocked or restricted (with a moveable flap or a permanent obstruction, such a plastic or metal insert) just proximal to the side access port **15** to serve as a guide or ramp that helps the wire guide being loaded from the distal opening **19** to be able to more readily exit through the side access port, rather than continuing on into the proximal passageway. The blocking means (not shown) may also advantageously restrict fluid or other materials from passing through the passageway retrograde direction. In a related embodiment, the wire guide passageway **27** extends proximally only to the side access port **15**, terminating at that point.

[**0088**] While the illustrative coupling region **14** of **FIGS. 4-5** represent a preferred embodiment for applications in which having the wire guide **11** extending from the distal opening **19** of the tubular member **77** is particularly advantageous, such as for primary access devices used to cannulate a tight stricture, such as the ampullary orifice, it should be noted that any structural adaptation that allows for temporary coupling of the wire guide to a device being introduced therewith or thereover can comprise an embodiment of the coupling region **14** for purposes of remote uncoupling. For example, **FIG. 6** depicts a alternative embodiment of the present invention in which the coupling region **14** comprises an external coupling element or channel **30**, rather than a portion of the tubular member passageway **27**. The illustrative external channel **30**, which includes a passageway **31** extending therethrough, can either be integrally formed with the catheter body, or can be bonded or otherwise attached to the outside thereof. Additionally, the external channel **30** can comprise a short piece of sheath encircling the tubular member **77**, a plastic or metal ring, or any structure that can form a passageway **31** capable of forming a coupling region **14** with the wire guide.

[**0089**] **FIG. 30** depicts an embodiment of an external channel **30** for a device not having an internal passageway. The elongate medical device **10** comprises a wire-guided wire **111** in which the coupling region **14** comprises a outer channel **30** comprising a outer sleeve **112** of shrink wrap material bonded to the wire **111** and a inner sleeve **113** of a radiopaque material bonded to the first sleeve **112** as indicator **17**,**18** of the first and second ends **75**,**76** of the coupling region **14**. Either a standard wire guide (such as a 0.021" METRO™ wire guide) is fed through the coupling region and the two wires are advanced through an already indwelling tubular member to the work site, or the wire-guide wire **111** is fed over the proximal end of an indwelling standard wire guide (which could also be coupled to a tubular member) and advanced to the work site, where it is uncoupled therein.

[**0090**] **FIG. 14** depicts another alternative embodiment in which the coupling region **14** comprises a coupling ring **63**, which in the illustrative embodiment is attached to the distal

tip **74** of a retrieval apparatus **64**, such as the illustrative wire retrieval basket **64** for capturing biliary stones (a modification of the WEB™ Extraction Basket, Wilson-Cook Medical, Inc.). The illustrative ring **63** is advantageously made to pivot so that it can better accommodate the wire guide **11** which passes therethrough to engage with the first device **10**. Coupling rings **63**, while not providing as secure of an engagement of the internal passageway, represents an option for certain types of devices lacking a suitable passageway within the shaft portion of the elongate medical device **10** (made of coiled wire in this particular embodiment). The ring **63** requires the least amount of relative movement between devices for uncoupling, which can be advantageous in short work sites or when faced with other anatomical constraints.

[**0091**] **FIGS. 31-36** depict a series of alternative coupling region **14** embodiments. **FIG. 31** depicts a tubular member **77** in which the coupling region **14** is located on a separate element, which in the illustrative embodiment, comprises an elongate engagement member **89** comprising a shaft portion **164** slidably disposed in a second passageway **115** and extends from the distal end **12** of the tubular member **77** and engages the wire guide **11** via a cannula portion **115** that includes first and second openings **75,76** through which the wire guide **11** is fed. By locating the elongate engagement member **89** within a second passageway **115**, the first passageway **27** remains available for infusing materials or passing a second wire guide therethrough. The embodiment of **FIG. 32** also includes a separate elongate engagement member **89** in a second passageway **115** with the elongate engagement member **89** further comprising the coupling region **14**. In this illustrative embodiment, the elongate engagement member **89** extends from the side access port **15** and includes a distal ring or loop **45** which ensnares the wire guide and couples the devices together. Optionally, the loop **45** can be made collapsible to pull through the passageway **115** after uncoupling.

[**0092**] **FIG. 33** depicts a tubular member in which the first end **75** of the coupling region **14** terminates proximal to the distal end **12** of the member, and the second end **76** comprises a side access port **15** located about the distal portion **13** of the tubular member. The wire guide **11** is fed into the coupling region **14** such that the distal end **25** of wire guide **11** is directed at an angle from the tip **12** as it exits the most distal side access port (first end **75**). This configuration allows the physician to be able to rotate the tubular member **77** to advantageously direct the tip **25** of the wire guide **11** in an intended direction, such as into a particular branch **48,49** of a bifurcated duct or vessel. The distal end **12** of the tubular member **77** can be closed, or it could include an opening about the tip that could represent a second, alternative first end **75** of the coupling region so that if preferred, the wire guide **11** can also be coupled in the manner similar to **FIG. 5**.

[**0093**] **FIGS. 34-35***b* depict embodiments of the present invention in which the wire guide **11** is adapted to hook into the coupling region **14** in a coupled configuration. In the embodiment of **FIG. 34**, the wire guide **11** includes a hooked distal portion **116**, such as the illustrative 'shepherd's crook' in which the distal end **25** and adjacent distal portion **60** engage the coupling region **14** of the tubular member **77** via the side access port **15**, residing within the passageway **27** by an amount sufficient to accomplish a secure engagement. Preferably, the wire guide **11** is sized such that there is a adequate frictional engagement with the passageway **27** in which it resides to help prevent accidental dislodgement. In a related embodiment shown in **FIGS. 35***a-b*, the distal hook portion **116** of the wire guide **11** is configured to be inserted into the distal opening **19** of the tubular member **77**, which includes a radiopaque marker band **17** closely proximate thereto. The illustrative distal hook portion **116** comprises nitinol or another superelastic material which allows it to be heat set in a helical configuration **117** that once disengaged from the passageway **31** of the coupling region **14**, the hook **116** assumes its predetermined shape and wraps back over itself to create a closed loop end **118**. This configuration better permits a second device to be fed back over the wire guide **11** without the hooked portion **116** interfering with its passage thereover. Optionally, the tubular member **77** can include an open longitudinal channel or recess extending proximally from the side access port **15** or distal opening **19** in which the coupled wire guide **11** can at least partially reside while the devices are being advanced together into the work site.

[**0094**] Another embodiment of a method of coupling a tubular member **77** to a wire guide **11** is shown in **FIGS. 36-37** in which the tubular member comprises a pair of coaxial members **100,119** that each include a slotted opening or channel **120,121** extending the length of the coupling region **14** (distal end **12** to side access port **15**) such that when aligned with one another, the wire guide **11** can laterally disengage from the open passageway **31**, which is otherwise enclosed by one of the inner **119** and outer **100** sheath members when they are not aligned. Preferably, the proximal portions of the inner and outer members **100,119** (not shown) include proximal makings or structure that allows the physician to determine when rotational alignment has occurred for uncoupling. Alternatively, the slots **120,121** can include radiopaque stripes extending therealong that when superimposed on one another or are otherwise aligned in some manner, indicate radiographically that alignment has occurred such the wire guide can disengage from the passageway **31**.

[**0095**] The above coupling region **14** embodiments are merely exemplary of the many options from which a skilled person might select to couple a catheter and wire guide together for introducing them to a work site, the choice being influenced by the nature of the procedure and the devices being used. Other selected examples include, but are not limited to releasable or breakable sutures or wires extending along or through the catheter to capture the wire, compatible, engageable surface structure or elements located on both devices, temporary or dissolvable bonds or adhesives, magnets, or other means of temporarily coupling two medical devices.

[**0096**] Preferably, devices configured for remote uncoupling include an alignment indicator system that allows the clinician to determine the current state of alignment or engagement between a given device and the wire guide or guiding member to which it is temporarily coupled for a particular procedure. In procedures that utilize fluoroscopic guidance of devices within the work site, strategically located radiopaque indicia conveniently provide a means for determining relative alignment and confirmation that uncoupling has occurred. The invention does not require that a particular imageable maker be of a particular type. For

example, ultrasonically reflective markers can be used in place of radiopaque bands or other markers. Further, the number and arrangement of the markers is not critical. The alignment indicator system of the present invention may comprise any suitable system in which the first elongate device **10** and wire guide **11** include a predetermined or precalibrated method or means of providing guidance to the physician via external imaging, direct observation (external or endoscopic), tactile sensation, or monitoring of an audible or visual alarm sensor (e.g., activating an indicator light located about the proximal end of the apparatus) to indicate that uncoupling of the two device has occurred within the work site.

[**0097**] Referring now to **FIGS. 4 and 5**, the procedure for uncoupling the first device **10** and wire guide **11** within the work site is greatly facilitated by the addition of a first system of indicia **16** located about the distal portions **13,60** of the first device **10** and the wire guide **11**, respectively, that comprise a series of radiopaque markers which provide visual guidance under fluroscopic imaging to the physician or operator as to when the first device is coupled with the wire guide and when the wire guide has passed through and out of the coupling region **14**. Since relatively few exchange procedures can be performed under direct visual observation, the distal indicia **16** typically include a series of externally imageable bands, marking, or other indicia comprising a radiopaque (high density) material, such as, iridium, platinum, tungsten, gold, barium, tantalum, etc. The indicia are overlaid upon, bonded to, or incorporated into the device at the desired locations, typically a location useful for relative alignment with other radiopaque indicia or structure. The illustrative first (or distal) system of indicia **16** comprises a series of radiopaque markings on both the first elongate medical device **10** (tubular member **77**) and the wire guide **11**, including an optional distal imageable marking **17** located about the distal end **12** of the tubular member (or first end **75** of the coupling region), a proximal imageable marking **18** located proximate and distal to the side access port **15**, and a distal imageable portion **26** or marker located about the distal end **25** or distal portion **60** of the wire guide **11**. The illustrative distal marking **17** of **FIG. 4** comprises radiopaque ink having sufficient radiopacity to contrast with the catheter shaft, which in the illustrative embodiment, is also made radiopaque by the addition of barium sulfate or other suitable material into the base polymer. The proximal imageable marking **18** comprises an iridium or platinum band that is glued or otherwise affixed to the catheter surface closely adjacent the distal end of the scive comprising the side access port **15**. This band comprises sufficient radiopacity such that it contrasts well with the tubular member to which it is attached, which also may include radiopaque material or pigment. In **FIG. 5**, the distal radiopaque marker **17** of the tubular member **77** comprises a band similar to band **18** at the proximal end **76** of the coupling region (side access port **15**). The illustrative distal radiopaque wire guide portion **26** (**FIG. 5**) comprises a coilspring comprising platinum, or another radiopaque material such as tungsten or gold. Use of radiopaque filler material or ink is also contemplated as a means for creating a radiopaque wire guide tip portion **26**. Placement of a radiopaque marker **18** about the second end **76** of the coupling region **14** advantageously provides a target point at which the physician knows if the radiopaque tip **26** of the wire guide has passed proximal thereto and disengagement has occurred. Although in the illustrative embodiments, the marker **18** is typically located proximal and closely adjacent to the side access port, it may also be placed in any suitable position that is useful for alignment with the wire guide, such as proximal of the port or in alignment therewith, such as depicted in **FIG. 6**. Alternatively, the marker **18** can comprise a radiopaque stripe or sleeve that extends the length of the coupling region, rather than being limited to the area adjacent the side access port. One such example is depicted in **FIG. 31** in which the illustrative metal coupling cannula **114** comprises a highly radiopaque material such as platinum or iridium. In the embodiments of **FIGS. 14 and 32**, the coupling region **14** comprises a coupling ring **63** which preferably includes enhanced radiopacity to assist the physician in determining when the radiopaque distal portion **26** of the wire guide has passed through and disengaged from the ring.

[**0098**] A second system or type of indicia **21** is depicted in **FIGS. 4 and 8**, and is located on a proximal portion **36** of the first device **10**/tubular member **77** that is external to the patient when the distal portion **13** of the device is residing within the work site. During normal operation, the proximal indicia **21** are directly visible by the clinician during the procedure as a primary or secondary means of determining alignment. In the biliary embodiment of **FIG. 8**, the proximal indicia **21** comprise indicia **35** located about the tubular member **77** and include a series of printed bands that are preferably of a color or pattern contrasting with that of the tubular member **77**, and which extend from **160** cm (the first or distal end **62**) to the **166** cm mark (second or proximal end **61**), as measured from the distal tip of the catheter. The first end **62** (160 cm) represents the point at which alignment with a corresponding proximal alignment mark **37** located on the wire guide, comprises the point of alignment **81** which indicates that uncoupling is imminent with further relative repositioning between the two devices **10,11**. Repositioning the proximal alignment mark **37** of the wire guide toward the second end mark **61** results in the two devices reaching the point of detachment **82** at which uncoupling takes place, the colored bands serving as warning that the uncoupling is imminent with further repositioning. In the embodiment of **FIG. 4**, the proximal indicia **21** comprise a continuous band of contrasting coloration extending from 160 to 166 cm. As noted, the location of the proximal indicia is not particularly critical, but it is preferably configured such that it remains visible to the operator during a typical procedure. The band **35** can include a gradation of colors, (e.g., yellow to orange to red) to indicate the relative proximity to the point of detachment **82**. In the illustrative embodiment, the 166 cm mark at the proximal end of the indicia band **35** lies proximate the distal end of an optional proximal side access port **20**, which comprises an entry point for a second wire guide into the passageway **27**, the technique therefor being discussed below. For non-biliary applications, such as for vascular, pulmonary, or urological procedures, etc., any proximal indicia **21** most likely would be located at a different lengths from the distal tip of the catheter, one appropriately correlated with the distance required to access the work site. The length of the first device indicia **35** (6 cm) preferably corresponds with the length of the coupling region **14** (shown in **FIG. 5**).

[**0099**] As noted above, the 160-166 cm area of indicia **35** of the proximal indica system **21** advantageously provides a location on the tubular member **77** that will most always be

external to the patient and endoscope accessory channel such that it can be viewed by the clinician during the procedure. In the illustrative embodiment, the second alignment point **37** of the wire guide is indicated by a color change between the distal portion **60**, which includes helical striping characteristic of the METRO® Wire Guide (Wilson-Cook Medical, Inc.), and the proximal portion **59**, which comprises solid coloration, such as a section of shrink wrap or coating of a different color and/or pattern that visually contrasts with the distal portion **60** and/or intermediate portion **97** such that the distal 160 cm of the illustrative wire guide are distinct from and different in appearance from the proximal 25 cm. Alternatively, a contrasting color or ink or suitable material can be applied to the outer surface of the wire guide **11**, or a single band can be affixed about the junction **37** between the distal **60** and proximal **59** portions at an appropriate location to establish the point of detachment **82** which occurs by alignment with point **61** of the first device **10**. The second alignment point **37** is located on the wire guide **11** such that when it is aligned with the distal end **62** of the proximal indicia **21**, the distal end **25** of the wire guide is aligned with the distal end **12** of the first device **10**/tubular member **77**. Alternatively, the wire guide could include a single, narrow marking at the second alignment point **37**, or multiple markings, e.g., corresponding to both the proximal and distal ends **61**,**62** of the proximal indicia **21**. The proximal indicia **21** of the wire guide **11** and catheter **10** comprise any suitable means of providing a visual indicator, such as shrink wrap, ink, bands, surface etching or other treatment, etc.

[**0100**] A third type of alignment **83** is depicted in **FIGS. 26***a* and **26***b* in which the first and second endoscopic alignment indicators **84**,**85** are located about the intermediate portions of the first elongate medical device **10** (or second catheter, etc.) and wire guide **11**, respectively, in a location such that when the distal portions thereof are advanced within the work site **41**, the first and second indicators **84**,**85** are typically disposed within the viewable area **86** between the Papilla of Vater **40** and the distal end **87** of the accessory channel. This allows the operator to monitor the relative alignment of both to determine when uncoupling has occurred within the duct **41** (biliary system). In the illustrative example, the distal ends of the wire guide and first catheter member (not shown) have both traversed the Papilla of Vater **40**, and entered the bile duct **41**. An optional marking **29** at 10 cm (depicted in **FIG. 4** as a pair of printed bands) can be included on the first elongate medical device **10**, which is viewable as the device is being introduced into the duct **41**. The 10 cm mark **29** can be used for guidance to indicate that the first device **10** has been advanced a minimally 'safe' or sufficient distance into the duct, this occurring once the 10 cm mark **29** has disappeared from view, as shown in **FIG. 26***a-b*. At this point, the endoscopic alignment indicators **84**,**85** are normally located within the viewable area **86**. In **FIG. 26***a*, the first endoscopic alignment indicator **84** of the catheter is located proximal to the corresponding second endoscopic (wire guide) indicator **85**, indicating that the wire guide **11** is fully coupled to the first device **10** (i.e., completely traversing the coupling region). In the illustrative method, the operator utilizes the intermediate system of indicia **83** to determine when uncoupling of the devices **10**,**11** has occurred by advancing the first device **10** relative to the stationary wire guide **11** (which typically is locked down or secured against movement to maintain access within the duct), as shown in **FIG. 26***b*. As the two indicators **84**,**85** become aligned, the distal end of the wire guide exits the proximal end of the coupling region or side access port (not shown) and uncoupling or disengagement takes place. As a further endoscopic indicator to prevent loss of wire guide access out of the duct during uncoupling, the distal portion **60** (e.g., the distal 6 cm) of the wire guide **11** can comprise a different coloration, such as black, so that it contrasts with the intermediate portion **97** (depicted in **FIG. 7**). When the physician sees the black portion of the wire guide emerging from the papilla, the wire should be advanced back into the duct to minimize the risk of having to recannulate. If uncoupling has yet to take place and the distal black portion **60** of the wire guide is visible endoscopically, then both the wire guide **11** and tubular member **77** should be advanced further into the duct so that uncoupling can safely take place without risking loss of access.

[**0101**] An example of a non-visual system of alignment is depicted in **FIG. 40** in which the wire guide **11** includes a surface irregularity **160**, such as the illustrative bead, that is configured such that when it passes through the second end **75** of the coupling region **14**, e.g., through the side access port **15**, the operator feels or senses the contact between them, thus indicating that uncoupling is imminent with further repositioning. The illustrative side access port **15** is configured to include a flexible skirt **158** that includes an opening **159** sized to allow free passage of the wire guide **11**, but causing temporary resistance as the bead **160** passes therethrough. Furthermore, the skirt portion **158** can advantageously act as a seal to help prevent leakage of bile, blood, and air into the passageway of the tubular member. Other possibly surface irregularities include ridges, bumps, teeth, indentations, or a roughened portion that along with an appropriately configured side access port **15** or coupling region **14**, provide tactile feedback to the operator and thus, guidance to the state of alignment and engagement between the two devices.

[**0102**] Endoscopic devices used to perform medical procedures within the biliary system are typically divided into what could be called 'primary access devices', which typically comprise the initial device used in the procedure to cannulate the Spincter of Oddi and access the duct, and 'secondary access devices' for which the primary access device is exchanged to perform one or more operations within the work site. Examples of primary access devices of the present invention include sphincterotomes for ablating the sphincter to enlarge the opening to the duct (depicted in **FIGS. 10-11**), needles knives (not shown), which are also used to cut the sphincter, and ERCP catheters (**FIGS. 4-5**), which are adapted to infuse contrast media into the duct for radiographic imaging. Sphincterotomes and needles knives may also be configured to perform dual or multiple functions or operations, such as the infusion of contrast media and other agents. Some sphinctertomes include balloon used for sweeping the duct to remove calculi or stones lodged therein. Other devices, such as extraction balloons, may be used as both primary and secondary access devices. In pancreatobiliary procedures, primary access devices are exchanged for secondary access devices that are typically configured to perform a therapeutic function, such as to extract or crush stones, sample tissue, deliver radiation or light therapy, dilate or stent strictures (e.g., tumors), or place stents for drainage. If the secondary access device represents the last device used in a particular procedure, it need not be

adapted for remote uncoupling, although it preferably would include at least a distal coupling region so the device can be advanced over a short wire without requiring an extension being added thereto. Generally speaking, virtually any secondary access device (extraction, dilation, or phototherapy balloons, dilator, forceps, brush, stent delivery catheter, brachytherapy catheter, lithotriptor, basket, snare, etc.) that is normally introduced into the biliary system over a wire can be adapted for remote uncoupling by the addition of a suitable coupling region within the distal portion of the device and preferably, but not necessarily, at least one of the three aforementioned systems of indicia to provide positive confirmation of uncoupling and relative alignment of the devices.

[0103] An exemplary method of using a primary access device (first elongate medical device **10**), a wire guide **11**, and a secondary access device (third elongated medical device **44**) of the present invention to access and perform a medical operation in a work site **41** is depicted in **FIGS. 9***a-f*. The initial steps of the illustrative method include a standard endoscopic technique for accessing the biliary duct **41** to perform diagnostic and therapeutic procedures. **FIG. 9***a* shows a duodenoscope **38** that has been introduced via the oral cavity into the duodenum **39** to visualize the Papilla of Vater **40** and Sphincter of Oddi, which lie at the opening to the common bile duct **41** and the pancreatic duct. In the exemplary method, a dilator catheter **88** and wire guide **11** are advanced from the accessory channel of the scope **38** to cannulate a stricture **42** within the work site **41** (duct). It is general physician preference that determines whether the wire guide **11** is advanced past the tip of the primary access device **10** to assist in cannulation or whether the distal end **25** of the wire guide is within the passageway **27** during this part of the procedure. As depicted in **FIG. 9***b*, the dilator catheter **10** (or other secondary access device) is advanced over the wire guide **11** with the proximal portion of the wire guide exiting the side access port **15** and extending through the channel alongside the catheter so that both separately exit the accessory channel of the scope as depicted in **FIG. 12**. For applications where the size of the scope channel is restricted or other applications where there is limited room to accommodate both devices side by side, the catheter can be modified to allow for the wire guide to lie alongside without increasing the overall diameter. This can be done by forming an open channel (preferably one that would not capture the wire) or creating a flattened longitudinal portion along the length of the catheter (not shown).

[0104] Still referring to **FIG. 12**, the proximal portion **59** of the wire guide **11** is typically, but not necessarily, secured in place once the distal end **25** thereof has been advanced to the desired position within the work site **41**. The illustrative wire guide holder **50** represents an improvement over prior art devices in that it is configured to be partially inserted into or over the opening **52** of the access port **51** to the accessory channel and provide a seal, rather than being secured elsewhere on the scope. The holder **50** further includes an optional integrated sealing element **65** having one or more types of seals, including duckbill, membrane with slit (e.g., polystyrene, silicone, or another compliant polymer material), foam seal with small central aperture (e.g., silicon, polyurethane, etc.), or other designs having the ability to seal around the catheter and wire guide to prevent any proximally migrating fluid from exiting the channel. The wire guide **11** is locked in place by interweaving it through a first series of spaces **53** (or channels, grooves, slots, etc) between spaced elements located along one side of a locking portion **66** of the device, such as the illustrative curved 'spine', using an alternating under/over manner as depicted. The illustrative holder includes three slots **53** or spaces on the first side and a second series of three slots **54** or spaces on the opposite side of the locking portion **66** to accommodate a second wire, if one is necessary for the procedure.

[0105] Unlike other wire guide exchange procedures where the proximal end of the wire guide is well out of the way of the physician, the short wires typically used in the illustrative remote uncoupling or ultra-short wire techniques usually result in the proximal end of the wire guide being within the physician's working area so that access thereto is readily available for introducing secondary devices to the work site. While the illustrative holder is configured to direct the proximal end portion of the wire guide downward and out of the way of the physician, the proximal end, when unsecured to feed another device over the wire, may deflect back up into the working area around the access port of the scope and can interfere with the physician during the procedure. To help alleviate this problem, **FIG. 7** depicts a wire guide **11** in which the proximal end portion **59** thereof is oriented at an angle **79** with respect to the distal and intermediate portions of the wire so that the proximal end **58**/proximal end portion **59** is typically oriented down and away from the operator (when rotated as such) and thus, out of the working area surrounding the access port of the endoscope while still allowing the physician to access the proximal end for the advancing the next device. In the illustrative embodiment, which comprises an 185 cm nitinol core wire guide **11** in which approximately 40-45 cm thereof typically is extending proximally out of the scope as the third elongate medical device is being advanced thereover, the bend **80** or point of deflection is preferably located about 20-30 cm from the proximal end, although the useful range may be anywhere from 0-50 cm. The useful angle **79** of deflection depends on physician preference, the configuration of the scope and wire guide holder, and other factors, but is generally about 30-120° for endoscopic procedures with a more preferred range of 45-90° for the illustrative embodiment. To create the bend **80** in a nitinol wire guide **11**, the material can either be heat set or mechanically overstressed ('cold working') to achieve the desired angle **79** of deflection and radius of the bend **80** (e.g., small, relatively acute bend or a large, more gradual or rounded bend).

[0106] Referring now to **FIG. 9***c*, once the wire guide has been advanced to the desired location within the work site, the catheter is advanced or drawn back over the wire guide to position it for performing the intended operation. In the illustrative method, this involves the injection of contrast media **43** into the duct **41** to visualize the obstruction, which comprises a stricture **42** in this particular instance. Another common alternative approach to diagnosing potential obstructions in the ducts would be to initially introduce a sphincterotome **32 (FIG. 10)** to inject contrast media. **43**. If an obstruction is found, such as a stone, the sphincter might be ablated and a second device, such as a basket or balloon, is introduced over the original wire guide to extract the stone from the duct. A variety of other treatment possibilities exist and thus, it should be understood that the nature and sequence of the devices used is not critical to the present invention.

[0107] Once the initial operation has been concluded, the first elongate device **10** can be removed from the duct **41**. As depicted in **FIG. 9***d,* the operator can conduct a device IDE by repositioning the distal ends of the ERCP catheter and wire guide **12,25** toward one another by advancing the catheter (as depicted), or preform a wire guide IDE by unlocking the wire guide **11** from the wire guide holder and drawing it back until the distal end **25** disengages from the catheter. Alternatively, the clinician can disengage or uncouple the device and wire guide **10,11** by moving both devices simultaneously until the wire guide exits the coupling region, typically keeping them within the work site **41** while uncoupling takes place. As discussed earlier, imageable indicia **18,26** on the distal portion **13** of the catheter **10** and the distal end **25** of the wire guide **11**, respectively, are utilized to confirm under fluoroscopy that disengagement or uncoupling has occurred, as shown in **FIG. 9***e*. The proximal indicia **21**, depicted in **FIGS. 4 and 8**, and/or intermediate indicia **83** (**FIGS. 26***a-b*) may also be utilized to provide confirmation that uncoupling has taken place within the work site. This optional step is shown in **FIG. 12** in which the wire guide **11** is in the locked position **161** within the illustrative wire guide holder **50**, which is attached about the opening **52** of the biopsy port of the scope (over the rim of the port and/or inserted therein), is subsequently disengaged and placed in the unlocked position **162** adjacent the primary access device **10** so that the proximal indicia **21** of the two devices **10,11** can be aligned. As long as the proximal mark **37** of the wire guide **11** remains distal of the alignment mark **81** of the primary access device **10**, the operator knows that distal tip of the wire guide is still protruding from the distal end of the catheter within the duct (not shown). When the wire guide **11** is withdrawn (or primary device **10** advanced) such that the two marks **37,81** are in alignment, the operator knows the distal ends **12,25** of the two devices **10,11** are generally aligned within the duct. As the operator continues to draw back the wire guide **11** or advance the catheter **10**, the alignment mark **37** becomes aligned with the disengagement mark **82**, which in the illustrative embodiment is indicative that the distal end of the wire guide has pulled completely out of the passageway or coupling area such that the two devices are uncoupled within the duct.

[0108] Once uncoupling has taken place, either device **10,11** becomes available as a conduit for introduction of a third elongate medical device to the work site. In the illustrative method depicted, the third elongate device **44** comprises a dilation catheter **88** (**FIG. 9***f*) that is introduced over the wire guide **11** by feeding the back end **58** of the wire guide **11** (not shown) into the distal opening **19** of the dilation catheter **88** and out of the side access port **15**, then advancing the dilation catheter **88** into the accessory channel of the scope, over the wire, and on into the duct **41**. Typically, the operator would choose to remove the first device **10**, if no longer needed, before introducing the third device **44**. This is done simply by having the operator pull the catheter out of the duct and scope channel in one continuous motion while maintaining the wire guide in position (e.g., such as locked within the wire guide holder **50** of **FIG. 12**). Once the first device **10** is removed and the third device **44** is advanced to the work site, the second medical operation (e.g., dilation of the stricture) can be performed. If another operation is required, a third catheter-type device (fourth elongate medical device) can be advanced over the original wire guide **11** and so on.

[0109] As noted above, the present system of introducing and exchanging devices over a wire guide is adaptable such that a long wire guide can be introduced through a suitably configured medical device that has been introduced using the ultra-short wire method. In other instances, it may be desirable to convert an indwelling ultra-short wire to a longer wire for use with a non-compatible device. **FIG. 13** depicts a wire guide extender **56** for use with the present system to accommodate an external exchange with either a conventional medical device ('long wire') lacking the side access port for intraductal exchange, or conventional rapid exchange devices in which a somewhat longer external exchange (e.g., 30 cm) is required. In the illustrative system, the wire guide **11** includes a coupling mechanism **55**, such as a thread or wire loop, on the proximal end **58** that is configured to engage with a second coupler **57**, such as the illustrative hook, located on the distal end of the wire guide extender **56**. This effectively extends the length of the wire guide so that a conventional over-the-wire exchange can take place in the event that a particular device not designed for ultra-short wire exchange is to be used with the present system. One skilled in the art would readily appreciate the various types of coupling mechanisms that would be suitable to accomplish the extension of the wire guide for purposes of an exchange. They include locking or screw mechanisms, sheaths, bands, etc. that permit the two portions **11,56** to be joined temporarily or permanently. Another option is to use an adhesive strip or similar device to attach the wire guide **11** and extender **56** to one another.

[0110] The illustrative system of devices that allow for uncoupling within the work site and elimination of the external exchange over the wire can also be adapted for the introduction of second wire guide via an indwelling, uncoupled catheter into the work site, after placement of the first wire guide. **FIG. 10** depicts catheter **10** that includes a proximal access port **20** (third opening) located within the proximal portion of the catheter at a point that typically lies outside of the patient during a procedure (approximately 166 cm in the illustrative biliary device example). The proximal side access port **20** may include an optional sleeve cover that slides over and closes the access port when it is not in use.

[0111] To introduce a second wire **46**, the illustrative sphincterotome **32**, once disconnected from the first wire guide **11**, is not removed from the patient as in the method depicted in **FIGS. 9***a-f*. Rather, the tip of the second wire guide **46** (third elongate medical device **44**) is fed into the wire guide passageway **27** via the proximal opening **20** and advanced through the scope and into the duct **41**. In the example of **FIG. 11**, the first wire guide **11** resides in a first branch **48** of a bifurcation, such as where the common bile duct **41** branches into the two lobes of the liver. The sphincterotome **32** carrying the second wire guide can be rotated and deflected by the physician, by using the handle to pull back the cutting wire, to advantageously direct the advancing second wire guide into the opposite branch **49** such that each branch is now cannulated by the wire guide **46**. A sphincterotome **32** having a handle that provides axial rotation of the catheter body is preferable for orienting the distal cutting portion **33** into or toward the opposite duct for placement of the wire. Once the second wire **46** is in its desire location, it can be locked in place (e.g., using the second series of slots **54** of the illustrative wire holder **50** of **FIG. 12**). After the sphincterotome or other primary access device **10** has been removed from the second wire **46**, both

wires **11,46** are available for subsequent placement or introduction of additional devices, such as stents to restore or improve patency of the ducts.

[**0112**] Removal of the original catheter device **10** from the short second wire **46** requires that either an exchange must take place, such as by adding the wire guide extender **56** of **FIG. 13** to perform a long-wire exchange; or the catheter may be peeled off of the wire **46** if the portion of the wire guide lumen **27** that lies between the distal (side) and proximal side access ports **15,20** is configured to allow wire to laterally exit the passageway. This can be accomplished in a number of well-known ways including forming a weakness in the wall, such as making a score line, slit **67** or other pre-weakened area inside of the wall, such as that depicted in **FIG. 15**, or intermittent perforations formed partially or completely through the wall to weaken it longitudinally. Alternatively, the tubular member can comprise an intact catheter wall that is configured to fail when sufficient lateral pressure is exerted by the wire guide residing in the passageway. One method of doing this is to make the wall **68** adjacent the wire guide lumen **27** sufficiently thin **(FIG. 16)** and and/or of a suitable polymer such that when lateral force is applied against the catheter, the wire guide **46** readily splits or tears through the thin wall **68** as the catheter is being withdrawn from the patient. A material with a suitable molecular structure to encourage splitting, such as an isotropically oriented polymer, may be used or the polymer may be treated in some manner to encourage splittability. The entire catheter wall can be configured to facilitate splittability, or the splittable portion may be limited to one specific region along the circumference thereof, such as including a longitudinal coextrusion of a second, lower durometer extending to the outside of the wire guide lumen. Rather than (or in addition to) configuring the wall to increase splittability, a tab or other element can be attached or integrated into the catheter to facilitate a manual split to remove the wire guide. A sharp tool or similar device represents yet another alternative method of accessing the guide wire lumen to separate the catheter from the wire. Another option is to extend the groove completely through the wall to form a narrow, open channel or a sealable or locking seam such that the two edges either are biased against one another or interlock by virtue of their complimentary structure. The seam is designed to split open or unlock when the lateral force supplied by pulling the wire guide thereagainst is sufficient to force it open.

[**0113**] Returning now to the IDE method depicted in **FIGS. 9***a-f,* it has been noted that the friction encountered when introducing a primary access device and a coupled wire guide through the accessory channel of an endoscope can, in some instances, cause premature disengagement of the two device before they reach the work site. **FIGS. 23-25** depict different embodiments of an elongate engagement member **89** which is configured to releasably secure the wire guide **11** to the tubular member **77**, such that unwanted disengagement or relative movement does not occur as the devices are being introduced or manipulated within the patient. In **FIG. 23**, the elongate engagement member comprises a wire stop member **90** preferably made of a flexible polymeric material with adequate column strength, such as nylon, which is similar in configuration to a standard pusher member. Preferably, the wire stop member **90** comprises a diameter (e.g., 0.035") that substantially fills the inner diameter of the passageway **27** of the tubular member **77** such that when fully advanced to a point distal to the side access port **15** where the wire guide **11** enters the coupling region **14** (passageway **31**), the wire stop member contacts and wedges the wire guide **11** against the inner wall of the passageway, thereby substantially preventing longitudinal movement of the wire guide **11** relative to the tubular member **77**. **FIG. 23** illustrates the wire stop member **90** disposed within a single-lumen tubular member **77**; however, it may be used in multi-lumen device (e.g., a sphincterotome) as well. **FIG. 24** depicts the proximal hub **92** (a male luer fitting) of the wire stop member **90** in a retracted position **94** in which the wire stop member **90** is not sufficiently advanced to engage and lock or wedge the wire guide **11** within the passageway **27** a region or point **91** just distal to the side access port **15**. To do so, the proximal hub **92** is advanced to a forward position **95** in which the hub **92** contacts and engages the proximal (female) fitting **93** located at the proximal access port **23** of the primary access device **10**. Once the operator wishes to reposition the two devices **10,11** relative to one another, the proximal (male) hub **92** is disengaged from the female proximal hub **93** and drawn back until the wire guide **11** is released. Preferably, but not necessarily, the wire stop member **90** is removable from the passageway **27** such that agents, additional wire guides, etc., may be introduced therethrough. An elongate engagement member **89** is typically not used with a secondary access device insomuch that the wire is already indwelling within the work site and the need to secure the wire guide to the device is unnecessary.

[**0114**] A second embodiment of an elongate engagement member **89**, depicted in **FIG. 25**, comprises a thread-like snare member **96** made of suture, wire, cable, or other strand of material which loops around, ensnares, or otherwise releasably engages the wire guide within the passageway **27**. The snare member **96** can be attached to an actuating portion of the handle to give the operator sufficient control over its operation. When the operator wishes to disengage the wire guide **11** from the tubular member **77**, tension is released on the snare member **96**, or it can be cut or one end released so that it can be withdrawn from the passageway **27**. Alternatively, the snare member **96** can be disposed on the outside of the tubular member **77** to releasably engage and secure the wire guide **11**. The depicted embodiments represent but two possible types of devices adapted for securing the first elongate medical device **10** and wire guide **11** so that they can be co-introduced through a channel without disengaging therein.

[**0115**] The elongate engagement member **89** embodiments of **FIGS. 31 and 32** also include the coupling region **14** of the device **10** that may be configured to be partially retractable back into the secondary passageway **115**. This action creates a frictional engagement with the wire guide such that the elongate engagement member **89** further acts as a stop to prevent the wire guide **11** from sliding freely within the coupling region **14**.

[**0116**] The present invention and method includes using devices in procedures where once the primary access device is used within the work site, a secondary access device is introduced over the guiding device (wire guide) which has been uncoupled from the primary device within the work site. In the biliary tree, a number of possible devices may be introduced to perform a variety of medical procedures, a few selected examples of which are depicted in **FIGS. 9F, 14,**

17, **19-22**, **27-28**, **39**, **41-44**, **51**, and **53**. The exemplary devices are certainly not representative of all secondary access devices appropriate for use in the bilary tree, nor is their use particularly limited to being a secondary device used following a primary device. The illustrative devices depict some of the general types of medical devices used endoscopically in the biliary tree, as well as other non-biliary and non-endoscopic procedures performed elsewhere in the body.

[**0117**] **FIG. 17** depicts a system for delivering a biliary or pancreatic drainage stent **69** mounted on a delivery catheter **110** (elongate medical device **10**) of the present invention. The illustrative COTTON-LEUNG® Biliary Stent (Wilson-Cook, Medical Inc.) is mounted on an OASIS® One Action Stent Delivery System (Wilson-Cook Medical, Inc.), modified for IDE, which extends through the internal lumen **72** of the stent **69**, which is slidably mounted thereover (when used with a pusher member **101** (see **FIGS. 29***a-c*). It should be noted that the illustrative stent delivery catheter **110** is configured to accept different kinds of tubular drainage stents in addition to the type shown. The coupling portion **14** of the delivery catheter **110** comprises the passageway **27** between the distal opening **19** and the side access port **15**, which is located 1.5-2.0 cm from the distal tip. A proximal marking **18**, such as the illustrative iridium band, is located at about 1 cm, just distal to the access port **15**. The wire guide **11** exits the side access port **15** at a point distal to the distal end **71** of the stent **69** to advantageously provide a means for withdrawing the stent **69** along with the delivery catheter **110**, which greatly assists in the ability to reposition the stent within the duct. When the catheter **10** and wire guide **11** are withdrawn together relative to the stent (which is held stationary by the pusher member), the distal edge **71** of the stent **69**, which is slidably positioned over the catheter, lodges in a triangular wedge point **70** formed by the junction of the delivery catheter and the wire exiting therefrom. Thus, the stent **69** is pulled backward along with the delivery catheter, providing the clinician with a simple and reliable means to pull the stent partially out of the duct so that the proximal anchor flaps **73** can extend outside of the duct, if so desired. Once positioned at the desired location, the wire guide **11** and delivery catheter **110** are uncoupled and the latter is withdrawn from the lumen **72** of the stent **69**. In delivery systems in which the wire guide **11** extends through the lumen **72** of the stent **69**, pulling back on the delivery catheter **110** would not allow the clinician to pull the stent back with it without an additional mechanism to releasably couple the stent to the delivery catheter. It should be noted that this method can be readily adapted for other stent designs as well, particularly other non-expandable tubular stents and those having pusher members.

[**0118**] The illustrative stent delivery system of **FIG. 17** is particularly well-adapted for placement of multiple stents as depicted in the method of **FIGS. 29***a-e,* insomuch that remote uncoupling of the wire guide **11** and apparatus **10** can be performed within the duct, unlike previous biliary stent delivery systems, thereby eliminating the need for recannulating the papilla for each stent placed. As depicted in **FIG. 29***a,* the inner delivery member **110**, which is coupled to the wire guide **11**, is advanced out of the endoscope **38**, through the ampullary orifice **40** and into the duct **41**. The wire guide **11** does not extend through the lumen of the stent **69** and pusher member, which is not yet shown. In **FIG. 29***b,* the pusher member **101** urges the stent over the inner member **110** until the distal end **71** thereof reaches the junction **70** formed where the wire guide **11** exits the side access port (alternatively, the inner member **110** and stent **69** can be pulled back while the pusher member **101** contacts the stent and causes it to advance further up over the inner member **110**). As noted above, the junction **70** can be used to contact the distal end **71** of the stent and pull back or reposition the stent **69**, such as when it had been advanced too far into the duct for ideal deployment. Once the stent **69** is in the proper position for deployment, as depicted in **FIG. 29***c,* the inner member **110** is advanced further into the duct **41** so that there is sufficient room for the uncoupling procedure to take place. The wire guide **11** is unlocked from the wire guide holder **50** (see **FIG. 12**) and pulled back until it exits the side access port **15**, as depicted in **FIG. 29***d.* The inner member **110** is then withdrawn through the stent **69**, along with the pusher member **101**, and removed from the channel of the endoscope. The wire guide **11** is then re-advanced further into the duct to serve as a conduit for the next stent delivery system, shown in **FIG. 29***e,* such that a second stent **109** can be deployed alongside the first in the manner shown in **FIGS. 29***a-d.* Subsequent deployments of additional stents can be also be made using the same technique over the original wire guide.

[**0119**] Other stent or prosthesis delivery systems configured for use with the present invention are depicted in **FIGS. 22, 27**, and **39**. **FIG. 22** depicts a delivery system **99** for a self-expanding prosthesis **98**, which could include a self-expanding stent, such as the Wilson-Cook ZILVER™ Biliary Self-Expanding Stent or any nitinol, stainless steel, or other self-expanding stent; artificial valve (e.g., venous, heart, pulmonary, etc.) prosthesis, vessel occluder, filter, embolic protection device, shunt, stent graft, etc. The illustrative apparatus comprises an inner member (elongate medical device **10**) on which the prosthesis **98** is mounted and an outer member **100** or sheath which constrains the self-expanding prosthesis **98** until deployment. The side access port **15** is located about 3 cm from the distal tip **12** of the inner member **10** with the coupling region **14** being completely distal to the prosthesis **98**.

[**0120**] An alternative system for deploying a self-expanding prosthesis is depicted in **FIG. 39** which includes a series of corresponding slots in the inner and outer members **10**,**100** to allow for relative repositioning during deployment (the sheath **100** typically being drawn back while the inner member **10** of the delivery system is maintained in position). This permits the coupling region **14** to extend through the prosthesis **98** and allow the wire guide **11** to exit the side access port **15** proximal to the prosthesis **98**, which would allow the wire guide to reside inside and be deployed inside prosthesis **98**, and as a result, less chance of losing access to the work site. This may be especially advantageous in deployment of stents, other prostheses, and other ancillary devices, such as dilation balloons, within the vascular system in that recannulation through the deployed stent may be problematic, possibly leading to complications such as dislodgement or catching on the deployed stent, dislodgement of plaque, etc. With regard to placement of artificial venous and other types of artificial valves, maintaining wire guide access through the valve may be particularly advantageous in that recannulation through the leaflets or valve structure to deploy additional valves or introduce a seating balloon to fully expand the valve support frame against the walls of the

vessel may prove particularly difficult, possibly leading to damage of delicate leaf structure and compromise of valve function.

[0121] **FIG. 27** depicts an endoscopic biliary stent **69** and pusher apparatus **101** (typically 5.0-7.0 FR) which is configured for ultra-short wire and rapid exchange use. It primarily differs from the embodiment of **FIG. 17** in that it lacks the inner member. Both the stent **69** and pusher member **101** (the elongate medical device **10** in this particular embodiment) are introduced through an outer introducer member **100**, where the distal end **12** of the pusher apparatus **101**, which includes the coupling region **14** about its distal portion **13**, urges the stent forward for deployment within the duct. The side access port **15** is located about 6 cm from the distal end **12** of the pusher member **101** (elongate medical device **10**) such that the wire guide traverses the passageway of the stent **69**.

[0122] **FIGS. 41-42** depict another embodiment in which the stent **69** comprises a pigtail drainage stent **126**, such as the illustrative naso-biliary drainage stent, that includes a curved anchor portion **127** in the deployed configuration **128** (**FIG. 41**) that is configured to assume a straightened configuration **129** when placed over a wire guide **11** for introduction into the bile duct, as shown in **FIG. 42**. Preferably, but not necessarily, the drainage holes **130** disposed along the distal portion of the stent **126** are sized such that the wire guide **11** cannot readily exit therethrough (e.g., 0.025"), whereas the side access port **15** is sized to easily accommodate the exiting wire guide (e.g., 0.035" or larger). In the illustrative naso-biliary embodiment, there are five drainage holes distributed about 6 mm apart along the distal portion **13** distal to the side access port **15** and marker band **18**. In this particular embodiment, there is a series of optional drainage holes **130** proximal to the side access port **15** as well. The spacing of the drainage holes can vary according to the diameter of the curl, generally ranging from 5 mm to 1 cm or more. As the wire guide **11** is repositioned relative to the stent **126** to perform an intraductal exchange, the anchoring portion **127** recoils into its intended shape when the wire guide is no longer inside the coupling region passageway **31**. The illustrative embodiment could also be adapted for use as a naso-pancreatic drainage stent, ureteral or urethral stent, or other stent having one or more curved or pigtailed end portions and various configurations of drainage holes. The illustrative embodiment of **FIG. 41** further includes an intermediate curved portion that allows the stent to better conform with the anatomy of the pancreatobiliary tract and duodenum into which it is placed.

[0123] Another embodiment of naso-biliary and naso-pancreatic drains is depicted in **FIG. 43** that is similar to the embodiment of **FIGS. 41-42**, except that it includes a pair of distal anchoring flaps **180** and lacks the pigtail anchoring portion. Furthermore, the side access port is preferably located closer to the distal end **12** of the device (e.g., about 2 cm vs. about 6 cm for the pigtail embodiment). Typically naso-biliary drains are 5-10 FR in diameter while the naso-pancreatic drains are 5-7 FR. Both the pigtail and non-pigtail drain embodiments may advantageously include a stiffening stylet (depicted in **FIG. 43**) that extends to about the side access port **15** and provides pushability, as well as straightening out a loop or bend, if present, located proximal to the side access port. Such a bend may allow the device to conform to the anatomy of the patient, such as to better traverse the contours of the duodenum. An example of the bend or curved portion **172** is shown in **FIG. 41**.

[0124] **FIGS. 19-20** depict balloon **47** embodiments of the present invention that are adapted for short wire use. **FIG. 19** comprises a dilation balloon **47** (a modified QUANTUM™ Biliary Balloon, Wilson-Cook Medical, Inc.), which is made of a non-compliant material (e.g., PET) such that balloon member **102** can be inflated to a predetermined diameter to dilate a stricture within the duct. **FIG. 20** comprises an extraction balloon **47**, such as a modified TRI-EX™ Triple Lumen Extraction Balloon (Wilson-Cook Medical, Inc.), which comprises a non-compliant material (latex, silicone, etc.) which is adapted for sweeping the duct of material, such as stones, sludge, etc. Both embodiments include a side access port **15** about 6 cm from the distal end **12** of the catheter **10** such that the coupling region **14** extends through the balloon member **102** and exits proximal thereto. The embodiment of **FIG. 20** further illustrates a removable stiffening stylet **103** that is maintained within the passageway **27** of the catheter member **10** to provide rigidity, especially across the side access port **15** (and optional proximal side access port, not shown) such that kinking is less likely to occur at that point. The stylet, preferably made of metal (e.g., stainless steel) or a relatively stiff plastic or other material, would not provide any engagement function similar to the distal wire lock **90** of **FIG. 23** in most applications since that would interfere with the ability to advance the device over the wire guide.

[0125] **FIG. 21** depicts a biopsy device **104** for collecting cells within the biliary tree. The illustrative embodiment, which comprises a modified CytoMAX II™ Double Lumen Biliary Brush (Wilson-Cook Medical, Inc.), includes a side access port **15** about 6 cm from the distal end **12** of the tubular portion **77** of the device **10** and a brush element **105** disposed about the distal end and extending beyond such that the coupling region **14** terminates proximal of the brush element **105**, the distal opening **19** for the wire guide **11** being disposed about the distal end of the tubular member **77** about the base of the brush element **105**. An alternative device for delivering a biopsy device **104** or other device within a work site is depicted in **FIG. 39**. The illustrative tubular member **77** includes a standard coupling region **14** about the distal end except that the passageway **27** of the tubular member, rather than communicating with the passageway **31** of the coupling region **14**, terminates about a ramped external opening **122** that is configured to accommodate a separate elongate medical device for introduction to the work site which is not directly coupled to the wire guide **11**. The illustrative biopsy device **104** can be advanced to gather a tissue sample, then withdrawn back into the passageway **27** and either removed from the patient with the introducing member **77**, or removed therefrom and a second medical device advanced into the passageway to perform a different procedure. In addition to the radiopaque marker band **18** to indicate the location of the second end of the coupling region **14**, the illustrative tubular member includes an additional marker **123** located about the ramped opening which provides additional guidance to the operator. The illustrative biopsy device is but one example of a device deliverable in the manner shown in **FIG. 39**.

[0126] Another secondary access device is depicted in **FIG. 38**, which comprises a brachytherapy or radioactive seed delivery catheter **106** which includes a passageway **27**

for the wire guide **11** (and which includes the coupling region **14**) and second, closed-ended passageway **107** for receiving a radioactive element **108**, such as a catheter, stylet, or individual radioactive seeds that are introduced thereinto. The brachytherapy device **106** is introduced over the wire guide **11** to the treatment site, where it is positioned for a period of time sufficient to deliver an effective therapeutic dose of radiation to adjacent tissue, such as a tumor within the biliary tree. Typically, the side access port **15** is located about 6 cm from the tip which is preferably made of a pliable, atraumatic polymer material. The second passageway is preferably located centrally so that radiation is dispersed evenly in all directions. As a result, the first wire guide passageway may either terminate distal thereto, about the side access port **15**, or be offset therefrom, at least becoming so at a point proximal to the side access port **15** and coupling region **14**.

[**0127**] **FIGS. 44-57** depict a series of non-biliary devices configured for introduction through the patient's mouth, rather than through the accessory channel of a duodenoscope, such as the aforementioned embodiments. Placement of the embodiments of **FIGS. 44-57** typically involves using an ultra-short wire guide **11** that is advanced to the treatment site by being coupled to the outside of an endoscope. The wire guide is then uncoupled from the scope and locked in place to serve as a pathway for the introduction of other devices, such as within the esophagus or elsewhere within the gastrointestinal tract. Optionally, the wire guide **11** (**FIG. 57**) can include a hydrophilic or otherwise lubricious coating or surface **173** (e.g., SLIP-COAT® Biopolymer, STS Biopolymers, Inc., Henrietta N.Y.) to facilitate the advancement of devices thereover after the wire guide has been placed. The coating is advantageously restricted to a portion of the wire guide **11**, such as the intermediate portion **97**, with the proximal portion **59** that extends out of the patient and is manipulated and locked by the operation (e.g., the proximal 10-15 cm) having a standard non-hydrophilic surface (e.g., PTFE) to make it easier to secure the wire guide in place. The distal portion **60** (e.g., 2-6 cm) of the wire guide may also be left uncoated to give the operator a better degree of control to help avoid accidental, premature uncoupling of the wire guide from the coupling region of the devices being advanced thereover. The lubricious intermediate portion **97** of the illustrative wire guide of **FIG. 57** is especially advantageous when used in the small or colon to allow the device to slide more easily therewithin, while still allowing the wire to be secured at each end by the bite block and distal loop **144**, respectively.

[**0128**] **FIG. 44** and **45** depict a dilator catheter **88** and wire guide **11** comprising a system for dilating strictures within the esophagus. The dilator **88** includes a system of scale indicia **133** located about the proximal portion of the tubular member. In the illustrative embodiment, which is about 75 cm in length, indicia are located to indicate the 40, 50, and 60 cm mark to help align the device with the indwelling wire guide **11**, which includes a similar series of indicia **134**, such as the illustrative bands that increase in number at each 10 cm interval to indicate the distance from a reference point. The alignment indicia **133**,**134** advantageously permit accurate positioning of the device at the treatment site, such as the GE (gastroesophageal) junction, a stricture, or other site that is to be dilated, irradiated, or otherwise treated, after the treatment site has been confirmed using the endoscope used to carry the wire guide thereto.

[**0129**] A method for introducing the wire guide **11** and dilator catheter **88** of **FIGS. 44 and 45** into the esophagus to perform a series of esophageal dilations using successively larger dilator catheters is depicted in **FIGS. 55***a-f*. The basic method can also be used for introducing other devices that are too large to be introduced through an accessory channel of an endoscope or where standard endoscopic placement techniques either are not appropriate or not possible. As shown in **FIG. 55***a,* the wire guide **11** is carried to the work site using an endoscope **38** and a wire guide carrying mechanism **174**, which in the illustrative embodiment comprises the endoscopic wire guide holder **140** depicted in **FIG. 48**, which resides within the accessory channel **165** of the scope and includes a mechanism to couple with the wire guide **11** via a distal loop **144** about the distal end **25** thereof. As shown, the endoscopic wire guide holder **140** comprises a catheter portion having a lateral recess **142** proximate the distal end **12** thereof and a longitudinal slidable pin member **141**, disposed within a passageway **145** in the shaft **146** of wire guide holder **140**, that is adapted to traverse the distal loop **144** of the wire guide. The pin member **141** is advanced to secure the loop **144** within the recess **142** to carry the wire guide **11**, which is at least substantially outside of the scope accessory channel **165**, down to the work site, where it is released by the operator by actuating the finger ring portion **148** of the handle **147** relative to the thumb ring **149** until the loop **144** slips off the retracting pin member **141**. When the pin **141** is fully advanced into a locking channel **143** that extends distally from the lateral recess **142**, the loop **144** is secured and cannot slip free. The endoscopic wire guide holder **140**, which is then withdrawn from the work site along with the endoscope, can either carry the wire guide **11** while partially extending from the accessory channel, or be withdrawn into the accessory channel **165** (as shown) such that the distal end **25** of the wire guide is pulled thereinto.

[**0130**] A second embodiment of a wire guide carrying mechanism **174** is depicted in **FIGS. 46-47** comprising a ring element **136** that attaches to the outside of the endoscope **38** about the distal end thereof using a friction fit, clamping mechanism, or some other well-known means, and is configured to releasably secure the wire guide **11** being carried to the work site. The wire guide **11** includes a detachable element **135**, such as the illustrative distal ball, which is crimped, glued, or otherwise fastened about the end **25** of the wire guide and designed to slide off or break apart with the application of a sufficient amount of pull force (e.g., 3 lbs.) and be safely passed through the gastrointestinal system or be absorbed thereby. The ball tip **135** is inserted into an open slot **137** in the ring **136** and then slipped laterally beneath a lip portion **138** and into a recess **139** that together, help secure the wire guide and allow it to be pulled along with the scope. With the ball **135** residing in the recess **139** formed along the distal edge of the ring, the wire guide **11** can be uncoupled from the scope **38** by pulling on the proximal portion of the wire guide while maintaining a counter force against the scope **38** to keep it in place. When the ball **135** is dislodged (**FIG. 45***a*), the wire guide **11** can slip under the lip portion **138** (**FIG. 47**) and the endoscope **38** can be withdrawn from the patient, leaving the wire guide in place.

[**0131**] Referring again to **FIG. 55***a,* the endoscope is typically positioned within the work site **41** just proximal to the specific site (sphincter, stricture, lesion, etc.) therein that

is to be treated. In the illustrative method, the scope **38** is advanced to the GE junction **156** while depth markings located about the proximal portion of the scope exiting the patient (not shown) provide the operator with the distance from the mouth to the treatment site. At this point, the distal end **25** of the wire guide **11** is also generally positioned at the GE junction **156** since it is engaged proximate the distal end of the scope **38**. The endoscope **38** and wire guide are advanced through the esophagus **155** and positioned at the GE junction **156**, where that distance is noted. The operator may advance the scope **38** 10 cm (or some other similar, predetermined distance), which places the distal end **25** well within the stomach **157** (about 10 cm past the GE junction **156**). Or, as depicted in **FIG. 55***b,* the operator may advance the wire guide holding device **140**, which may include proximal depth indicia as well, a similar distance beyond the scope **38** and into the stomach **157**. The wire guide **11** in the embodiments depicted in **FIGS. 45 and 50** include a reference mark **175** located 10 cm from the distal end **25** (or whatever distance the wire guide is to be advanced past the GE junction or other anatomical reference point). The wire guide **11** of the illustrative embodiment depicted in **FIG. 45** includes a series of proximal indicia **134** that can comprise varying numbers of markings at selected intervals thereal-ong (e.g., 30,35,40,45,50, and 55 cm from the reference mark **175**). In another embodiment depicted in **FIG. 50**, the wire guide includes five 5 cm bands **150** of different colors that span from the 30 cm mark to the 55 cm mark as measured from the reference mark **175** which is 10 cm from the tip **25**. The indicia **134** may further include 1 cm reference marks **177** (e.g., hash marks) within each colored band **150**. Preferably, the bands **150** of the embodiment of **FIG. 50** comprise colors that contrast with the adjacent band. For example, cool and warm colors may be advanta-geously placed adjacent one another to create a sequence such as yellow, green, red, blue, and then orange.

[0132] Once the wire guide **11** has been advanced 10 cm past the GE junction **156**, it is uncoupled from the wire guide carrying mechanism **174** and secured in place by some means such as using the illustrative bite block **151** depicted in **FIG. 52** with integral wire guide securing portion **154**, and which includes straps **153** that secure the bite block **151** around the patient's head. In addition to functioning as a mechanism **50** for securing the wire guide in place, it also maintains an open working area **152** through which the scope, wire guide **11**, and primary or secondary devices are passed to the work site.

[0133] In instances where a narrow stricture exists that cannot accommodate the scope without risking creating a tear in the esophagus (at least without being properly dilated beforehand), the wire guide holding device **140** advanta-geously provides a means to safely advance through and traverse the stricture to carry the wire therebeyond and serve as a pathway for advancing the dilators, the smallest of which may be less than the scope diameter.

[0134] Now referring to **FIG. 55***c,* the endoscope **38** and wire guide holding device **140** are typically withdrawn from the work site **41** such that the primary access device **10**, which in the illustrative method comprises a first dilator **167**, can be advanced over the wire guide **11** to perform a medical operation, as depicted in **FIG. 55***d.* To advance the first dilator **167**, the wire guide **11** is temporarily unlocked from the holding device so that the proximal end thereof can be threaded through the coupling region **14** of the dilator. Alternatively, the primary device **10** (e.g., dilator **167**) can be coupled to the wire guide **11** prior to the wire guide being advanced to the work site **41**. The illustrative dilator **167** includes optional radiopaque marker bands **18**,**132** located at the side access port **15** and distal edge of the widest portion of the device before the tapered end, respectively. While it is the GE junction that is established as the anatomical reference point to which the illustrative wire guide **11** and primary access device **10** are aligned, the region of the esophagus having the stricture to be dilated may lie any-where proximal to the GE junction. Reference to the GE junction is preferred to provide a consistent known distance within the stomach for uncoupling.

[0135] The dilator **167** (**FIG. 44**) also preferably includes a series of proximal indicia **133** as well that are aligned with the wire guide indicia **134** so that the operator can determine when a particular point along the dilator (e.g., distal end of the widest portion **132**, distal tip **12**, side access port **15**, etc.) has reached the GE junction, the tip of the wire guide, or some other reference point.

[0136] Once the first dilator **167** has been advanced past the esophageal stricture or the GE junction **156** as the first step of enlarging the opening thereof, the distal portion **13** is advanced fully into the stomach **157** of the patient so that uncoupling can occur, as depicted in **FIG. 55***e.* Typically, this is accomplished by advancing the side access port **15** past the distal end **25** of the wire guide **11**, which remains locked in place, until the distal end **25** thereof slides free of the coupling region **14**. As with the biliary techniques depicted in **FIGS. 9***a-f* and **29***a-e,* the uncoupled primary access device **10** is then removed from the patient and a secondary access device (third elongate medical device **44**) such as second (larger) dilator **168**, is introduced to the work site **41** as depicted in **FIG. 55***f.* Esophageal dilations typi-cally involve passage of a series of progressively larger dilators, although one or more of the smaller sizes may be skipped if resistance is not felt during the initial dilation.

[0137] An alternate embodiment of a dilator catheter **167** is shown in **FIG. 56** in which the side access port **15** is located on a proximally facing surface or plane **169** formed as the distal (larger) diameter portion **170** of the dilator transitions down to the smaller, proximal portion **171**. This advantageously eliminates having the wire guide **11** lying alongside the widest part of the dilator **167** during passage of both through the stricture. The illustrative stepped con-figuration can also be useful in other embodiments of the present invention to eliminate friction caused by a wire guide passing within a sheath or channel, such as within an endoscope.

[0138] The general method of **FIGS. 55***a-f* can also be adapted for placement of other devices outside of the endoscope, such as a photodynamic therapy (PDT) balloon **47**, depicted in **FIG. 51**, or an achalasia balloon **53**, depicted in **FIG. 53**. Both devices depicted are commercially avail-able from Wilson-Cook Medical, Inc. and shown herein as modified for ultra short wire delivery. Positioning of the PDT balloon **47** is performed by using the endoscope to locate the GE junction and place the wire guide **11** at a suitable, known distance therebeyond, such as 10 cm, that distance corresponding to the reference (or 'zero') mark **175** of the wire guide. In the illustrative embodiment of **FIGS.**

50-52, the wire guide includes colored bands **150** that correspond to those comprising the proximal indicia **133** of the PDT balloon catheter **47** such that when the colors are aligned **(FIG. 52)**, the reference point **176** of the device **10**, which in the case of the PDT balloon, is the distal edge of the light-emitting portion **178** of the balloon member **102**, is located at the GE junction. This places the light-emitting portion **178** at the optimal location to treat the disease (e.g., Barrett's esophagus). It should be noted that the colored bands **150** or other indicia **133,134** of the illustrative embodiments are configured for aligning the treatment device **10** with the wire guide **11** and thus, the site selected for treatment and may or may not have other functions such as to aid in the alignment of the tips **12,25** of the device with one another or with the side access port **15** to indicate that uncoupling is imminent. Separate indicia may be used for alignment relating to coupling and uncoupling. While the colored bands **150** of the wire guide **11** are configured to refer back to the reference mark **175** that corresponds (in this embodiment) to the GE junction, the colored bands **150** of the primary access device **10** are configured such that alignment with those of the wire guide places the device in the correct position for treating the disease. Thus, they are not necessarily (and usually are not) of the same reference scale.

[0139] **FIG. 53** depicts an embodiment in which the primary access device **10** comprises an achalasia balloon. With the treatment of achalasia differing in that the balloon is placed across the GE junction rather than proximal thereto, the reference point **176** that corresponds to the proximal reference indicia (not shown) and permits the device to be aligned with the GE junction, is located at the center of the balloon member **102** rather than the distal edge as in the PDT balloon.

[0140] The technique of dragging the wire guide outside of the scope to the work site, uncoupling it, and advancing a device thereover, is also applicable to a number a larger diameter catheters **(FIG. 54)**, such as feeding tubes (e.g., nasojejunal, nasoenteric, etc.) which are advanced via the mouth into the stomach or small intestines for placement. These catheters may advantageously include a stiffening stylet **103** in the passageway **27** to prevent the scope from dragging the catheter device **10** with it as it is being backed out of the work site, which in turn, could cause the wire guide **11**, which is typically locked in place, to pull out of the coupling region **14**. The stiffening stylet **103** is removed prior to or after the devices are uncoupled using radiographic, endoscopic, and/or proximally visible indicia located on the two devices **10,11**.

[0141] While the gastrointestinal tract may at present provide the most obvious anatomical sites for practicing the methods and techniques of the present invention, further changes in interventional medicine may bring about increasing opportunities where remote uncoupling and ultra-short wire techniques may offer a viable alternative to traditional rapid exchange or other current techniques. For example, many common urological procedures were preformed using wire guide exchange until the introduction of videoendoscopes ideal for urological use. This resulted in direct visualization becoming the standard methodology for manipulating and placing devices in the urological tract. Future developments and improvement in external visualization methodology may result in a return to wire guided procedures where remote uncoupling offers a true advantage to the urologist. Similar advancements in other specialties, especially in vascular and coronary medicine, may create situations where the potential benefits of remotely uncoupling may be realized.

[0142] Any other undisclosed or incidental details of the construction or composition of the various elements of the disclosed embodiment of the present invention or methods of their use are not believed to be critical to the achievement of the advantages of the present invention, so long as the elements possess the attributes needed for them to perform as disclosed. The selection of these and other details of construction are believed to be well within the ability of one of even rudimentary skills in this area, in view of the present disclosure. Illustrative embodiments of the present invention have been described in considerable detail for the purpose of disclosing a practical, operative structure whereby the invention may be practiced advantageously. The designs and methods described herein are intended to be exemplary only. The novel characteristics of the invention may be incorporated in other structural forms without departing from the spirit and scope of the invention. The invention encompasses embodiments both comprising and consisting of the elements and steps described with reference to the illustrative embodiments. Unless otherwise indicated, all ordinary words and terms used herein shall take their customary meaning as defined in The New Shorter Oxford English Dictionary, 1993 edition. All technical terms shall take on their customary meaning as established by the appropriate technical discipline utilized by those normally skilled in that particular art area. All medical terms shall take their meaning as defined by Stedman's Medical Dictionary, 27th edition.

What is claimed is:

1. A system for introducing multiple medical devices into a work site within a bodily lumen of a patient comprising:

an elongate medical device comprising a shaft extending between a distal end and a proximal end, a first indicator disposed on the shaft, and a lumen extending through at least a portion of the shaft, the lumen comprising a coupling region extending between a distal opening and a proximal opening; and

a wire guide having a distal end, a proximal end, and a second indicator,

wherein the wire guide is movable from a coupled position to an uncoupled position while maintaining the distal end of the elongate medical device and the distal end of the wire guide within the bodily lumen of the patient, the wire guide extending through the coupling region of the elongated medical device when in the coupled position, the wire guide not extending through the coupling region of the elongated medical device when in the uncoupled position, and

wherein the first indicator is positioned relative to the second indicator to determine whether the wire guide has moved from the coupled position to the uncoupled position.

2. The system of claim 1, wherein the first indicator comprises a first distal system of indicia located near the proximal opening of the elongate medical device and the

second indicator comprises a second distal system of indicia located near the distal end of the wire guide.

3. The system of claim 2, wherein the wire guide is moved from the coupled position to the uncoupled position by positioning the first distal system of indicia substantially adjacent to the second distal system of indicia.

4. The system of claim 2, wherein the wire guide is moved from the coupled position to the uncoupled position by positioning the first distal system of indicia distal to the second distal system of indicia.

5. The system of claim 2, wherein the first distal system of indicia and the second distal system of indicia each comprise a radiopaque marker.

6. The system of claim 5, wherein the wire guide is moved from the coupled position to the uncoupled position by positioning the radiopaque marker of the first distal system of indicia substantially adjacent to or distal of the radiopaque marker of the second distal system of indicia.

7. The system of claim 2, wherein the first distal system of indicia and the second distal system of indicia each comprise an ultrasonic reflective marker.

8. The system of claim 7, wherein the wire guide is moved from the coupled position to the uncoupled position by positioning the ultrasonic reflective marker of the first distal system of indicia substantially adjacent to or distal of the ultrasonic reflective marker of the second distal system of indicia.

9. The system of claim 1, wherein the first indicator comprises a first proximal system of indicia located a substantial distance from the distal end of the elongate medical device and the second indicator comprises a second proximal system of indicia located a substantial distance from the distal end of the wire guide.

10. The system of claim 9, wherein the first proximal system of indicia and the second proximal system of indicia are each disposed outside of the bodily lumen of the patient when the wire guide is moved from the coupled position to the uncoupled position.

11. The system of claim 9, wherein the wire guide is moved from the coupled position to the uncoupled position by positioning the first proximal system of indicia substantially adjacent to the second proximal system of indicia.

12. The system of claim 9, wherein the wire guide is moved from the coupled position to the uncoupled position by positioning the first proximal system of indicia distal to the second proximal system of indicia.

13. The system of claim 9, wherein the first proximal system of indicia and the second proximal system of indicia each comprise a directly viewable marker.

14. The system of claim 13, wherein the wire guide is moved from the coupled position to the uncoupled position by positioning the directly viewable marker of the first proximal system of indicia substantially adjacent to or distal of the directly viewable marker of the second proximal system of indicia.

15. The system of claim 9, wherein the first proximal system of indicia comprises a visual marker disposed along the shaft of the elongate medical device, the visual marker comprising a color that contrasts with a color of the shaft of the elongate medical device.

16. The system of claim 9, wherein the wire guide comprises a first portion having a first color and a second portion having a second color, the first color contrasting with the second color, further wherein the second proximal system of indicia is defined by a transition between the first portion and the second portion.

17. The system of claim 9, wherein the wire guide comprises a first portion having a first surface pattern and a second portion having a second surface pattern, the first surface pattern being distinguishable from the second surface pattern, further wherein the second proximal system of indicia is defined by a transition between the first surface pattern and the second surface pattern.

18. The system of claim 1, wherein the first indicator comprises a first intermediate system of indicia located a substantial distance from the proximal end of the elongate medical device and a relatively shorter distance from the distal end of the elongate medical device, and the second indicator comprises a second intermediate system of indicia located a substantial distance from the proximal end of the wire guide and a relatively shorter distance from the distal end of the wire guide.

19. The system of claim 18, wherein the first intermediate system of indicia and the second intermediate system of indicia are each directly viewable by a scope device when the wire guide is moved from the coupled position to the uncoupled position.

20. The system of claim 19, wherein the distal end of the elongate medical device and the distal end of the wire guide are not directly viewable by the scope device when the wire guide is moved from the coupled position to the uncoupled position.

21. The system of claim 20, wherein the scope device comprises a video or fiberoptic endoscope.

22. The system of claim 18, wherein the wire guide is moved from the coupled position to the uncoupled position by positioning the first intermediate proximal system of indicia substantially adjacent to the second intermediate system of indicia.

23. The system of claim 18, wherein the wire guide is moved from the coupled position to the uncoupled position by positioning the first intermediate system of indicia distal to the second intermediate system of indicia.

24. The system of claim 18, wherein the first intermediate system of indicia and the second intermediate system of indicia each comprise a visual marker.

25. The system of claim 24, wherein the wire guide is moved from the coupled position to the uncoupled position by positioning the visual marker of the first intermediate system of indicia substantially adjacent to or distal of the visual marker of the second intermediate system of indicia.

26. The system of claim 1, wherein the first indicator comprises a first tactile system of indicia located near the proximal opening of the elongate medical device and the second indicator comprises a second tactile system of indicia located near the distal end of the wire guide.

27. The system of claim 26, wherein the wire guide is moved from the coupled position to the uncoupled position by engaging the first tactile system of indicia with the second tactile system of indicia.

28. The system of claim 27, wherein the first tactile system of indicia comprises a flexible skirt disposed about the proximal opening of the elongate medical device and the second tactile system of indicia comprises a raised portion that projects outwardly from a surface of the wire guide.

29. The system of claim 27, wherein the first tactile system of indicia comprises a first magnet disposed near the proximal opening of the elongate medical device and the

second tactile system of indicia comprises a second magnet disposed near the distal end of the wire guide.

30. The system of claim 27, wherein the first tactile system of indicia comprises a first sensor and the second tactile system of indicia comprises a second sensor, the first sensor and the second sensor generating a signal indicating the relative position of the first sensor to the second sensor.

31. The system of claim 1, wherein the proximal opening comprises a side access port located a substantial distance from the proximal end of the elongate medical device and a relatively shorter distance from distal end of the elongate medical device, and further wherein the lumen extends proximally from the coupling region to a proximal access port located a substantial distance from the distal end of the elongate medical device and a relatively shorter distance from the proximal end of the elongate medical device.

32. The system of claim 31, wherein at least a portion of the shaft of the elongate member is configured to permit the wire guide to be moved out of the lumen by passing laterally through a wall portion of the shaft.

33. The system of claim 32, wherein the wall portion of the shaft comprises one of an open channel, a split, a score, a perforation, a reduced cross-section, and a relatively weak material for facilitating the lateral movement of the wire guide there through.

34. The system of claim 1, further comprising an introducer member having a distal end, a proximal end, and a working channel extending there between, wherein the distal end of the introducer member is positioned within the bodily lumen of the patient near the work site and the proximal end of the introducer member is positioned outside of the bodily lumen of the patient, wherein a portion of the elongate medical device and a portion of the wire guide extend through the working channel of the introducer member, and wherein the coupling region of the elongate medical device is disposed distally of the distal end of the introducer member when the wire guide is moved from the coupled position to the uncoupled position.

35. The system of claim 34, wherein the first indicator and the second indicator are each disposed distally of the distal end of the introducer member when the wire guide is moved from the coupled position to the uncoupled position.

36. The system of claim 34, wherein the first indicator and the second indicator are each disposed proximally of the working channel of the introducer member when the wire guide is moved from the coupled position to the uncoupled position.

37. The system of claim 34, wherein the work site is the patient's biliary system, the introducer member comprises an endoscope, and the elongate medical device comprises a biliary catheter having an overall length sufficient to reach the patient's biliary tree.

38. The system of claim 37, wherein the elongate medical device is one of an ERCP catheter, a sphincterotome, a needle knife, an extraction balloon, a dilation balloon, an extraction basket, a cytology brush, a dilator catheter, and a stent delivery catheter.

39. The system of claim 1, wherein the elongate medical device has a first overall length and the wire guide has a second overall length, the first overall length being greater than the second overall length.

40. The system of claim 31, wherein the elongate medical device further comprises a second side access port located a substantial distance from the distal end of the elongate medical device and a relatively shorter distance from proximal end of the elongate medical device, the second side access port being in communication with the lumen.

41. The system of claim 40, wherein at least a portion of the shaft of the elongate member extending between the side access port and the second side access port is configured to permit the wire guide to be moved out of the lumen by passing laterally through a wall portion of the shaft.

42. The system of claim 1, wherein the proximal opening comprises an elongated opening through a wall of the shaft.

43. The system of claim 1, wherein the wire guide comprises an elongate shaft extending between the distal end and the proximal end, the elongate shaft comprising a plurality of shaft sections having different properties.

44. The system of claim 43, wherein the plurality of shaft sections comprise different flexibilities.

45. The system of claim 43, wherein the plurality of shaft sections comprise different frictional surface coefficients.

46. The system of claim 1, wherein the wire guide comprises an elongate shaft extending between the distal end and the proximal end, the elongate shaft including an internal lumen extending along at least a portion thereof.

47. The system of claim 1, wherein the wire guide is uncoupled from the elongate medical device, and wherein the system further comprises a second elongate medical device having a distal end, a shaft, and a lumen extending through a portion of the shaft, the wire guide extending through the lumen of the second elongate medical device, and the distal end of the second elongate medical device is disposed within the bodily lumen of the patient and near the distal end of the elongate medical device.

48. The system of claim 1, wherein the wire guide is uncoupled from the elongate medical device, and wherein the system further comprises a second wire guide having distal end, the second wire guide being extending through the lumen of the elongate medical device, and the distal end of the second wire guide is disposed within the bodily lumen of the patient and near the distal end of the wire guide.

49. The system of claim 1, further comprising a third indicator disposed on one of the elongate member and the wire guide, wherein the third indicator is positioned relative to one of the first indicator and the second indicator to determine whether the distal end of the elongate member is aligned with the distal end of the wire guide when the wire guide is coupled with the elongate member.

50. The system of claim 49, wherein the third indicator is disposed on the wire guide and is spaced proximally of the second indicator by a distance equal to a length of the coupling region.

51. The system of claim 49, wherein the third indicator is disposed on the shaft of the elongate member and is spaced distally of the first indicator by a distance equal to a length of the coupling region.

52. An elongate medical device for use with a wire guide having a distal end, the elongate medical device comprising a shaft extending between a distal end and a proximal end, an alignment system disposed on the shaft, and a lumen extending through at least a portion of the shaft, the lumen comprising a coupling region extending between a distal opening and a proximal opening, the proximal opening being located a substantial distance from the proximal end, the coupling region being configured to receive a wire guide extending there through,

wherein the alignment system provides a user with a determination as to whether the wire guide extends through the lumen of the coupling region, the determination being provided while the distal end of the elongate medical device is disposed within a bodily lumen of a patient.

53. The elongate medical device of claim 52, wherein the wire guide is movable from a coupled position to an uncoupled position while maintaining the coupling region of the elongate medical device and the distal end of the wire guide within the bodily lumen of the patient, the wire guide extending through the coupling region of the elongated medical device when in the coupled position, the wire guide not extending through the coupling region of the elongated medical device when in the uncoupled position, and wherein the alignment system provides a determination as to when the wire guide has moved from the coupled position to the uncoupled position.

54. The elongate medical device of claim 52, wherein the alignment system comprises a first indicator on the elongate medical device that is configured to align with a second indicator on the wire guide when the distal end of the wire guide is near the proximal opening of the coupling region.

55. The elongate medical device of claim 54, wherein the first indicator is a first radiopaque marker located near the proximal opening, and wherein the second indicator is a second radiopaque marker located near the distal end of the wire guide.

56. The elongate medical device of claim 54, wherein and the first indicator is a first visual marker located on a proximal portion of the shaft of the elongate member and the second indicator is a second visual marker located on a proximal portion of the wire guide such that the first and second visual markers remain outside of the bodily lumen of the patient while the distal ends of the elongate medical device and the wire guide are disposed within the bodily lumen of the patient.

57. The elongate medical device of claim 54, wherein and the first indicator is a first visual marker located on a distal portion of the shaft of the elongate member and the second indicator is a second visual marker located on a distal portion of the wire guide such that the first and second visual markers are within the visual range of a scope device while the distal ends of the elongate medical device and the wire guide are disposed within the bodily lumen of the patient, the distal ends of the elongate medical device and the wire guide being disposed distally of the visual range of the scope device.

58. The elongate medical device of claim 54, wherein the first indicator is a first tactile indicator located near the proximal opening, and wherein the second indicator is a second tactile indicator located near the distal end of the wire guide, the first and second tactile indicators being configured to provide the user with a tactile indication as to when the distal end of the wire guide is near the proximal opening of the coupling region.

59. The elongate medical device of claim 52, wherein the lumen extends proximally from the coupling region to a proximal access port located a substantial distance from the distal end of the elongate medical device and a relatively shorter distance from proximal end of the elongate medical device.

60. The elongate medical device of claim 59, wherein at least a portion of the shaft of the elongate member is configured to permit the wire guide to be moved out of the lumen by passing laterally through a wall portion of the shaft.

61. The elongate medical device of claim 50, wherein the wall portion of the shaft comprises one of an open channel, a split, a score, a perforation, a reduced cross-section, and a relatively weak material for facilitating the lateral movement of the wire guide there through.

62. The elongate medical device of claim 54, wherein the alignment system comprises a third indicator that is configured to align with the second indicator on the wire guide when the distal end of the wire guide is near the distal end of the elongate medical device.

63. The elongate medical device of claim 62, wherein the third indicator is disposed on the shaft of the elongate member and is spaced distally of the first indicator by a distance equal to a length of the coupling region.

64. A wire guide for use with an elongate medical device having a coupling region, the coupling region having a length that is substantially shorter than that of the elongate medical device, the wire guide comprising elongated shaft extending between a proximal end and a distal end, and an alignment system disposed on the elongated shaft,

wherein the alignment system provides a user with a determination as to whether the wire guide extends through the coupling region of the elongate medical device, the determination being provided while the distal end of the wire guide is disposed within a bodily lumen of a patient.

65. The wire guide of claim 64, wherein the wire guide is movable from a coupled position to an uncoupled position while maintaining the distal end of the wire guide and the coupling region of the elongate medical device within the bodily lumen of the patient, the wire guide extending through the coupling region of the elongated medical device when in the coupled position, the wire guide not extending through the coupling region of the elongated medical device when in the uncoupled position, and wherein the alignment system provides a determination as to when the wire guide has moved from the coupled position to the uncoupled position.

66. The wire guide of claim 64, wherein the alignment system comprises a first indicator on the wire guide that is configured to align with a second indicator on the elongate medical device when the distal end of the wire guide is near a proximal end of the coupling region.

67. The wire guide of claim 66, wherein the first indicator is a first radiopaque marker located near the distal end of the wire guide, and wherein the second indicator is a second radiopaque marker located near a side access port of the elongate medical device, the side access port defining the proximal end of the coupling region.

68. The wire guide of claim 66, wherein and the first indicator is a first visual marker located on a proximal portion of the elongated shaft of the wire guide and the second indicator is a second visual marker located on a proximal portion of the elongated medical device such that the first and second visual markers remain outside of the bodily lumen of the patient while the distal end of the wire guide and the coupling region of the elongate medical device are disposed within the bodily lumen of the patient.

69. The wire guide of claim 66, wherein and the first indicator is a first visual marker located on a distal portion of the shaft of the wire guide and the second indicator is a

second visual marker located on a distal portion of the elongate member such that the first and second visual markers are within the visual range of a scope device while the distal end of the wire guide and the coupling region are disposed within the bodily lumen of the patient, the distal end of the wire guide and the coupling region being disposed distally of the visual range of the scope device.

70. The wire guide of claim 66, wherein the first indicator is a first tactile indicator located near located near the distal end of the wire guide, and wherein the second indicator is a second tactile indicator located near the proximal end of the coupling region, the first and second tactile indicators being configured to provide the user with a tactile indication as to when the distal end of the wire guide is near the proximal end of the coupling region.

71. The wire guide of claim 66, wherein the alignment system comprises a third indicator that is configured to align with the second indicator on the elongate medical device when the distal end of the wire guide is near a distal end of the elongate medical device.

72. The wire guide of claim 71, wherein the third indicator is disposed on the shaft of the wire guide and is spaced proximally of the first indicator by a distance equal to a length of the coupling region of the elongate medical device.

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