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(54) **SYSTEM AND METHOD FOR  
TRANSLUMINAL ACCESS**

**Publication Classification**

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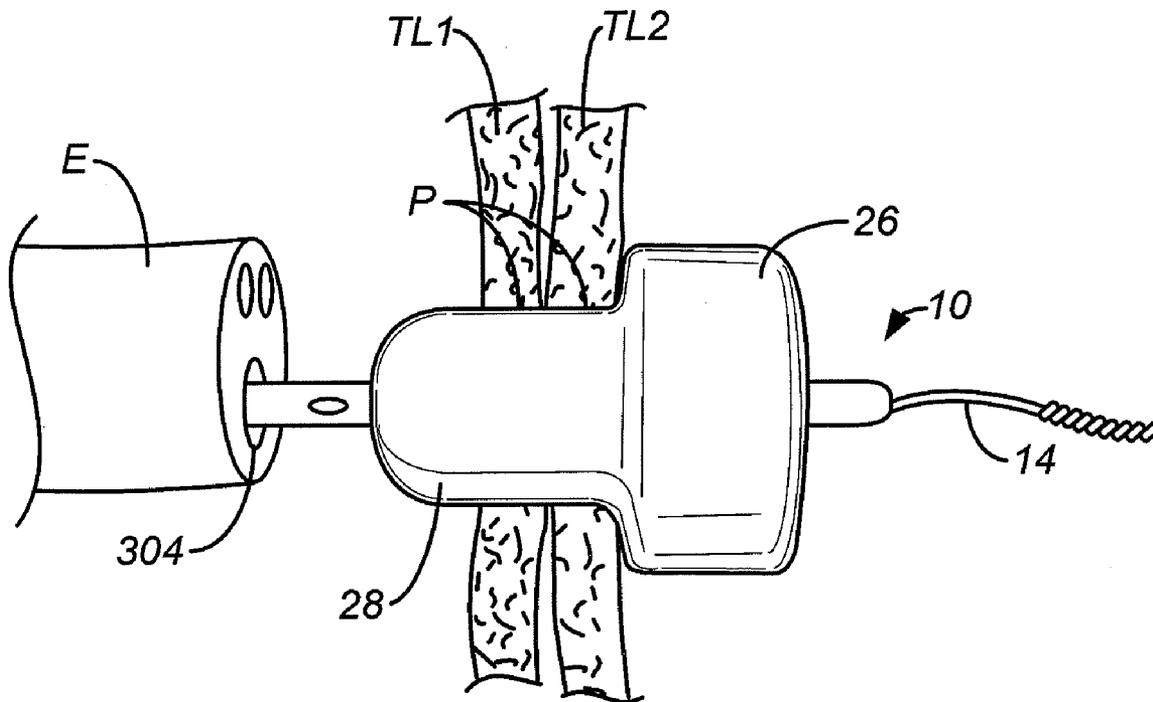
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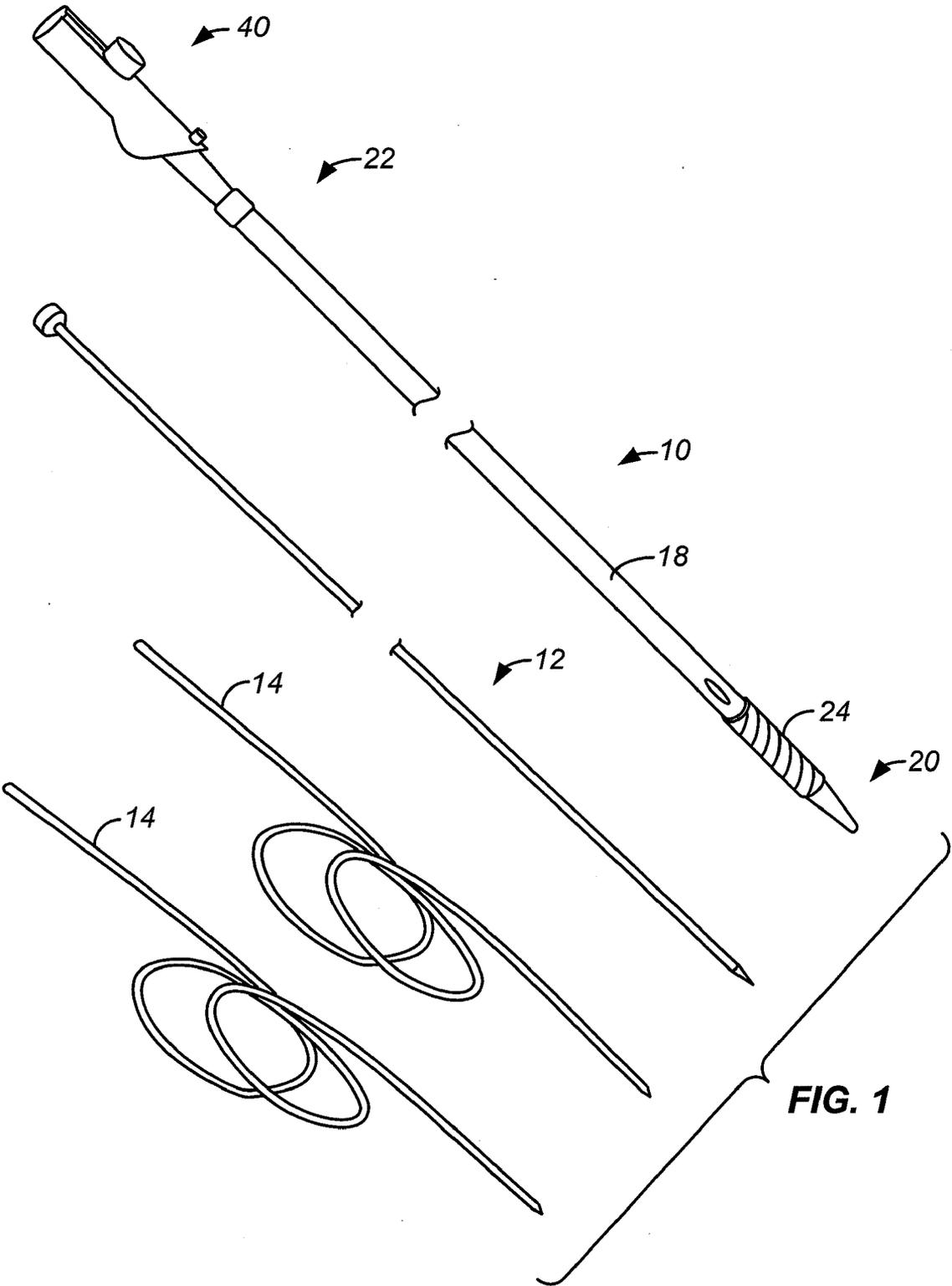
**Related U.S. Application Data**

(60) Provisional application No. 61/052,460, filed on May 12, 2008.

(57) **ABSTRACT**

A transluminal access system includes a transluminal access catheter, a trocar, and one or more guidewires. The trocar may be introduced through adjacent tissue layers, typically from an endoscope, and the transluminal access catheter introduced through the resulting penetration over the trocar. A balloon on the catheter may be used to dilate the penetration, and an enlarged distal portion of the balloon may be used to draw the tissue layers into apposition. The first stent may be exchanged for the trocar and a second stent may be introduced through a side port on the access catheter. The stents may be then used to introduced catheters or other interventional tools, optionally for delivering one or more stents to the enlarged tissue penetration.





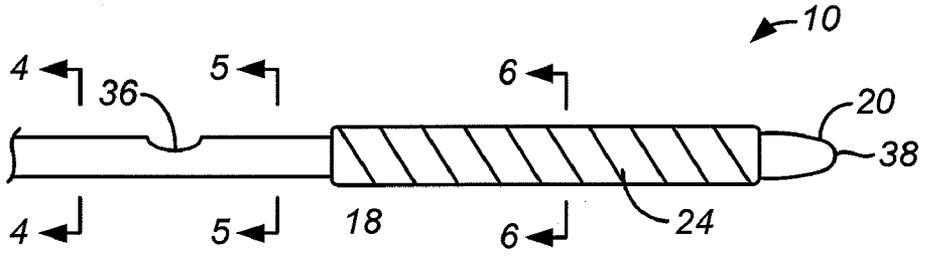


FIG. 2

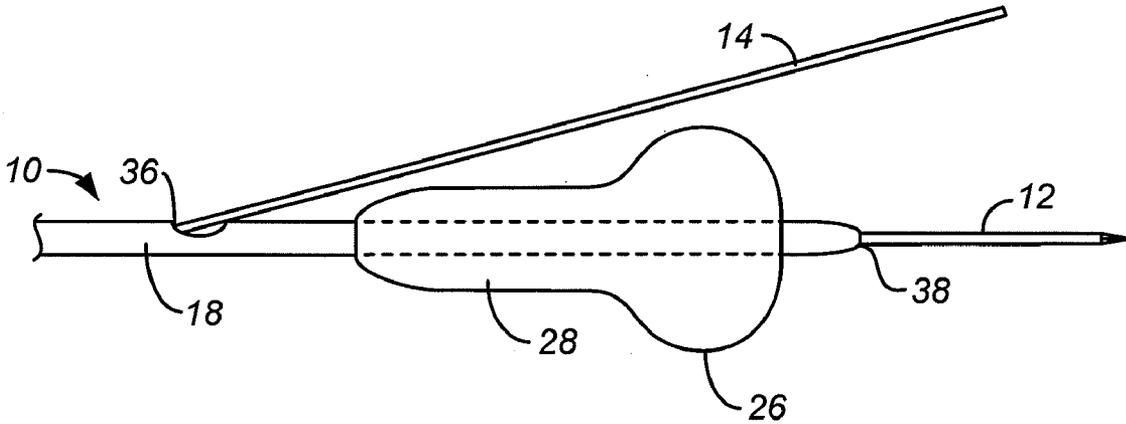


FIG. 3A

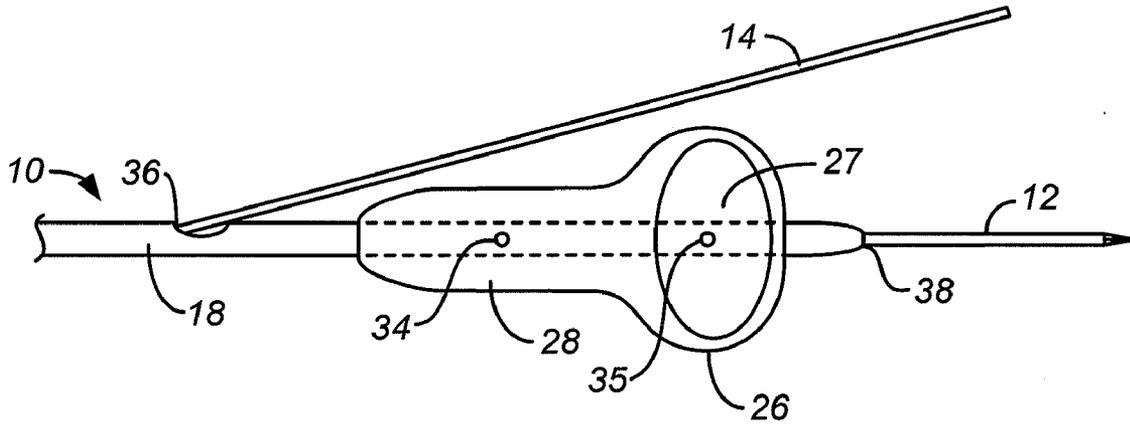
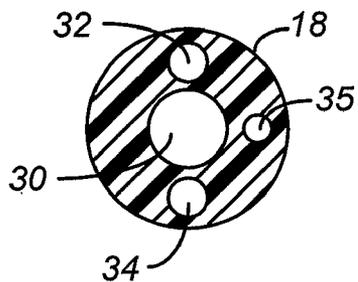
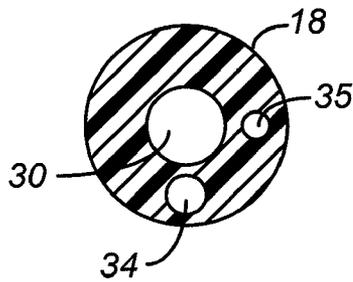


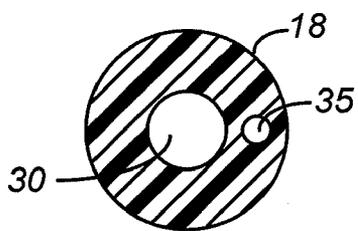
FIG. 3B



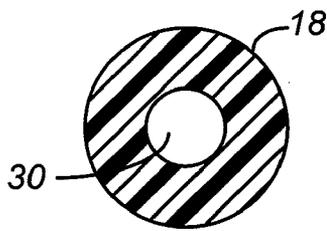
**FIG. 4**



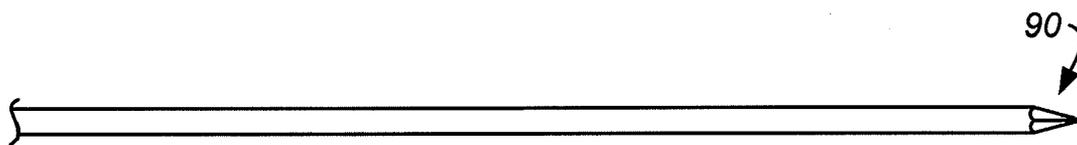
**FIG. 5**



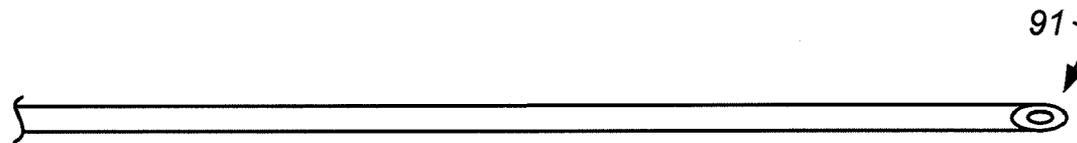
**FIG. 6**



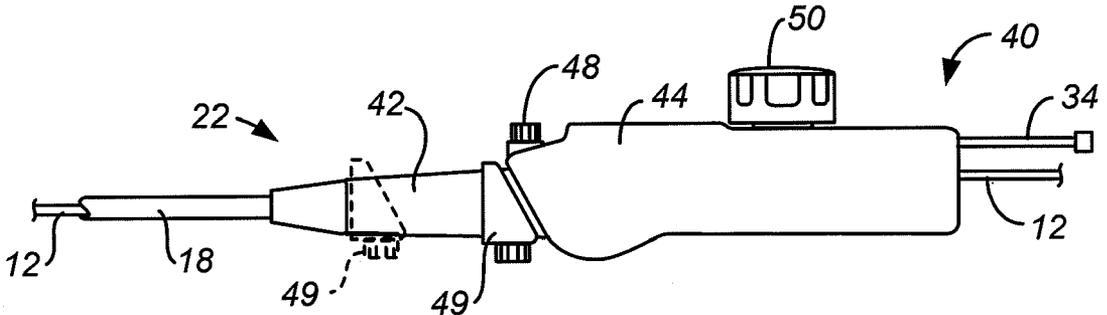
**FIG. 7**



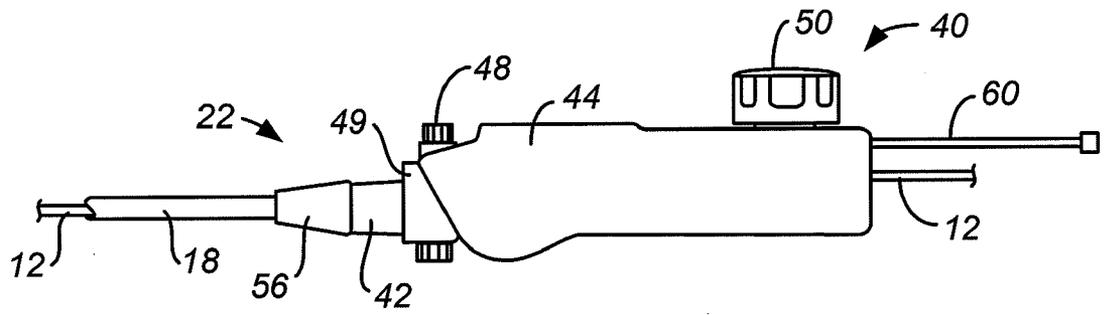
**FIG. 11A**



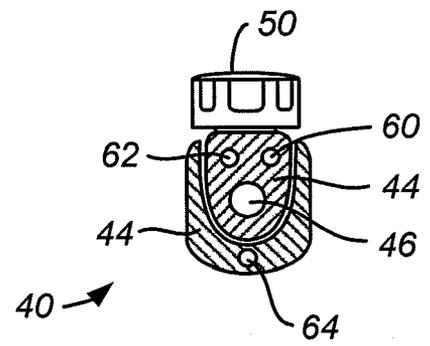
**FIG. 11B**



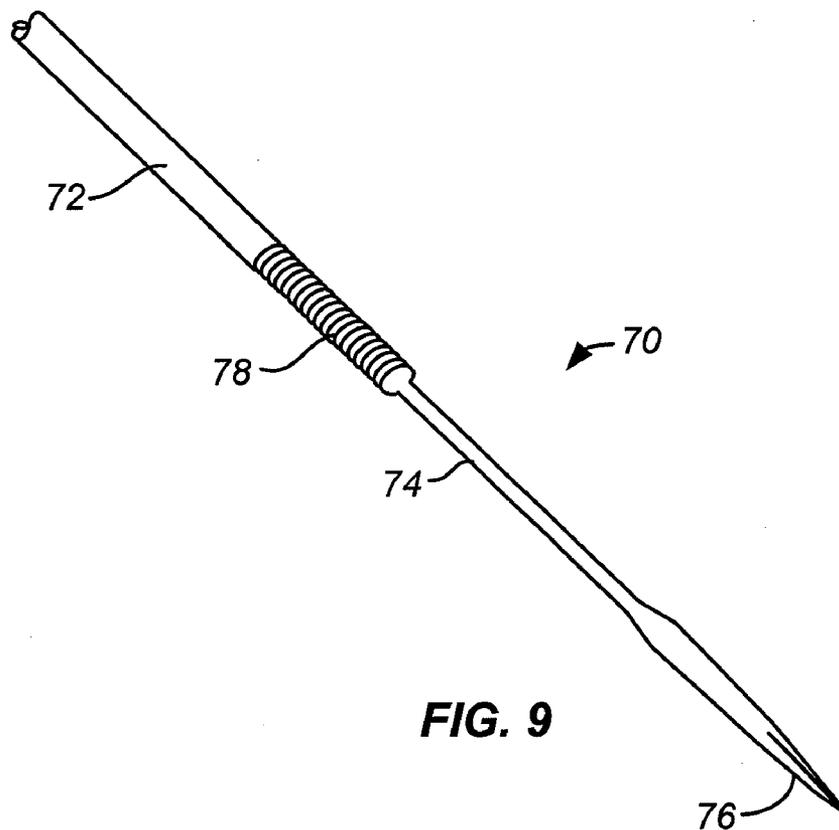
**FIG. 8A**



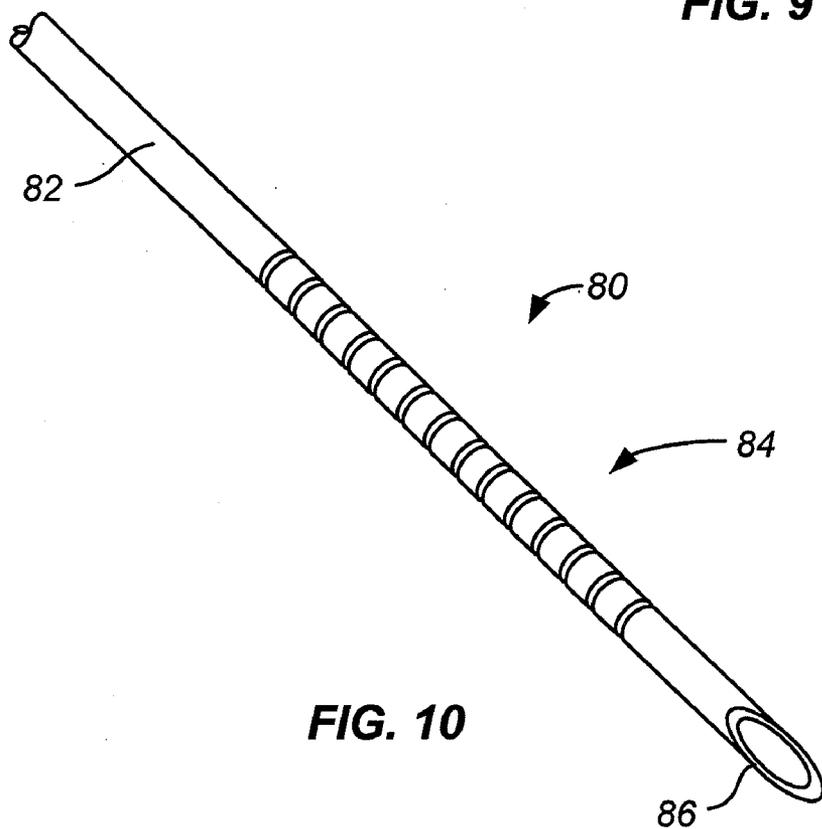
**FIG. 8B**



**FIG. 8C**



**FIG. 9**



**FIG. 10**

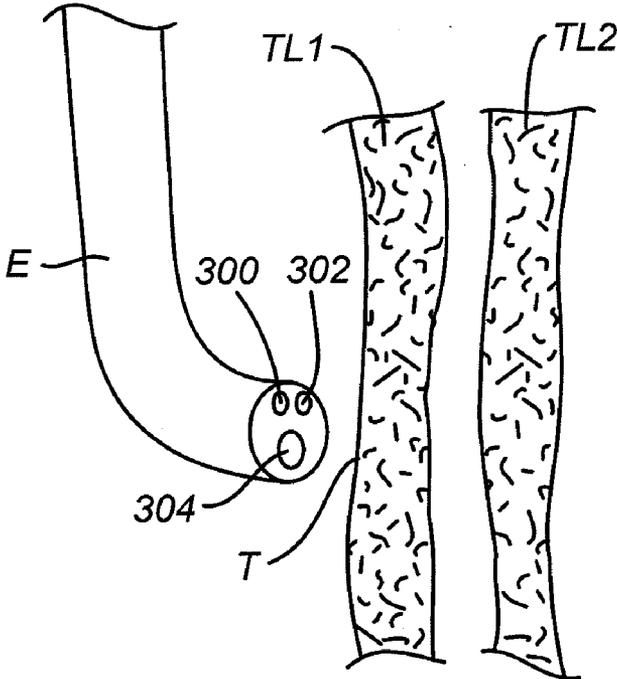


FIG. 12A

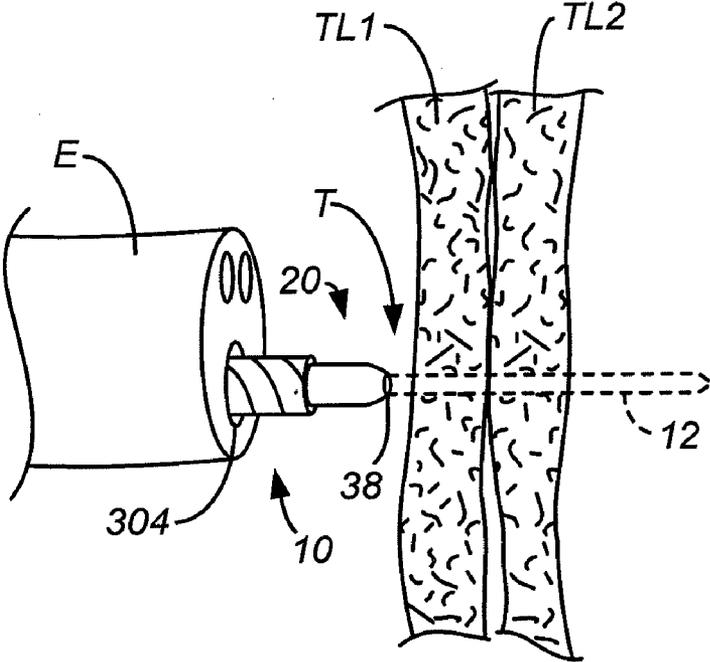
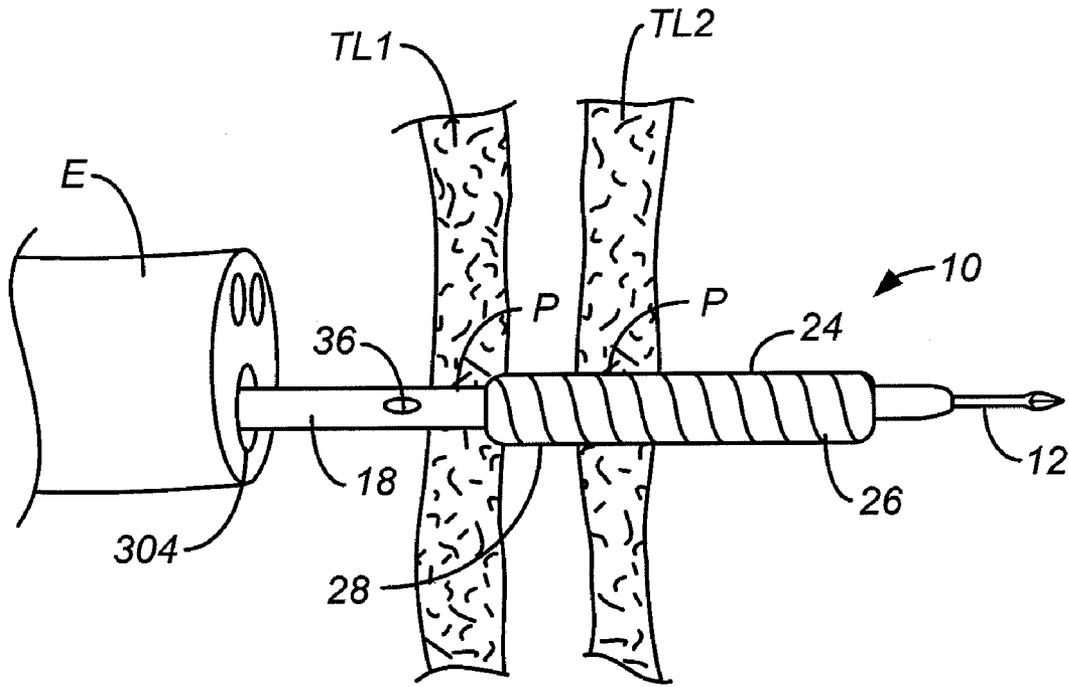
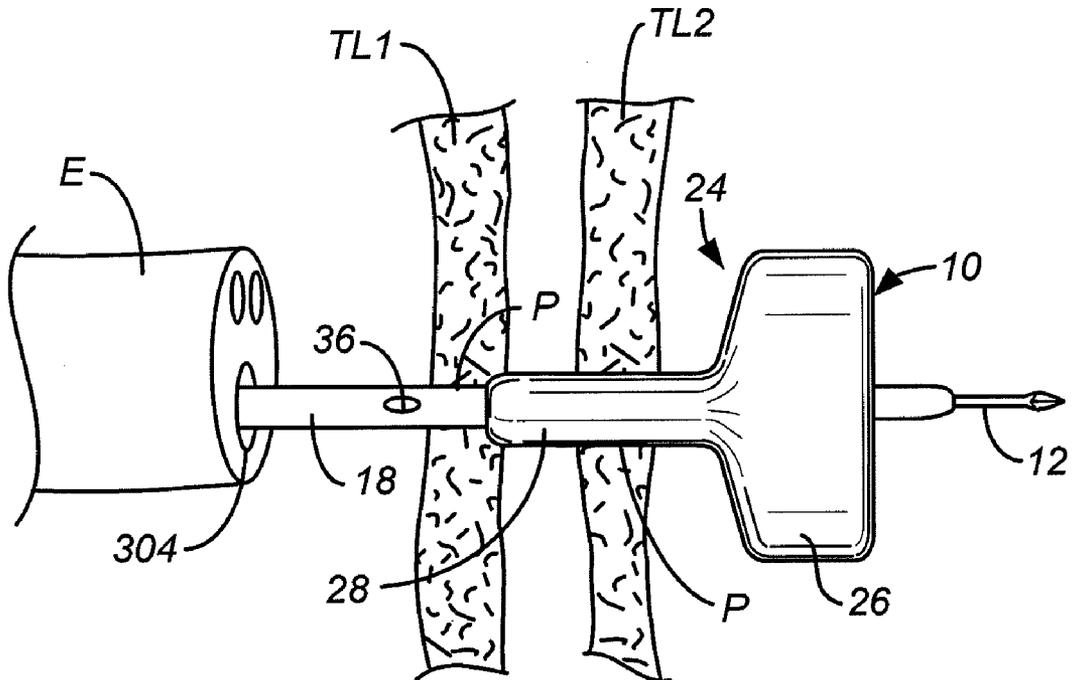


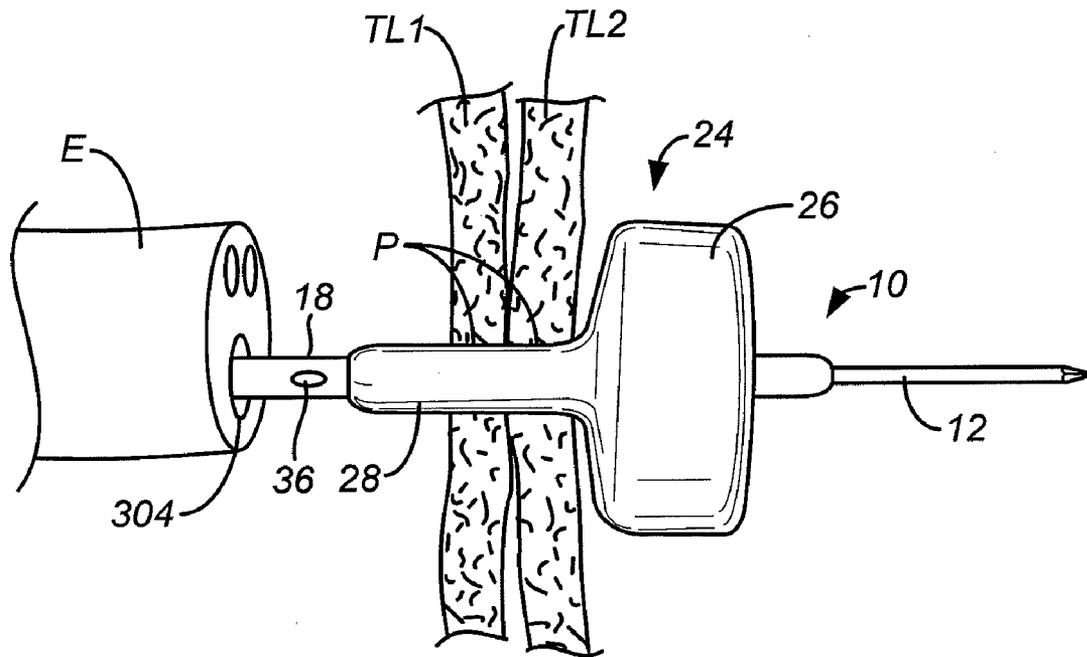
FIG. 12B



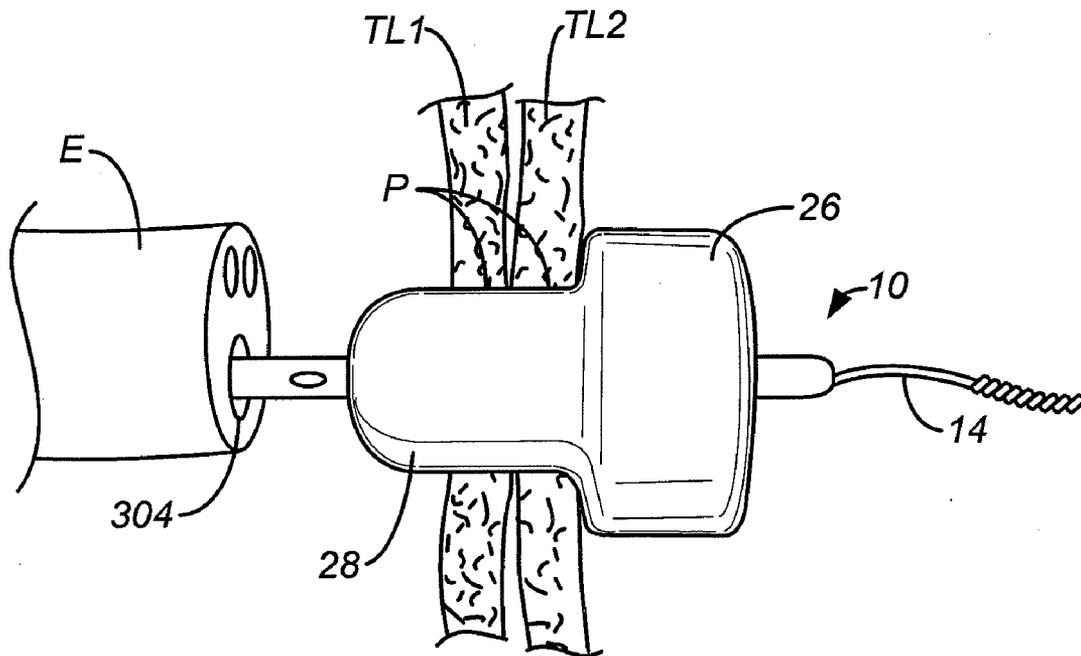
**FIG. 12C**



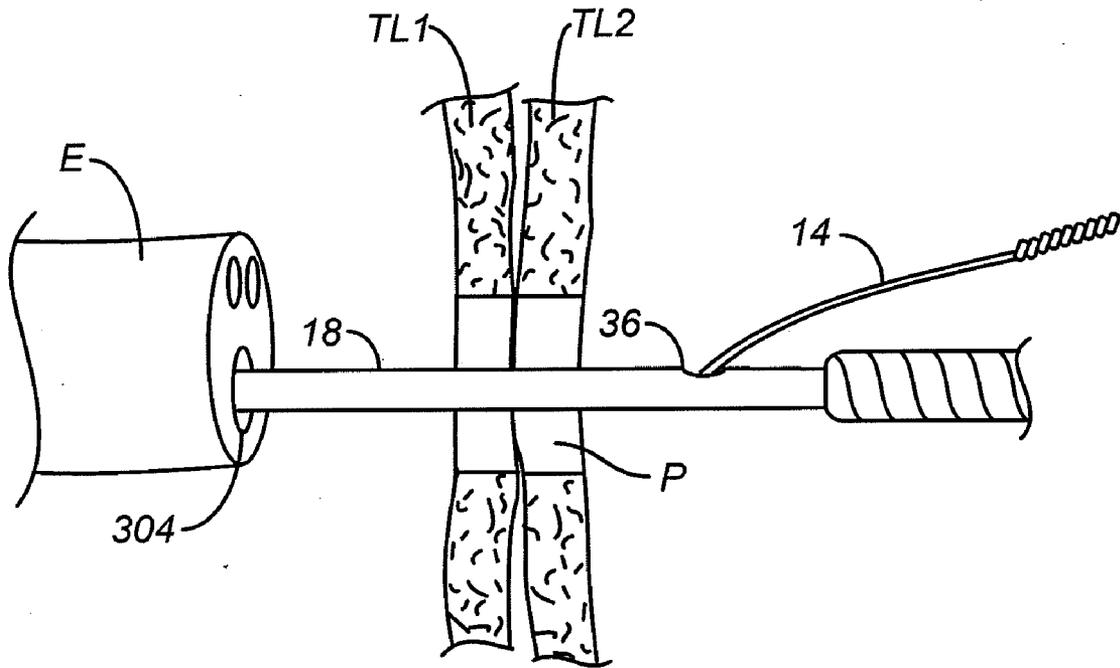
**FIG. 12D**



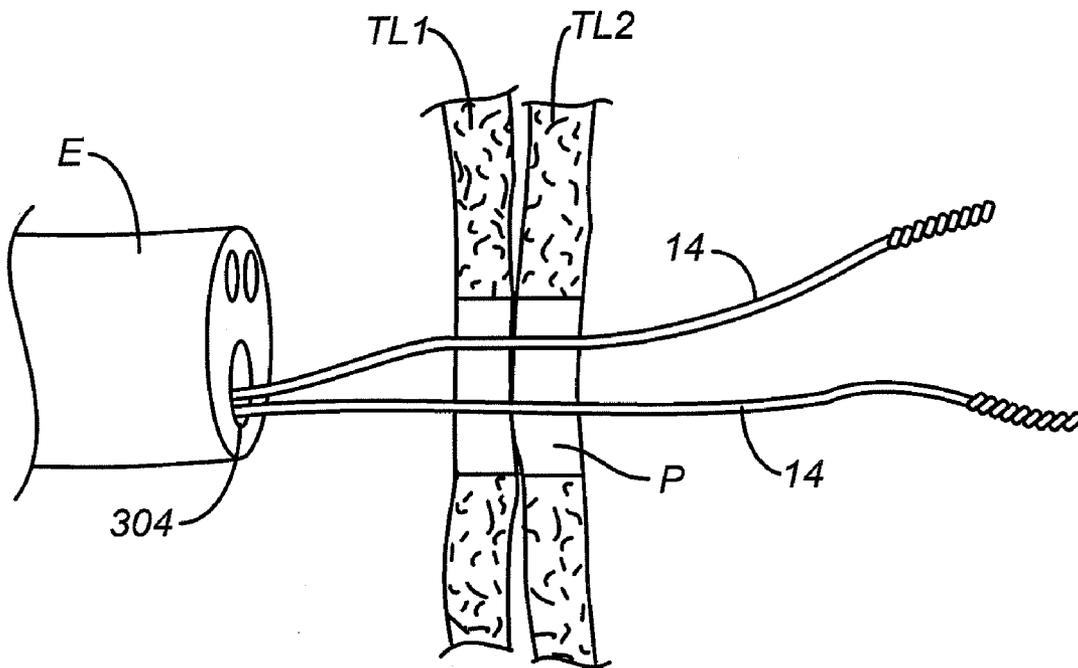
**FIG. 12E**



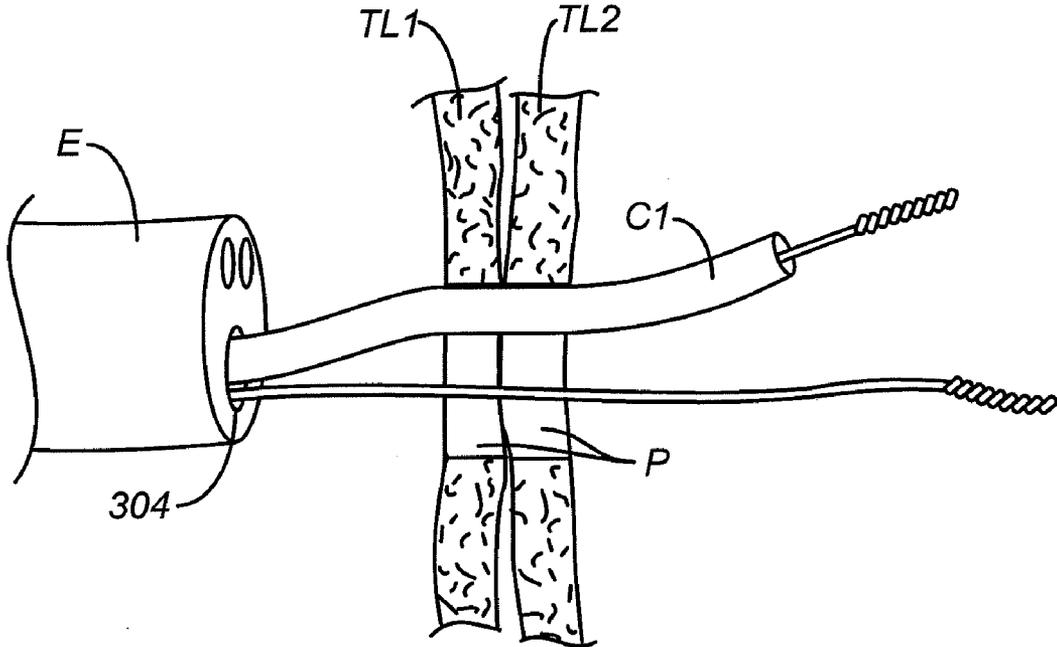
**FIG. 12F**



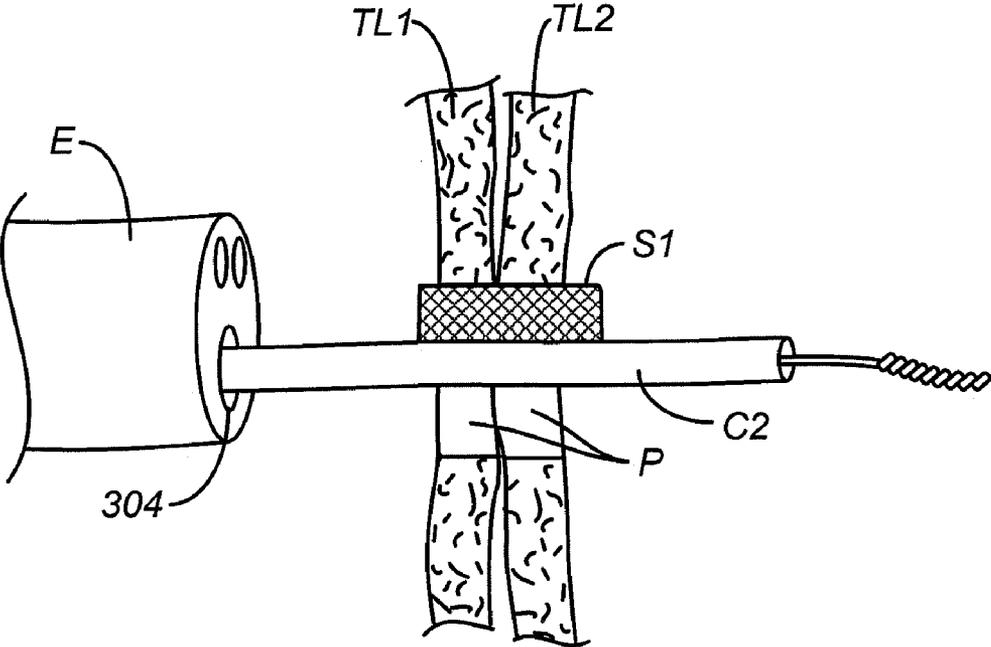
**FIG. 12G**



**FIG. 12H**



**FIG. 12I**



**FIG. 12J**

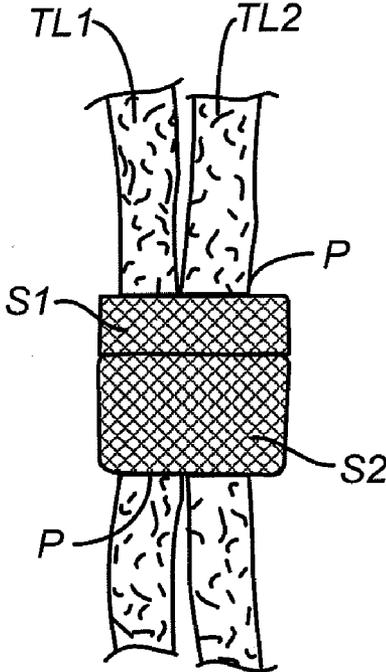


FIG. 12K

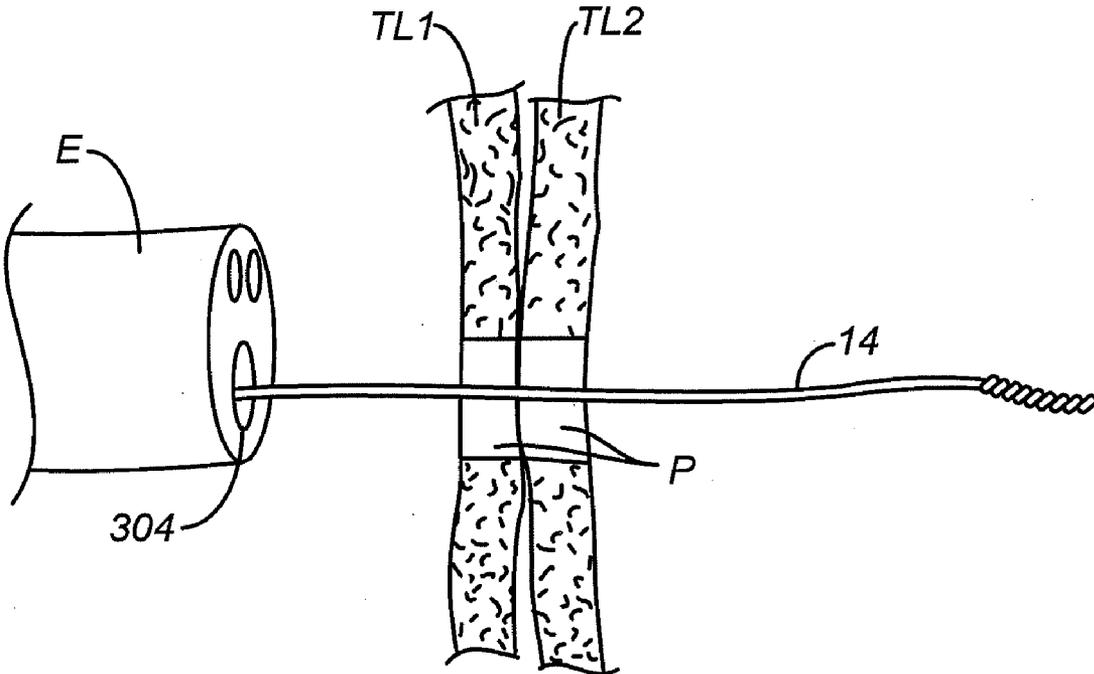
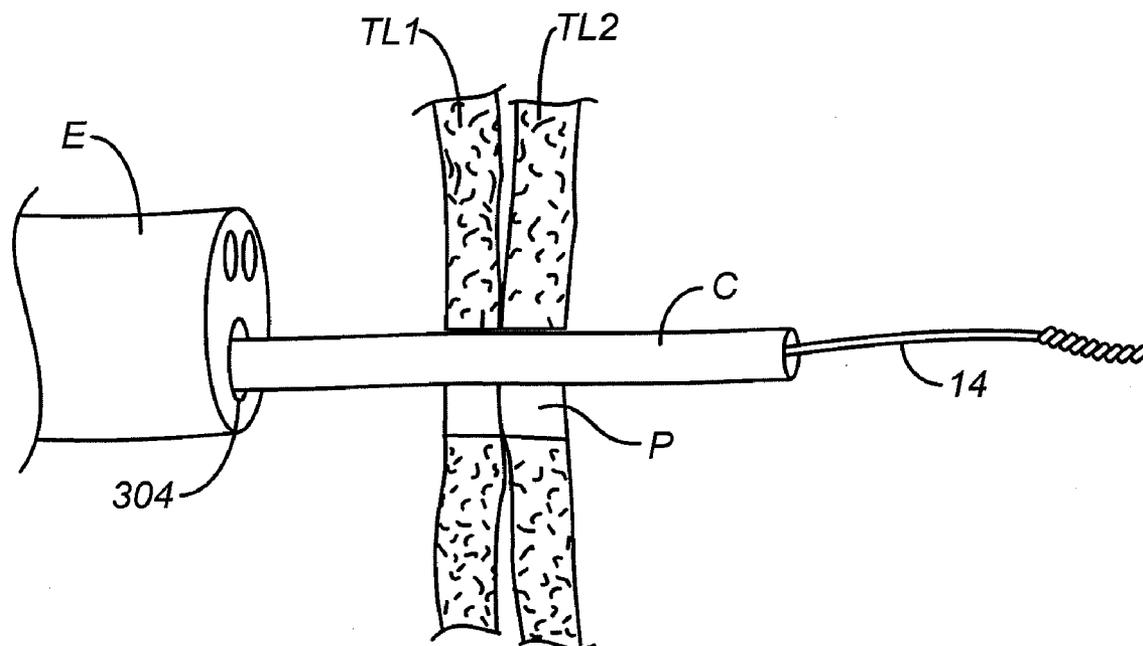
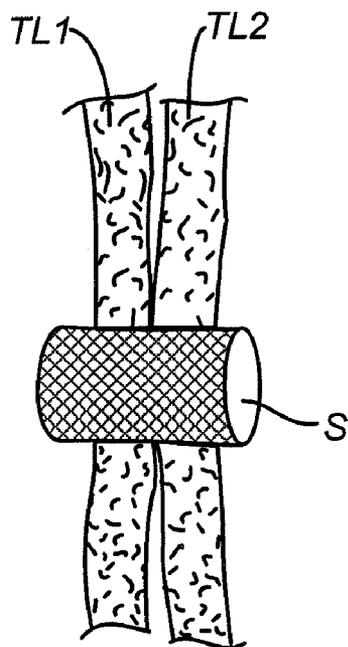


FIG. 13A



**FIG. 13B**



**FIG. 13C**

**SYSTEM AND METHOD FOR  
TRANSLUMINAL ACCESS**

**CROSS-REFERENCES TO RELATED  
APPLICATIONS**

**[0001]** This application claims the benefit of provisional application No. 61/052,460 (Attorney Docket No. 026923-000700US), filed on May 12, 2008, the full disclosure of which is incorporated herein by reference. The disclosure of the application also relates to those of commonly owned application Ser. No. 11/886,499 (Attorney Docket No. 026923-000410US), filed on Sep. 14, 2007; and Ser. No. 12/\_\_\_\_\_ (Attorney Docket No. 026923-000710US), filed on the same day as the present application.

**BACKGROUND OF THE INVENTION**

**[0002]** 1. Field of the Invention

**[0003]** The present invention relates generally to medical methods and devices. In particular, the present invention relates to catheters and other tools for providing access and placing guidewires between adjacent body lumens.

**[0004]** A number of endoscopic and other intraluminal procedures require remote access from one body lumen into an adjacent body lumen. For example, a number of procedures may be performed by entering the gastrointestinal (GI) tract, particularly the esophagus, stomach, duodenum, small intestine, or large intestine, and passing tools from the GI tract into adjacent organs and structures, such as the bile duct, the pancreatic duct, the gall bladder, the pancreas, cysts, pseudocysts, abscesses, and the like. Such access into the adjacent body lumen will usually require forming a penetration or other access hole from within the first body lumen, through a wall of the first body lumen, through a wall of the second body lumen, and into the interior of the second body lumen. Depending on the procedure being performed, catheters or other tools will usually be advanced through the penetration for stent placement, drainage tube placement, or the like.

**[0005]** As with many medical access procedures, it is desirable that the catheters and other access tools be introduced over a guidewire when advanced through the luminal wall penetration. Additionally, it is often desirable that the luminal wall penetrations be dilated prior to stent placement or other interventional procedure. Such dilation can be problematic as the luminal walls will not necessarily be in close apposition, particularly after penetration and access formation, thus making positioning of a dilation balloon difficult. A further challenge arises from the need to employ multiple tools for forming the initial access penetration, dilating the penetration, placing one or more guidewires, and subsequently placing the stents or performing other interventional procedures.

**[0006]** It would be desirable to be able to provide methods and systems for creating transluminal access passages with the ability to dilate the passages and place one or more guidewires through the passage. It would be particularly desirable to reduce the number of tools and method steps needed for such protocols. At least some of these objectives will be met by the inventions described and claimed below.

**[0007]** 2. Description of the Background Art

**[0008]** US 2003/069533 describes an endoscopic transduodenal biliary drainage system which is introduced through a penetration, made by a trans-orally advanced catheter having a needle which is advanced from the duodenum

into the gall bladder. U.S. Pat. No. 6,620,122 describes a system for placing a self-expanding stent from the stomach into a pseudocyst using a needle and an endoscope. US 2005/0228413, commonly assigned with the present application, describes a tissue-penetrating device for endoscopy or endosonography-guided (ultrasonic) procedures where an anchor may be placed to form an anastomosis between body lumens, including the intestine, stomach, and gallbladder. See also U.S. Pat. No. 5,458,131; U.S. Pat. No. 5,495,851; U.S. Pat. No. 5,944,738; U.S. Pat. No. 6,007,522; U.S. Pat. No. 6,231,587; U.S. Pat. No. 6,655,386; U.S. Pat. No. 7,273,451; U.S. Pat. No. 7,309,341; US 2004/0243122; US 2004/0249985; US 2007/0123917; WO 2006/062996; EP 1314404 Kahaleh et al. (2006) *Gastrointestinal Endoscopy* 64:52-59; and Kwan et al. (2007) *Gastrointestinal Endoscopy* 66:582-586. Shaped balloons having differently sized segments and segments with staged opening pressures are described in U.S. Pat. Nos. 6,835,189; 6,488,653; 6,290,485; 6,022,359; 5,843,116; 5,620,457; 4,990,139; and 3,970,090.

**BRIEF SUMMARY OF THE INVENTION**

**[0009]** The present invention provides improved methods and systems for establishing transluminal access between a first body lumen and a second body lumen. Such transluminal access may be intended for any medical purpose but will usually be intended for performing transluminal therapeutic endoscopy where the first body lumen is typically within the gastrointestinal (GI) tract, including the esophagus, the stomach, the duodenum, the small intestines, and the large intestines. The second body lumen will typically be an organ or other tissue structure which lies adjacent the gastrointestinal tract, including the bile duct, the pancreatic duct, the gall bladder, cysts, pseudocysts, abscesses, the pancreas, a pancreatic pseudocyst, the liver, the urinary bladder, and the like. Exemplary medical procedures will typically involve initially establishing a transluminal access tract, typically by penetrating a trocar or other sharpened instrument from an endoscope. The procedures may also involve placing one or more guidewires which are useful for advancing one or more catheters into the transluminal access tract. The exemplary procedures may also include dilating the transluminal access tract, typically before placing guidewire(s) or performing other therapeutic or diagnostic procedures.

**[0010]** The methods and systems of the present invention provide a number of advantages over previous access protocols and techniques. In particular, the present invention provides an integrated device which can be advanced over a trocar or other penetrating tool which has been delivered from an endoscope to form the initial tissue penetration. The integrated access device will typically perform one or more additional functions to simplify the access protocol as well as facilitate subsequent therapeutic protocols. For example, the access device may be used for the controlled advancement of the trocar or other penetrating tool in order to form the initial tissue penetration. The access device may also incorporate a dilation balloon which allows the luminal penetrations to be dilated without the need to exchange access devices. The balloon or other expansible member on the access device may also be adapted to provide for improved luminal wall apposition as well as for enhanced positioning of the balloon prior to dilation. Additionally, the access device may provide for the placement of two or more guidewires within the intraluminal penetration which facilitates the advancement of separate catheters or other interventional or diagnostic tools.

**[0011]** In a first aspect, the present invention provides methods for positioning two or more guidewires between a first body lumen and a second body lumen. A trocar is advanced from the first body lumen into the second body lumen to form a passage through the luminal walls. A balloon catheter is then advanced over the trocar to position a dilation balloon within the passage. The balloon is inflated to dilate the passage, and a first guidewire is exchanged for the trocar. The trocar-guidewire exchange can be carried out either before or after the balloon dilation. The catheter is then further advanced over the first guidewire or trocar into the second body lumen so that a side port on the catheter located proximal of the balloon enters into the second body lumen. A second guidewire is then advanced through the side port into the second body lumen, and the balloon catheter may then be withdrawn to leave the first and second guidewires in place through the dilated passage.

**[0012]** Once in place, the first and second guidewires, and optionally additional guidewires if further side ports were provided on the access catheter, may be utilized for any desired therapeutic or diagnostic procedure. Typically, the guidewires will be utilized for advancing therapeutic or diagnostic catheters, often for stent placement to establish a drainage path between the body lumens. In a specific procedure, the guidewires can be used to place a pair of stents in order to drain a cyst, pseudocyst or abscess into the stomach or duodenum.

**[0013]** In a second aspect, the present invention provides a method for forming, dilating, and optionally positioning at least one guidewire between a first body lumen and a second body lumen, organ, or structure. A trocar is advanced from the first body lumen into the second body lumen or structure to form a passage through the luminal walls. A balloon catheter is advanced over the trocar to position a distal portion of a dilation balloon is positioned beyond the passage so that said distal portion lies within the second body lumen or structure. The distal portion of the balloon is then inflated while a proximal portion of the balloon remains uninflated (or inflated to a lesser extent), and the balloon catheter is pulled or otherwise tensioned proximally so that the inflated distal portion of the balloon engages the wall of the second body lumen and draws the second luminal wall against the first luminal wall to place said walls in apposition. The proximal portion of the balloon may then be inflated to dilate the tissue members. It is a particular advantage that the inflated distal portion of the balloon both draws the tissue layers into close apposition and optimally positions the proximal portion of the balloon for dilation.

**[0014]** The dilated passage may then be treated by introducing further catheters or tools. Typically, the trocar will be exchanged with a guidewire, and a second guidewire may optionally be advanced through a side port (as described above with respect to the first aspect of the present invention), either before or after balloon dilation of the passage. A treatment, diagnostic, or other catheter may then be introduced over the guidewire. For example, the treatment catheter may be used to place a stent into the dilated passage for drainage or for other purposes.

**[0015]** In a third aspect, the present invention provides a transluminal access system, which comprises a first guidewire, a second guidewire, a trocar, and a transluminal access catheter. The transluminal access catheter includes a catheter body having a proximal end, a distal end, a central lumen, and a side port and lumen. A dilation balloon is dis-

posed on the catheter body at or near the distal end, and the central lumen extends from the proximal end to the distal end so that it can exchangeably receive the trocar and the first guidewire. The side wire lumen extends from the proximal end of the catheter body of the side port which is located immediately proximal of the dilation balloon, and the side wire lumen removably receives the second guidewire. The transluminal access system is particularly suited for performing the methods for placement of two guidewires previously described.

**[0016]** The transluminal access system will usually further include a handle assembly attachable to the proximal end of the catheter, where the handle is configured to lock to or within an endoscope when the catheter body is within a working channel of the endoscope. The handle comprises an inner core which couples to the catheter body and an outer grip which couples to the trocar. The inner core comprises a catheter adjustment mechanism that is movable with respect to the inner core, said catheter adjustment mechanism typically being attached at its distal end to the catheter. A control knob or slide mechanism is usually part of the adjustment mechanism which controls the movement of the catheter. Thus, using the handle, a user can advance and retract the grip relative to the inner core to thereby advance and retract the trocar relative to the catheter body. Further, a user can rotate the control knob in a clockwise or counterclockwise direction or advance the slide mechanism in a proximal or distal direction to thereby advance and retract the catheter relative to the inner core and the trocar. In this way, after the endoscope has been used to locate a target location on a body lumen, the transluminal access catheter may be introduced through the working channel of the endoscope so that its distal end is adjacent the target location on the body wall. The trocar will be axially retracted during the initial positioning. Once the distal end of the access catheter is properly located, the catheter can be locked relative to the endoscope and the outer grip can then be rapidly advanced (thrust forward) to penetrate the trocar through the luminal walls while the catheter body remains fixed relative to the endoscope. Such rapid advancement of the trocar is particularly advantageous in penetrating relatively loose or flaccid luminal walls which might otherwise resist penetration.

**[0017]** In preferred aspects, the handle assembly will comprise a catheter body adjustment mechanism on the inner core, where the adjustment mechanism permits axial advancement and retraction of the catheter body relative to the handle and the trocar. Thus, once the trocar has penetrated the luminal walls, the catheter body may be advanced over the trocar while the trocar and endoscope remain stationary. The handle assembly will also preferably include a trocar depth adjustment mechanism on the inner core, positioned immediately distal to the outer grip and a trocar lock mechanism located on the outer grip. The trocar depth adjustment mechanism allows the maximum depth position of the trocar to be set prior to trocar advancement and the trocar lock mechanism allows the trocar to be locked to the central member which is locked to the endoscope during operation. The trocar depth adjustment mechanism is particularly useful since it prevents over extension of the trocar and inadvertent tissue damage. The trocar lock is useful since it secures the trocar position, prior to advancement, thus eliminating unintentional damage to the scope or tissue, and after advancement, secures the trocar in place with respect to the catheter and the target lumen. The trocar can be precisely positioned immedi-

ately adjacent to the luminal walls prior to advancement by slowly moving the outer grip forward until the desired position is reached. The trocar can then be locked in place using the trocar lock mechanism, or released prior to trocar advancement.

**[0018]** In a fourth aspect, the present invention provides a catheter and trocar assembly comprising a catheter body, a trocar, and a handle attachable to the proximal end of the catheter body. The trocar is slidably disposed in a central lumen of the catheter body and has a tissue-penetrating distal end. The handle has an inner core and an outer grip, generally as described above, which allows the trocar to be advanced relative to the catheter body while the inner core remains fixed to the catheter body. The handle of the catheter and trocar assembly preferably further comprises a catheter body adjustment mechanism and a trocar adjustment mechanism, again as described previously in connection with the systems of the present invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0019]** FIG. 1 illustrates a system according to the present invention comprising a transluminal access catheter, a trocar, and a pair of guidewires.

**[0020]** FIG. 2 is a detailed view of the distal end of the transluminal access catheter of the system of FIG. 1.

**[0021]** FIG. 3A is a detailed view of the transluminal access catheter of FIG. 1, similar to that shown in FIG. 2, with the dilation balloon fully inflated and a pair of guidewires in place.

**[0022]** FIG. 3B is a detailed view of the transluminal access catheter of FIG. 1, similar to that shown in FIG. 2, with the anchor balloon fully inflated inside of the fully inflated dilation balloon, and a guidewire in place in the proximal location.

**[0023]** FIG. 4 is a cross-sectional view of the transluminal access catheter taken along line 4-4 of FIG. 2.

**[0024]** FIG. 5 is a cross-sectional view of the transluminal access catheter taken along line 5-5 of FIG. 2.

**[0025]** FIG. 6 is a cross-sectional view of the transluminal access catheter taken along line 6-6 of FIG. 2.

**[0026]** FIG. 7 is a cross-sectional view of the transluminal access catheter taken along line 7-7 of FIG. 2.

**[0027]** FIGS. 8A and 8B illustrate an exemplary handle construction for the transluminal access catheter shown with a grip in its fully proximal configuration (FIG. 7A) and the grip in its fully distal configuration (FIG. 7B).

**[0028]** FIG. 8C is a proximal end view of the handle of FIGS. 7A and 7B.

**[0029]** FIG. 9 illustrates a first embodiment of a trocar useful in the systems and methods of the present invention.

**[0030]** FIG. 10 illustrates a second trocar construction useful in the systems and methods of the present invention.

**[0031]** FIG. 11A illustrates a first embodiment of a trocar with a faceted solid trocar tip

**[0032]** FIG. 11B illustrates a second embodiment of a trocar with a chamfered hollow tip

**[0033]** FIGS. 12A-12K illustrate a method according to the present invention for positioning two catheters within a tissue penetration between adjacent body lumens and for deploying a pair of parallel stents within the tissue penetration.

**[0034]** FIGS. 13A-13C illustrate a modification to the method of FIGS. 10A-10I for placing a single guidewire and a single stent.

#### DETAILED DESCRIPTION OF THE INVENTION

**[0035]** Referring to FIG. 1, a transluminal access system according to the present invention comprises a transluminal access catheter 10, a trocar 12, and one or more guidewires 14 usually including at least two guidewires. The transluminal access catheter 10 comprises a catheter body 18 having a distal end 20 and a proximal end 22. An inflatable balloon 24 is located near the distal end 20 of the catheter body 18 and is shown in its radially conformed or deflated configuration in FIGS. 1 and 2 and in its radially expanded or inflated configuration in FIG. 3.

**[0036]** While in some instances, balloon 24 may inflate to a cylindrical, spherical, tapered, or other more conventional balloon configuration, it is preferred that the balloon 24 have a distal portion 26 which inflates to a larger diameter than does a proximal portion 28. It is also preferred that distal portion of balloon 24 inflate first, while proximal portion 28 remains substantially uninflated until inflation of the distal portion is substantially completed. The advantages of this configuration are described in more detail in connection with the method of the present invention with reference to FIGS. 12D-12F below.

**[0037]** As shown in the cross-sectional view of FIG. 4, the catheter body 18 includes at least a central lumen 30, a guidewire lumen 32, a balloon inflation lumen 34 and optionally a second balloon inflation lumen 35, through its proximal portion. As illustrated in FIG. 3A, the guidewire lumen 32 terminates in a side port 36 which permits a guidewire 14 to be advanced from the guidewire lumen 32 at a location proximal to the balloon. As illustrated in cross-sectional view FIG. 5 & FIG. 6, the central lumen 30 and balloon inflation lumens 34 and 35 continue to the balloon region, with the balloon inflation lumen(s) terminating to deliver inflation media within the balloon (not shown). The central lumen 30 continues all the way to the distal end 20 of the catheter body where it terminates in a port 38 through which the trocar 12 and subsequently a second guidewire 14 can extend, as illustrated in FIG. 3A and cross section FIG. 7.

**[0038]** Catheter body 18 will typically be formed as an extruded polymer, where suitable polymers include polyether block amide (Pebax®), nylon, polyethylene and the like. The lumens may be formed during extrusion and/or by forming over mandrels in a conventional manner or the lumens may be formed from individual tubes that are held together with an outer tubular liner which may be heated to fuse and/or shrink to hold the tubes in close apposition. The length of the catheter body 18 will vary depending on the intended use, but will typically be in the range from 50 cm to 250 cm, more usually being in the range from 100 cm to 200 cm. The guidewire lumens will be sized to receive conventional guidewires, typically up to an 0.035 inch wire, but could be smaller or larger, depending on the intended use. The central lumen will be large enough to receive the trocar as well as a guidewire, typically having a diameter in the range from 0.01 inch to 0.1 inch. Typically, the balloon will have a length in the range from 1 cm to 8 cm and a diameter in the range from 5 mm to 25 mm.

**[0039]** The balloon will typically be formed from a non-distensible polymer, such as polyethyleneterephthalate (PET), polyethylene (PE) or nylon, or may be formed from a

distensible polymer such as polyurethane, polyether block amide (Pebax®) or silicone, and will be heat treated or otherwise formed to have the desired geometry. As will be explained in more detail later, the balloon may comprise a single internal chamber, where the enlarged distal portion inflates fully at a first pressure, typically in the range from above 1 atm. to 4 atm., while the proximal portion inflates at a higher pressure, typically in the range from 6 atm. to 12 atm. Thus, a staged inflation of the balloon can be performed during the procedure where the distal portion is first inflated to its full diameter and the proximal portion is only later inflated to the lesser diameter. Alternatively, single or multiple balloons may be configured with different inflatable compartments and separate inflation lumens so that a larger distal portion can be inflated prior to the smaller proximal portion. One such balloon configuration includes an outer non-distensible balloon, including a larger distal portion 26 and a smaller proximal portion 28, and an inner distensible balloon 27, positioned distally coincident with the larger distal portion of the outer balloon as in FIG. 3B. Inflation lumen 34, for the outer balloon 24, and inflation lumen 35 for the inner balloon 27 are also shown in FIG. 3B. Methods for fabricating such shaped, staged-inflation balloons are well described in the technical and patent literature. See, for example, U.S. Pat. Nos. 6,835,189; 6,488,653; 6,290,485; 6,022,359; 5,843,116; 5,620,457; 4,990,139; and 3,970,090, the full disclosures of which are incorporated herein by reference.

[0040] A handle assembly 40, as illustrated in FIG. 8A-8C, is secured to the proximal end 22 of the catheter body 18, as best seen in FIG. 8A. The handle assembly 40 includes both an inner core 42 and an outer grip 44, where the grip 44 can be axially advanced and retracted over the inner core between a proximally disposed position, as shown in FIG. 8A, to a distally disposed position, as shown in FIG. 8B. The outer grip can be locked at any position along inner core 42 using locking mechanism 48. The trocar penetration depth can be set using the trocar depth adjustment mechanism 49 which slides over the inner core 42 and can be locked in any position along inner core 42. Trocar depth adjustment mechanism 49 is shown in solid line in its most proximal position and in its most distal position in broken line.

[0041] The trocar 12 is received through a port 46 (FIG. 8c) in the grip 44 of the handle assembly 40 and is constrained to the grip by a locking mechanism such as a luer lock. The trocar 12 passes into the central lumen 30 of the catheter body 18 (FIG. 4-7), but motion of the trocar relative to the catheter body is controlled by moving the grip 44 proximally and distally relative to the inner core 42. The catheter body 18 is fixedly attached to the catheter adjustment mechanism of the inner core 42 of the handle assembly 40 so that the catheter body moves independently from the outer grip and the trocar. Motion of the catheter body relative to the inner core 42 and the handle assembly 40 as a whole is controlled by a catheter adjustment mechanism including a control knob 50 or slide mechanism (not shown).

[0042] The handle assembly 40 will be adapted so that it can be detachably secured to a proximal end of an endoscope when the catheter body 18 is within a working channel thereof. Typically, a distal end 56 of the inner core 42 will be secured to the port of the working channel of the endoscope. This is typically done using a locking mechanism such as a luer lock positioned at the proximal end of the endoscope working channel. Thus, the inner core 42 will be will be

immobilized relative to the endoscope (and usually the patient), but the trocar can be advanced relative to the endoscope and the catheter body 18 by moving the outer grip 44 from its proximal configuration, as shown in FIG. 8A, to a distal position, as shown in FIG. 8B. This is particularly useful for thrusting the trocar through tissue as will be described in more detail hereinbelow. The trocar depth adjustment mechanism 49 can be set at any point along inner core 42, thus limiting the distal travel distance of grip 44 and trocar 12.

[0043] Referring to FIGS. 4 & 8C, the handle assembly 40 further includes at least one port or connector 60 for attachment of an inflation medium to the inflation lumen 34 and optionally a second inflation port or connector 62 for attachment of an inflation medium to the inflation lumen 35 of the catheter body 18. The handle assembly 40 will also include a guidewire port 64 to allow introduction of a guidewire into the guidewire lumen 32 of the catheter body 18.

[0044] The present invention can use a wide variety of trocars, including trocars having actuatable blades for enlarging a trocar penetration, as described in detail in co-pending, commonly-owned provisional application 61/\_\_\_\_\_ (Attorney Docket No. 026923-001200US), filed on the same day as the present application, the full disclosure of which is incorporated herein by reference. It is desirable that the trocar have a relatively flexible distal portion since it will have to be advanced through central lumen 30 of the catheter body, where the catheter will often be angled or deflected in order to be directed at the target wall site by the endoscope. Thus, a first suitable trocar assembly 70 is illustrated in FIG. 9. Trocar 70 includes a solid core proximal portion having a reduced diameter distal portion 74 and a tissue-penetrating tip 76. To provide for flexibility yet retain sufficient column strength to permit tissue penetration, the reduced diameter section 74 will often be covered by a reinforcing coil spring 78.

[0045] An alternative trocar assembly 80, in the form of an open needle-like structure, is illustrated in FIG. 10. The needle-like trocar 80 comprises a tubular body 82 which is laser cut or otherwise formed to have a helically cut region 84 over a portion near the distal end thereof. The helical cuts provide for flexibility while maintaining sufficient column strength so that the chamfered, sharpened end 86 may be advanced through the tissue layers from the catheter, as described in more detail below. In yet other trocar assemblies, as shown in FIGS. 11A and 11B, at least a distal portion of the trocar is made of a flexible memory metal such as nitinol or elgiloy, shown with a faceted solid trocar tip 90 in FIG. 11A and with a chamfered hollow tip 91 in FIG. 11B. These materials provide improved flexibility over stainless steel or other similar metals. Alternately any of the trocar assemblies previously mentioned (or other conventional tissue penetrating probes) can be energized with radiofrequency (RF) current to provide or assist in tissue penetration. The RF current may be provided by conventional electrocautery power supplies operating in a cutting mode.

[0046] Referring now to FIGS. 12A-12K, a first transluminal access method according to the present invention will be described in detail. As shown in FIG. 12A, an endoscope E may be advanced into an internal body space, typically in the GI tract, such as the esophagus, the stomach, the duodenum, the small intestine or the large intestine, to identify a target location T on a first luminal wall or other tissue layer TL1. For example, the endoscope E may include a viewing element 300 (typically an optical fiber or a small camera) and an illumi-

nating source through a tube (typically an optical fiber or LED) to permit visualization. The endoscope E may also include an ultrasound transducer (not shown) positioned at the distal end near the viewing element 300 to allow endoscopic ultrasound (EUS). The endoscope E will also include a working channel 304 which may be used to advance the trocar and the transluminal access catheter in accordance with the principles of the present invention.

[0047] As shown in FIG. 12B, a distal end 20 of the access catheter 10 is advanced from the endoscope E so that the distal port 38 is adjacent the target location T. Once the location is confirmed (for example by endoscopic ultrasound (EUS)), the outer grip 44 on the handle assembly 40 may be advanced to thrust the distal end of trocar 12 forward so that it penetrates the tissue layers TL1 and TL2, as illustrated in FIG. 12B. The quick advancement of the trocar 12 helps assure that both layers are penetrated.

[0048] As shown in FIG. 12C, the access catheter 10 can then be advanced over the trocar 12 so that the distal portion 26 of the balloon 24 passes fully into the second body lumen while the proximal portion usually remains at least partially within the tissue penetrations P. After positioning the balloon 24, the distal portion 26 is inflated while the proximal portion 28 remains uninflated (or only partially inflated), as shown in FIG. 12D. The catheter body 18 may then be drawn proximally, as shown in FIG. 12E, so that the inflated distal portion 26 of the balloon 24 engages the second tissue layer TL2 to apply force to the tissue layer and to draw layers TL1 and TL2 into apposition. By drawing the tissue into apposition using the expanded distal portion 26, the unexpanded proximal portion 28 is positioned within the passages P which have been formed into the tissue layers TL1 and TL2. Thus, the uninflated proximal portion 28 of the balloon 24 is optimally positioned to be expanded to dilate the passages P, as shown in FIG. 12F. At any time after the balloon catheter 10 is introduced into the second body lumen, as shown beginning in FIG. 12C, it will be possible to exchange to the trocar 12 for a guidewire 14, with the exchange being shown in FIG. 12F.

[0049] After the passages P have been dilated, the balloon 24 may be drawn down (deflated), and the catheter body 18 advanced so that the side port 36 lies within the second body lumen, as illustrated in FIG. 12G. The second guidewire 14 may then be advanced into the second body lumen through side port 36. With both guidewires 14 now advanced into the second body lumen, the catheter body 18 may be withdrawn, leaving the two guidewires 14 in place to provide access from the working channel 304 of the endoscope into the second body lumen through the enlarged penetrations P, as shown in FIG. 12H.

[0050] With the two guidewires 14 in place, catheters and/or other therapeutic or working tools may be advanced into the second body lumen. As illustrated for example in FIG. 12I, when the second body lumen comprises a pseudocyst, a first catheter C1 may be used to deliver one or several 5 Fr to 10 Fr plastic straight or pigtail stent(s) (not shown) or a self-expanding stent S1, as illustrated in FIG. 12J. Suitable stents and delivery means are described in commonly-owned, co-pending patent application 12/\_\_\_\_\_ (Attorney Docket No. 026923-000710US), filed on the same day as the present application, the full disclosure of which is incorporated herein by reference. Conveniently, the second guidewire 14 may be used to deliver a second stent using a second catheter C2, as shown in FIG. 12J. The two deployed stents S1 and S2 present in the enlarged penetrations P are shown in FIG. 12K.

[0051] Referring now to FIGS. 13A-13C, the methods and systems of the present invention may also be used to advance a single guidewire to deploy a single stent or perform other interventional protocols using a single catheter or tool. When the transluminal access catheter 10 is in the position shown in FIG. 12F, the balloon 26 may be deflated and the catheter immediately withdrawn, leaving only the first guidewire 14 in place, as shown in FIG. 13A. A catheter C may then be advanced over the single guidewire 14 through the enlarged penetration P, as shown in FIG. 13B, and the catheter used to deploy a single stent S, as shown in FIG. 13C.

[0052] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A method for positioning two guidewires between a first body lumen and a second body lumen, said method comprising:

advancing a tissue penetrating tool from the first body lumen into the second body lumen to form a passage through the luminal walls;

advancing a balloon catheter over the trocar to position a dilation balloon within the passage;

inflating the balloon to dilate the passage;

exchanging a first guidewire for the tool;

advancing the catheter further into the second body lumen so that a side wire port on the catheter proximal of the balloon is within the second body lumen;

advancing a second guidewire through the side port into the second body lumen; and

withdrawing the balloon catheter to leave the first and second guidewires in place through the dilated passage.

2. A method as in claim 1, further comprising advancing a first stent placement catheter over the first guidewire and placing a first stent in the dilated passage.

3. A method as in claim 1, wherein the first body lumen is selected from the group consisting of the esophagus, the stomach, the duodenum, the small intestines and the large intestines and the second body lumen or structure is selected from the group consisting of a bile duct, a gallbladder, a pancreas, a pancreatic duct, a pancreatic pseudocyst, a urinary bladder, and a liver.

4. A method as in claim 2, further comprising advancing a second stent placement catheter over the second guidewire and placing a second stent in the dilated passage adjacent to the first stent.

5. A method as in claim 3, wherein the first body lumen is a stomach and the second body lumen is a pseudocyst.

6. A method for dilating a tissue passage between a first body lumen and a second body lumen or structure, said method comprising:

advancing a tissue penetrating tool from the first body lumen into the second body lumen to form a passage through the luminal walls;

advancing a balloon catheter over the tool to position a distal portion of a dilation balloon beyond the passage to within the second body lumen or structure;

inflating said distal portion of the balloon beyond the passage while a proximal portion of the balloon remains uninflated;

tensioning the balloon catheter proximally so that said inflated distal portion of the balloon engages the wall of

the second body lumen and draws the second wall against the first wall to place said walls in apposition; and

inflating the proximal portion of the balloon to dilate the passage through the tissue layers.

7. A method as in claim 6, wherein the first body lumen is selected from the group consisting of the esophagus, the stomach, the duodenum, the small intestines and the large intestines and the second body lumen or structure is selected from the group consisting of a bile duct, a gallbladder, a pancreas, a pancreatic duct, a pancreatic pseudocyst, a urinary bladder, and a liver.

8. A method as in claim 6, further comprising exchanging the trocar for a guidewire.

9. A method as in claim 8, further comprising advancing a stent placement catheter over the guidewire and placing a stent in the dilated passage.

10. A transluminal access system comprising:

a first guidewire;

a second guidewire;

a tissue penetrating tool; and

a transluminal access catheter including:

(a) a catheter body having a proximal end, a distal end, a central lumen and a side lumen; and

(b) a dilation balloon on the catheter body near the distal end;

wherein the central lumen extends from the proximal to the distal end of the catheter body and exchangeably receives the tool and the first guidewire and wherein the side lumen extends from the proximal end of the catheter body to a location immediately proximal of the dilation balloon and removably receives the second guidewire.

11. A system as in claim 10, wherein the catheter further includes

(c) a handle assembly attachable to the proximal end of the catheter body, wherein the handle is configured to lock to an endoscope when the catheter body is within a working channel of the endoscope.

12. A system as in claim 11, wherein the handle comprises an inner core which couples to the catheter body and an outer

grip which couples to the tool, wherein a user can advance and retract the grip relative to the inner core to advance and retract the tool relative to the catheter body.

13. A system as in claim 12, further comprising a catheter body adjustment mechanism movably positioned in the inner core to axially advance and retract the catheter body relative to the inner core, outer grip, and the tool.

14. A system as in claim 13, further comprising a tool depth adjustment mechanism on the catheter body to limit the distal motion of the outer grip and the tool puncture depth.

15. A system as in claim 13, further comprising a tool looking mechanism on the outer grip to holder the outer grip and tool in a fixed position relative to the inner core.

16. A catheter and penetrating tool assembly comprising: a catheter body having a proximal end, and distal end, and a central lumen;

a tissue penetrating tool slidably disposed in the central lumen, said tool having a tissue-penetrating distal end; and

a handle attachable to the proximal end of the catheter body, said handle including an inner core with a catheter advancement mechanism which couples to the catheter body and an outer grip which couples to the tool, wherein a user can advance and retract the grip relative to the inner core to advance and retract the tool relative to the catheter body.

17. An assembly as in claim 16, further comprising a catheter body adjust mechanism on the inner core to axially advance and retract the catheter body relative to the handle and the tool.

18. An assembly as in claim 17, further comprising a tool adjustment mechanism on the outer grip to axially advance and retract the tool relative to the handle and the catheter body.

19. An assembly as in claim 16, wherein the tissue penetrating tool comprises a trocar.

20. An assembly as in claim 16, wherein the tissue penetrating tool has an electrosurgical tip which permits radiofrequency current assisted tissue penetration.

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