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(54) **Title**: A SYSTEM AND METHOD FOR SUBMUCOSAL TUNNELING OF THE GI TRACT FOR THE DIVERSION OF BODILY FLUIDS

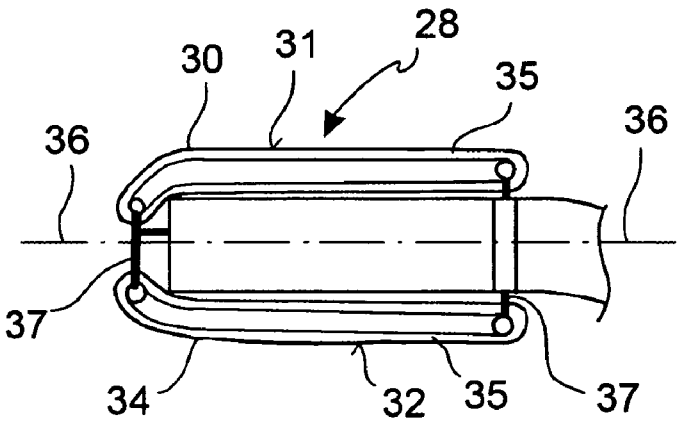

FIG. 3

(57) **Abstract**: A system for submucosal tunneling an intestinal wall (10) comprises a tunneling head (28) adapted to be inserted between a first layer (15) and an adjacent second layer (29) of the intestinal wall (10), a layer separation assembly (30) with a first layer guide (31) and a second layer guide (32) arranged to diverge the first layer (15) from the second layer (29) when the tunneling head (28) is moved in a forward direction, and an activating mechanism (33) operable to move the tunneling head (28) in the forward direction, thereby separating the first (15) and second layer (29) from each other.

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DESCRIPTION

"A SYSTEM AND METHOD FOR SUBMUCOSAL TUNNELING OF THE GI TRACT FOR THE DIVERSION OF BODILY FLUIDS"

The present invention relates, in general, to devices and methods for surgically influencing the digestion of a patient with the aim to treat metabolic disorders, such as morbid obesity and related co-morbidities, such as diabetes, heart disease, stroke, pulmonary disease, and accidents.

Numerous non-operative therapies for morbid obesity have been tried in the past with virtually no permanent success.

Surgical methods of treating morbid obesity, such as open, laparoscopic and endoluminal gastric bypass surgery aiming to permanent malabsorption of the food, have been increasingly used with greater success. However, current methods for performing a gastric bypass involve time-consuming and highly dexterity dependent surgical techniques as well as significant and generally highly invasive modifications of the patients gastrointestinal anatomy. These procedures are reserved only for the severely obese patients because they have a number of significant complications, including the risk of death. In order to avoid the drawbacks of gastric bypass surgery and to influence the digestion of a patient in a more specific and aimed way, the present invention focuses on methods and devices for primarily influencing and modifying the entero-hepatic bile cycling rather than the digestive tract itself. To this end, the following possible approaches and mechanisms of action on the entero-hepatic bile cycling are contemplated:

- modification of the entero-hepatic bile cycling frequency, particularly bile cycle acceleration;
- modification of the physiological signaling triggered by the contact and interaction of the bile with the food in the intestine and by the contact of the bile with the intestinal wall;
- modification of the food absorbability by modifying the contact space and time between the bile and the food or chime in the intestine as well as by an aimed separation of the bile from the food.

A known minimally invasive bypass system and method for modifying the location at which bile and pancreatic secretions interact with nutrients in a gastrointestinal tract has been discussed in US 2005085787 A1. The known system comprises a conduit having a first end which diverts bile and pancreatic secretions from the ampulla of Vater to a location downstream in the gastrointestinal tract and a second end attached to the ampulla of Vater.

The known conduit catheters tend to bundle up and to be displaced by the peristalsis of

the intestinal tract so that the distal end of the catheter is frequently relocated far away from the target position intended by the surgeon.

In view of the drawbacks of the known art, there is a need to provide a minimally invasive device and method of diverting bodily fluids, such as bile and pancreatic juices from their physiological flow path, e.g. the biliary tree including the gallbladder, into a section of the intestine distally to the papilla of Vater, which obviate undesired relocations of the diversion conduit from the target location.

There is a further need to avoid kinking, bending and interference of the diversion conduit with intestinal contents.

At least part of the above identified needs are met by a method for diverting bodily fluid, particularly biliopancreatic juices, from a physiological fluid flow path, e.g. the biliary tree, to a target location in the intestine distal to a duodenal papilla of Vater, the method comprising the steps of extending a catheter from the physiological fluid flow path, particularly the biliary tree, to said target location in the intestine and anchoring the catheter along at least a portion of its length to an intestinal wall.

This obviates the risk of bundling up and undesired relocations of the catheter.

The catheter may be anchored to the intestinal wall continuously or intermittently by a sequence of anchoring points, preferably along a prevalent portion which is greater than halve of its entire length or at least along a portion near a distal end of the catheter which may be shorter than halve of the entire catheter length.

In accordance with an aspect of the invention, a proximal end portion of the catheter is arranged within the biliary tree. This makes it possible to capture the bile and or pancreatic juices upstream (proximally to) the sphincter of Oddi and to reliably fixate the relative position of the proximal catheter end portion and the physiological bile flow path.

In accordance with an aspect of the invention, the method comprises the steps of creating a submucosal conduit path in the intestinal wall and extending the catheter from the physiological fluid flow path, particularly the biliary tree, through the submucosal conduit path in the intestinal wall to the target location in the intestine.

This makes it possible to extend at least a section of the catheter in the intestinal wall separate from the internal space of the intestine, so that it is reliably anchored and much less subject to peristalsis and direct contact with the chime.

In accordance with an aspect of the invention, the method comprises the steps of:

- creating a proximal otomy through the thickness of the mucosa in the duodenal wall (near the ampulla of Vater),
- inserting a submucosal tunneling device through the proximal otomy in the duodenal wall

and advancing the tunneling device distally to a target portion of intestine, such as the jejunum or ileum, thereby creating the submucosal conduit path in the intestinal wall,

- creating a distal otomy through the thickness of the mucosa to open the submucosal conduit path into the target portion of intestine,
- extracting the tunneling device from the submucosal conduit path,
- inserting the catheter in the submucosal conduit path so that a proximal end portion of the catheter emerges from the proximal otomy into the duodenum and a distal end portion of the catheter emerges from the distal otomy into the target portion of the intestine,
- inserting the proximal end portion of the catheter through the papilla of Vater into the biliary tree,
- fixating the proximal end portion of the catheter in the biliary tree.

In this way a continuous submucosal conduit path starting from the duodenum near the papilla of Vater is provided to receive and reliably hold the bile diversion catheter.

In accordance with a further aspect of the invention, the submucosal tunneling is performed starting from the stomach for gaining easier access with the tunneling device. In this case the method comprises the steps of:

- creating a first otomy through the thickness of the mucosa in the stomach wall,
- inserting a submucosal tunneling device through the first otomy in the stomach wall and advancing the tunneling device distally along the GI tract to a target portion of intestine, such as the jejunum or ileum, thereby creating a submucosal conduit path in the intestinal wall,
- creating a distal otomy through the thickness of the mucosa to open the tunnel into the target portion of intestine,
- extracting the tunneling device from the submucosal conduit path ,
- inserting the catheter through the first otomy in the submucosal conduit path so that a distal end portion of the catheter emerges from the distal otomy into the target portion of the intestine,
- creating a proximal otomy through the thickness of the mucosa to the tunnel in the duodenal wall near the ampulla of Vater,
- pulling a proximal end portion of the catheter, through the proximal otomy, from the tunnel into the duodenum,
- inserting the proximal end portion of the catheter through the papilla of Vater into the biliary tree,
- fixating the proximal end portion of the catheter in the biliary tree.

In accordance with an aspect of the invention, in order to speed up the procedure, an

intermittent sequence of submucosal tunnels are created in the intestinal wall, rather than one single continuous tunnel, and the catheter is inserted in the sequence of submucosal tunnels which protect the catheter and anchor it to the intestinal wall at preferably regular intervals.

In accordance with a yet further aspect of the invention, an anchorage of the catheter at intervals can be obtained by

- endoluminal positioning a plurality of anchoring rings inside the intestine between the duodenum near the papilla of Vater and a target portion of intestine distal to the papilla of Vater and connecting the anchoring rings to the intestinal wall,
- inserting the catheter through the anchoring rings, so that a distal end portion of the catheter emerges from a distal ring of the anchoring rings into the target portion of the intestine and a proximal end portion of the catheter emerges from a proximal ring of the anchoring rings into the duodenum,
- inserting the proximal end portion of the catheter through the papilla of Vater into the biliary tree,
- fixating the proximal end portion of the catheter in the biliary tree.

At least part of the above identified needs are also met by a system for submucosal tunneling an intestinal wall, the system comprising:

- a tunneling head adapted to be inserted between a first layer and an adjacent second layer of the intestinal wall,
- a layer separation assembly connected to the tunneling head and having a first layer guide adapted to rest against the first layer and a second layer guide adapted to rest against the second layer, the first and second layer guides being arranged to diverge the first layer from the second layer when the tunneling head is moved in a forward direction inside the intestinal wall,
- a tunneling activating mechanism operable to move the tunneling head in the forward direction, thereby separating the first and second layer from each other.

This allows a continuous, easy and fast tunneling between selected layers of tissue of an intestinal wall. In accordance with an aspect of the invention, the tunneling activating mechanism is also operable to drag at least one of the first and second layers along the layer dissection assembly in a backward direction opposite the forward direction.

By dragging the tissue layer actively in the direction against the forward movement of the tunneling head, the intestinal wall is held tense at the point of separation of the tissue layers, obviating undesired local deformation and crinkling.

In accordance with an aspect of the invention, the layer separation assembly comprises at

least one belt and pulley system having a belt adapted to frictionally engage at least one of the first and second tissue layers and movable with respect to the tunneling head to drag the at least one of the first and second tissue layers in the backward direction, thereby advancing the tunneling head in the forward direction and separating the first and second tissue layers.

In accordance with a further aspect of the invention, the tunneling activating mechanism comprises at least one drive cable, belt or chain, guided at the tunneling head in movement transmission relationship with the pulley and belt system and extending from the tunneling head in the backward direction to an (extracorporeal) activating means for transmitting an activating movement from the (extracorporeal) activating means to the pulley and belt system.

In accordance with a further aspect of the invention, the tunneling activating mechanism comprises a magnetically susceptible coupling seat arranged at the tunneling head on a side intended to face inside the intestine, and an endoluminal pusher connectable to an endoscope and having a magnetic coupling roller adapted to magnetically connect to the coupling seat through the first layer (mucosa) of the intestinal wall and to transmit a forward movement of the endoluminal pusher to the tunneling head.

This allows to simplify the tunneling system by arranging the traction mechanisms outside the tunneling head and to precisely moving the tunneling device by means of an endoscope under direct endoscopic visualization of the coupling roller.

In accordance with an aspect of the invention, the coupling seat is formed in the first guide of the layer separation assembly and the coupling roller is adapted to frictionally engage the first layer (mucosa) of the intestinal wall so that, during a forward movement of the endoluminal pusher, the coupling roller moves also the tunneling head in the forward direction and rolls in a forward direction over the first layer (mucosa) thereby dragging the latter in the backward direction over the layer separation assembly.

In accordance with an aspect of the invention, the layer separation assembly comprises at least one dissector spray nozzle connected to a fluid duct and operable to spray jets of a fluid, e.g. saline solution or CO_2, between the first and second layer to facilitate their separation.

At least part of the above identified needs are also met by a catheter for submucosal tunneling an intestinal wall, the catheter comprising:

- a distal tip adapted to be inserted between a first layer and an adjacent second layer of the intestinal wall,
- a proximal end portion adapted to be connected to an injection fluid source,

- a tubular wall extending between the distal tip and the proximal end portion,

wherein the tubular wall defines:

- an internal injection fluid channel extending from the proximal end portion to a region near the distal tip,

- at least one injection hole provided near the distal tip and adapted to inject fluid from the injection fluid channel in the interstice between the first and second layer,

- a concave fluid drainage channel separate from the injection fluid channel and in fluid communication with an external surface of the tubular wall.

The thus configured tunneling catheter enables an access to a submucosal space of the intestinal wall and allows the simultaneous introduction and drainage of a pressurized dissecting fluid.

In accordance with an aspect of the invention, the concave fluid drainage channel comprises an externally open channel formed by the external surface of the tubular wall.

In accordance with a further aspect of the invention, the concave fluid drainage channel is formed inside the tubular wall and separated from the injection fluid channel by a septum.

At least part of the above identified needs are also met by an endoluminal submucosal access device, comprising:

- a tissue manipulation head defining a tissue attachment region,

- a plurality of suction openings formed in the tissue attachment region, the suction openings being connected to a vacuum suction system and adapted to hold a portion of mucosa of the intestinal wall tight against the attachment region,

- a guide channel adapted to slidingly receive a piercing wire, the guide channel having an exit section which opens into the tissue attachment region at an angle to the attachment region that directs the piercing wire in the planned submucosal space.

A thus configured submucosal access device enables and facilitates a safe, precise and repeatable creation of the above said otomies which form the starting end/or end points of the submucosal conduit path.

These and other aspects and advantages of the present invention shall be made apparent from the accompanying drawings and the description thereof, which illustrate embodiments of the invention and, together with the general description of the invention given above, and the detailed description of the embodiments given below, serve to explain the principles of the present invention.

- Figure 1 illustrates a method for a submucosal diversion of bile in accordance with an embodiment of the invention;

- Figure 2 is a cross-sectional view of a portion of a catheter for a submucosal diversion of

bile in accordance with an embodiment of the invention;

- Figure 3 is a schematic side view of a device for a submucosal tunneling of an intestinal wall in accordance with an embodiment of the invention;

- Figure 4 is a schematic side view of a device for a submucosal tunneling of an intestinal wall in accordance with a further embodiment of the invention;

- Figure 5 is a schematic perspective view of the device in figure 4;

- Figure 6 illustrates a method for a submucosal diversion of bile in accordance with an embodiment of the invention;

- Figure 6A is a schematic longitudinal sectional view of a sequential submucosal conduit path in figure 6;

- Figure 7 illustrates a method for a diversion of bile by means of an anchored bile conduit in accordance with an embodiment of the invention;

- Figures 8, 9 and 10 illustrate method steps and an instrumentation for a submucosal tunneling of an intestinal wall in accordance with an embodiment of the invention;

- Figures 11, 12 and 13 illustrate method steps and an instrumentation for a submucosal separation of tissue layers of an intestinal wall in accordance with further embodiments of the invention;

- Figures 14 to 17 cross-sectional views of a catheter for a submucosal tunneling of an intestinal wall in accordance with embodiments of the invention;

- Figures 18 to 20 are schematic side views of a catheter and of catheter tips for a submucosal tunneling of an intestinal wall in accordance with embodiments of the invention;

- Figure 21 is a schematic longitudinal sectional view of an endoluminal submucosal access device in accordance with an embodiment of the invention;

- Figure 22 is a schematic perspective view of the submucosal access device in Figure 21.

Referring to the drawings where like numerals denote like anatomical structures and components throughout the several views, figure 1 is a partial view of the abdominal cavity of a patient, depicting the stomach 1, duodenum 2, ileum 3, colon 4, as well as the biliary tree 5 with gall bladder 6, the pancreatic duct 7 and the mayor duodenal papilla of Vater 8 through which the bile and pancreatic fluid normally enter the duodenum 2. Figure 1 shows further a method for diverting bodily fluid, particularly biliopancreatic juices, from a physiological fluid flow path, e.g. the biliary tree 5, to a target location in the intestine distal to the duodenal papilla of Vater 8.

In accordance with a general inventive idea, the method comprises the steps of extending a catheter 9 from the physiological fluid flow path, particularly the biliary tree 5, to said

target location in the intestine and anchoring the catheter 9 along at least a portion of its length to an intestinal wall 10.

This obviates the risk of bundling up and undesired relocations of the catheter 9.

The catheter 9 may be anchored to the intestinal wall 10 continuously or intermittently by a sequence of anchoring points, preferably along a prevalent portion which is greater than halve of the entire catheter length or at least along a portion near a distal end of the catheter 9 which may be shorter than halve of the entire catheter length.

A proximal end portion 11 of the catheter 9 may be arranged directly within the biliary tree 5 to capture the bile and or pancreatic juices upstream (proximally to) the sphincter of Oddi and to reliably fixate the relative position of the proximal catheter end portion 11 and the physiological bile flow path (Figures 1, 6 and 7).

In accordance with an exemplary embodiment (Figure 1), a submucosal conduit path 12 may be created in the intestinal wall 10 and the catheter 9 may be extended from the physiological fluid flow path, particularly the biliary tree 5, through the submucosal conduit path 12 in the intestinal wall 10 to the target location 13 in the intestine.

In this manner, at least a section of the catheter 9 is extended within the intestinal wall 10 separate from the internal space of the intestine, so that it is reliably anchored and much less subject to peristalsis and direct contact with the chime.

In accordance with an embodiment (Figure 1), an endoscope is inserted transorally in the duodenum 2 near the papilla of Vater 8 and a small proximal otomy 14 is created through the thickness of the mucosa 15 in the duodenal wall 10 near the ampulla of Vater 8, preferably distally to the ampulla of Vater 8 at a distance of about 3 cm to 15 cm to the latter. The otomy may be created by a heated wire or radiofrequency energized wire or other endoscopic surgical cutting instrument 16 which can be advanced to the surgical site through an instrument channel 17 of the endoscope 18 (Figure 8). Then, the cutting instrument 16 is extracted from the proximal otomy 14 and a submucosal tunneling device, embodiments of which will be described below in greater detail, is inserted through the proximal otomy 14 in the duodenal wall 10 and advanced distally to a target portion of intestine, such as the jejunum or the ileum, thereby creating the submucosal conduit path 12 in the intestinal wall 10. Then, a distal otomy (not illustrated in the figures) is created through the thickness of the mucosa 15 to open the submucosal conduit path 12 into the target portion of intestine and the tunneling device is eventually extracted. Subsequently, the catheter 9 is endoluminally advanced to the proximal otomy 14, e.g. through the instrument channel of the endoscope 18, and inserted through the proximal otomy 14 into the submucosal conduit path 12 so that the proximal end portion 11 of the catheter 9

emerges from the proximal otomy 14 into the duodenum 2 near the papilla of Vater 8 and a distal end portion 19 of the catheter 9 emerges from the distal otomy into the target portion 13 of the intestine. Before or after arranging the catheter 9 inside the submucosal conduit path 12, the proximal end portion 11 of the catheter 9 is inserted endoluminally through the papilla of Vater 8 into the biliary tree 5.

In accordance with an embodiment, the insertion of the proximal end portion 11 of the catheter 9 into the biliary tree 5 can be accomplished using e.g. an ERCP (Endoscopic Retrograde Cholangio Pancreatography) like technique. The ERCP procedure involves passing a flexible endoscope 18 through the mouth, esophagus, and stomach into the duodenum near the papilla of Vater 8. The doctor then passes a guide wire or directly the catheter 9 through a channel in the endoscope and out into view in the duodenum 2 and inserts it into the papilla of Vater 8. The proximal end portion 11 of the catheter 9 can be fixated in the biliary tree, e.g. by means of an anchoring stent. At the end of the procedure, the deployment instruments and the endoscope 18 are extracted from the body of the patient.

In this way a continuous submucosal conduit path starting from the duodenum near the papilla of Vater is provided to receive and reliably hold the bile diversion catheter.

In accordance with a further exemplary embodiment, the submucosal tunneling may be performed starting from the stomach 1 for gaining easier access with the tunneling device. In this embodiment, an endoscope is inserted transorally to a target zone in the stomach 1 and a small first otomy (not illustrated in the figures) is created through the thickness of the mucosa 15 in the gastric wall 10. The otomy may be created by a heated wire or radiofrequency energized wire or other endoscopic surgical cutting instrument 16 which can be advanced to the surgical site through an instrument channel 17 of the endoscope 18. Then, the cutting instrument 16 is extracted from the first otomy and a submucosal tunneling device is inserted through the first otomy in the gastrointestinal wall and advanced distally to the target portion of intestine, thereby creating the submucosal conduit path 12 in the intestinal wall 10. Then, a distal otomy (not illustrated in the figures) is created through the thickness of the mucosa 15 to open the submucosal conduit path 12 into the target portion of intestine and the tunneling device is eventually extracted.

Subsequently, the catheter 9 is endoluminally advanced to the first otomy, e.g. through the instrument channel of the endoscope 18, and inserted through the first otomy into the submucosal conduit path 12 so that the distal end portion 19 of the catheter 9 emerges from the distal otomy into the target portion 13 of the intestine. Then the endoscope 18 is inserted in the duodenum 2 near the papilla of Vater 8 and a small proximal otomy 14 is

created through the thickness of the mucosa 15 into the conduit path 12 in the duodenal wall 10 near the ampulla of Vater 8, preferably distally to the ampulla of Vater 8 at a distance of about 3 cm to 15 cm to the latter. The proximal end portion 11 of the catheter 9 is then pulled through the proximal otomy 14 out of the submucosal conduit path 12 into the duodenum 2 and inserted through the papilla of Vater 8 into the biliary tree 5. The proximal end portion 11 of the catheter 9 can be fixated in the biliary tree, e.g. by means of an anchoring stent. At the end of the procedure, the deployment instruments and the endoscope 18 are extracted from the body of the patient.

In accordance with an embodiment (Figures 6 and 6A), in order to speed up the procedure, an intermittent sequence of submucosal tunnels 20 (spaced by regions 22 where the catheter 9 is intended to be exposed) are created in the intestinal wall 10, rather than one single continuous submucosal conduit path 12, and the catheter 9 is inserted in the sequence of submucosal tunnels 20 which protect the catheter 9 and anchor it to the intestinal wall 10, e.g. at preferably regular intervals of about 15cm to 20cm distance between the tunnels 20 and length of the individual tunnels 20.

In accordance with an embodiment illustrated in figure 7, a fixation of the catheter 9 at intervals can be obtained by endoluminally positioning a plurality of anchoring rings 21 inside the intestine between the duodenum 2 near the papilla of Vater 8 and the target location 13 distal to the papilla of Vater 8 and connecting the anchoring rings 21 to the intestinal wall 10. After placement of the anchoring rings 21 which are preferably made of biocompatible plastic or metal, the catheter 9 can be inserted endoscopically through an annular seat of the anchoring rings 21, so that the distal end portion 19 of the catheter 9 is held by or emerges from a distal ring of the anchoring rings 21 near the target portion of the intestine and the proximal end portion 11 of the catheter 9 emerges from a proximal ring of the anchoring rings 21 into the duodenum 2.

Before or after insertion of the catheter 9 in the anchoring rings 21, the proximal catheter end portion 11 is inserted through the papilla of Vater 8 and fixated in the biliary tree 5 as described above in connection with the previous embodiments.

Advantageously, the endoscopic anchoring rings 21 comprise the above said annular seat adapted to receive the catheter 9 and an anchoring portion protruding radially outward from the annular seat and adapted to be anchored in the intestinal wall, e.g. by means of a T - anchoring shape or a root portion with a staple hole or suture hole adapted to be connected by a surgical staple or suture to the intestinal wall 10.

The otomies for accessing the submucosal space may be created by cutting or piercing into a previously created submucosal bleb, e.g. a saline solution bleb accomplished by

injecting a saline solution in the interface between the mucosa and the submucosa of the intestinal wall.

The catheter 9 may have internal or external bile conveying channels 22 (Figure 2) which may be additionally surface coated to increase adherence of the bodily fluid intended to be conveyed.

The submucosal tunneling of the intestinal wall 10 can be accomplished using standard methods of endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD) for opening a passage the mucosa layer and the underlying muscularus. In a first step, a guide wire may be advanced in the interface between the mucosa and the submucosa or muscolarus to create a smaller size submucosal path and, in a subsequent step, a catheter provided with one or more dilating portions, such as a series of balloon dilators, may be advanced through the smaller size submucosal path and dilating it to the desired dimensions.

Additionally, a path of separated tissue layers for the catheter to pass may be created by syringe injection (Figures 11 and 12) of a dilating fluid, such as saline solution, in the submucosal space, along the planned extension of the submucosal conduit path. For this purpose, a multi-needle injector 23 (Figures 12 and 13) may be provided, which comprises an injection head 24, a connector portion 25 extending from the injection head 24 and adapted do connect the injector 23 to an endoscope 18, as well as an injection needle array 26 with at least one line of injection needles protruding laterally outward from the injection head 24 and connected to an injection fluid pumping system (not illustrated). In accordance with an embodiment, the needle array 26 is arranged in an elongate cavity or groove 27 adapted to receive the bleb created by the needle injection during advancement of the endoscope with the multi-needle injector 23.

It may be in any case advantageous to move the scope together with the submucosal tunneling device or dilating device in order to assure a permanent visualization of the tunneling site from inside the intestine.

Figures 3-5 and 9-10 illustrate further systems for submucosal tunneling the intestinal wall 10. The system comprises a tunneling head 28 adapted to be inserted between a first layer (e.g. the mucosa 15) and an adjacent second layer (e.g. the muscularus or submucosa 29) of the intestinal wall 10, a layer separation assembly 30 connected to the tunneling head 28 and having a first layer guide 31 adapted to rest against the first layer 15 and a second layer guide 32 adapted to rest against the second layer 29, the first and second layer guides 31, 32 being arranged to diverge the first layer 15 from the second layer 29 when the tunneling head 28 is moved in a forward direction inside the intestinal

wall 10. A tunneling activating mechanism 33 is operable to move the tunneling head 28 in the forward direction, thereby separating the first 15 and second layer 29 from each other. This allows a continuous, safe and fast tunneling between selected layers of tissue of the intestinal wall 10.

In accordance with an embodiment, the tunneling activating mechanism 33 is also operable to drag at least one of the first 15 and second layers 29 along the layer separation assembly 30 in a backward direction opposite the forward direction. By dragging the tissue layer, e.g. the mucosa layer 15 actively in the direction against the forward movement of the tunneling head 28, the intestinal wall 10 is held tense at the point of separation of the tissue layers 15, 29, obviating their local deformation and crinkling.

In an exemplary embodiment (Figures 3-5), the layer separation assembly 30 comprises at least one, preferably two belt and pulley systems 34 having a belt 35 adapted to frictionally engage at least one of the first 15 and second tissue layers 29 and movable with respect to the tunneling head 28 to drag the at least one of the first and second tissue layers 15, 29 in the backward direction, thereby advancing the tunneling head 28 in the forward direction and separating the first and second tissue layers 15, 29. Advantageously, the two belt and pulley systems 34 are arranged on two diametrically or radially opposite sides of the tunneling head 28 with respect to a longitudinal axis 36 of the latter and comprise a support structure 37 which may form part of an autonomous tunneling head 28 and which may also be adapted to connect the layer separation assembly 30 to an endoscope 18.

The tunneling activating mechanism 33 may comprise at least one drive cable 38, such as a string, belt, thread, cord or chain, guided at the tunneling head 28 in movement transmission relationship with the pulley and belt system 34 and extending from the tunneling head 28 in the backward direction to an (extracorporeal) activating means (not illustrated) for transmitting an activating movement from the activating means to the pulley and belt system 34.

In accordance with an exemplary embodiment, the drive cable 38 is guided at least along a section of its extension in an instrument channel 17 of the endoscope 18 carrying the tunneling system or in a dedicated longitudinal channel of the tunneling head 28.

In accordance with a further embodiment (Figure 10), the tunneling activating mechanism 33 may comprise a magnetically susceptible coupling seat 39 containing ferromagnetic or magnetic material, arranged at the tunneling head 28 on a side intended to face inside the intestine (i.e. from inside the intestinal wall towards the mucosa 15), and an endoluminal

pusher 40 with a connector 41 for the detachable connection of the pusher 40 to an endoscope 18, and a magnetic coupling roller 42 adapted to magnetically connect to the coupling seat 39 through the first layer (mucosa 15) of the intestinal wall 10 and to transmit a forward movement of the endoluminal pusher 40 to the tunneling head 28. This simplifies the tunneling system by arranging the traction mechanisms outside the tunneling head 28 and allows to precisely moving the tunneling system by means of an endoscope under direct endoscopic visualization of the coupling roller 42.

In accordance with an embodiment, the coupling seat 39 is formed in the first layer guide 31 of the layer separation assembly 30 and the coupling roller 42 is adapted to frictionally engage the first layer (mucosa 15) from inside the intestine so that, during a forward movement of the endoluminal pusher 40, the coupling roller 42 moves also the tunneling head 28 in the forward direction and rolls in a forward direction over the first layer (mucosa 15) thereby dragging the latter in the backward direction over the layer separation assembly 30.

Advantageously, the coupling seat 39 comprises a concavity and the coupling roller 42 comprises a substantially ball-shaped or partially spherical or ellipsoid rolling member adapted to engage the concavity of the coupling seat 39 to assist the transmission of the forward movement.

The layer separation assembly 30 may further comprise one or more dissector spray nozzles 43 connected to a fluid conduit 44 and operable to spray jets of a fluid, e.g. saline solution or CO_2, between the first and second tissue layer to facilitate their separation. In this embodiment, a smooth circumferential (and preferably convex) sealing surface 45 may be formed around the layer separation assembly 30 or around the tunneling head 28 on a proximal side of (i.e. doctor's side or backward with respect to) the spray nozzles 43. The sealing surface 45 is adapted to intimately rest against the adjacent tissue to delay the sprayed fluid from draining backwards and generate a local fluid pressure increase at the dissecting site.

As can be seen in figures 3 and 10 the layer guides 31, 32 may be curved or inclined to each other such as to taper the layer separation assembly 30 in the forward direction.

Figures 14 to 20 illustrate further systems for submucosal tunneling the intestinal wall 10. These systems comprise a tunneling catheter 46 with a distal tip 47 adapted to be inserted between the first layer 15 and an adjacent second layer 29 of the intestinal wall 10, a proximal end portion 48 adapted to be connected to an injection fluid source (not illustrated) and a tubular wall 49 extending between the distal tip 47 and the proximal end portion 48. The tubular wall 49 defines an internal injection fluid channel 50 which extends

from the proximal end portion 48 to a region near the distal tip 47, at least one injection hole 51 provided near the distal tip 47 and adapted to inject fluid from the injection fluid channel 50 in the interstice between the first 15 and second layer 29, as well as a concave drainage channel 52 separate from the injection fluid channel 51 and in fluid communication with an external surface 53 of the tubular wall 49.

The thus configured tunneling catheter enables an access to the submucosal space of the intestinal wall 10 and allows the simultaneous introduction and drainage of a pressurized dissecting fluid, e.g. saline solution or CO_2.

The concave drainage channel 52 may comprise an externally open channel formed by the external surface 53 of the tubular wall 49 or, alternatively, the drainage channel 52 may be formed inside the tubular wall 49 and separated from the injection fluid channel 50 by a septum 54. Advantageously, the septum 54 forms a stiffening wall against local crouching or collapse of the flow section of the catheter.

Figures 14 and 15 illustrate possible cross-sections of the tunneling catheter 46 in the region of the distal tip 47, in which the tubular wall 49 defines only the injection fluid channel 50, while the drainage channel 52 ends proximally thereto, and may form an internally protruding stiffening wall against local crouching or collapse of the flow section of the catheter.

The distal tip 47 may be tapered or corkscrew shaped to facilitate the insertion between the tissue layers by pushing and/or rotating the tip 47 (Figures 19 and 20) during advancement of the tunneling catheter 46.

The present invention further contemplates a submucosal tunneling system with an endoluminal submucosal access device 55 (Figures 21 and 22) which comprises a tissue manipulation head 56 defining a tissue attachment region 57 and a plurality of suction openings 58 formed in the tissue attachment region 57. The suction openings 58 are connected to a vacuum suction system (not illustrated in detail) and adapted to hold a portion of mucosa 15 of the intestinal wall 10 tight against the attachment region 57. A guide channel 59 for a piercing wire 60 is formed in the tissue manipulation head 56 which comprises a channel exit section 61 which opens into the tissue attachment region 57 in a forward direction at an angle to the attachment region 57 that directs the piercing wire 60 in the planned submucosal space.

The submucosal access device 55 enables and facilitates a safe, precise and repeatable creation of the above said otomies which form the starting end/or end points of the submucosal conduit path 12.

Even though the functional aspects of the systems and devices for the creation of the

submucosal conduit path have been described in connection with these instruments, these functional aspects are at the same time possible embodiments and substeps of the submucosal tunnelization phases of the initially described methods.

Although preferred embodiments of the invention have been described in detail, it is not the intention of the applicant to limit the scope of the claims to such particular embodiments, but to cover all modifications and alternative constructions falling within the scope of the invention.

CLAIMS

1. A system for submucosal tunneling an intestinal wall (10), the system comprising:

- a tunneling head (28) adapted to be inserted between a first layer (15) and an adjacent second layer (29) of the intestinal wall (10),
- a layer separation assembly (30) connected to the tunneling head (28), the layer separation assembly (30) having a first layer guide (31) adapted to rest against the first layer (15) and a second layer guide (32) adapted to rest against the second layer (29), the first and second layer guides (31, 32) being arranged to diverge the first layer (15) from the second layer (29) when the tunneling head (28) is moved in a forward direction inside the intestinal wall (10),
- an activating mechanism (33) operable to move the tunneling head (28) in the forward direction, thereby separating the first (15) and second layer (29) from each other.

2. A system according to claim 1, in which the tunneling activating mechanism (33) is operable to drag at least one of the first and second layers (15, 29) along the layer separation assembly (30) in a backward direction opposite the forward direction.

3. A system according to claim 2, in which the layer separation assembly (30) comprises at least one belt and pulley system (34) having a belt (35) adapted to frictionally engage at least one of the first and second tissue layers (15, 29) and movable to drag the tissue layer (15; 29) in the backward direction, thereby advancing the tunneling head (28) in the forward direction.

4. A system according to claim 3, in which two belt and pulley systems (34) are arranged on two opposite sides of the tunneling head (28).

5. A system according to any one of the preceding claims, comprising a support structure (37) adapted to connect the layer separation assembly (30) to an endoscope (18).

6. A system according to claim 3, in which the activating mechanism (33) comprise at least one drive cable (38) guided at the tunneling head (28) in movement transmission relationship with the pulley and belt system (34) and extending from the tunneling head (28) in the backward direction for transmitting an activating movement to the pulley and belt system (34).

7. A system according to claim 6, in which said drive cable (38) is guided at least along a section of its extension in an instrument channel (17) of an endoscope (18) carrying the tunneling system.

8. A system according to claim 1 or 2, in which the activating mechanism (33) comprises a magnetically susceptible coupling seat (39) arranged at the tunneling head (28) and an endoluminal pusher (40) with a magnetic coupling roller (42) adapted to magnetically

connect to the coupling seat (39) through the first layer (15) of the intestinal wall (10) and to transmit a forward movement of the endoluminal pusher (40) to the tunneling head (28).

9. A system according to claim 8, in which the coupling seat (39) is formed in the first layer guide (31) of the layer separation assembly (30) and the coupling roller (42) is adapted to frictionally engage the first layer (15) from inside the intestine in a manner that, during a forward movement of the endoluminal pusher (40), the coupling roller (42) moves the tunneling head (28) in the forward direction and rolls contemporaneously in a forward direction over the first layer (15) thereby dragging the first layer (15) in the backward direction over the layer separation assembly (30).

10. A system according to claim 8 or 9, in which the coupling seat (39) comprises a concavity and the coupling roller (42) is adapted to engage the concavity of the coupling seat (39) to assist the transmission of the forward movement.

11. A system according to any one of the preceding claims, in which the layer separation assembly (30) comprises at least one spray nozzle (43) connected to a fluid conduit (44) and operable to spray jets of a fluid between the first and second tissue layer.

12. A system according to claim 11, comprising a smooth circumferential sealing surface (45) on a proximal side of the spray nozzles (43), the sealing surface (45) being adapted to rest against the adjacent tissue, thereby delaying the sprayed fluid from draining away from the nozzles (43).

13. A system for submucosal tunneling an intestinal wall (10), the system comprising a tunneling catheter (46) having:

- a distal tip (47) adapted to be inserted between a first layer (15) and an adjacent second layer (29) of the intestinal wall (10),
- a proximal end portion (48) adapted to be connected to an injection fluid source;
- a tubular wall (49) extending between the distal tip (47) and the proximal end portion (48),

wherein the tubular wall (49) defines:

- an internal injection fluid channel (50) extended from the proximal end portion (48) to a region near the distal tip (47), and
- at least one injection hole (51) provided near the distal tip (47) and adapted to inject fluid from the injection fluid channel (50) in the interstice between the first (15) and second layer (29), and
- a concave drainage channel (52) isolated from the injection fluid channel (51) and in fluid communication with an external surface (53) of the tubular wall (49).

14. System according to claim 13, in which the drainage channel (52) comprises an

externally open channel formed by the external surface (53) of the tubular wall (49). **15.** System according to claim 13 or 14, in which the tubular wall (49) comprises a stiffening wall against local crouching or collapse of the flow section of the tunneling catheter (46).

16. A system for submucosal tunneling an intestinal wall (10), the system comprising an endoluminal submucosal access device (55) having:

- a tissue manipulation head (56) defining a tissue attachment region (57),
- a plurality of suction openings (58) formed in the tissue attachment region (57) and being connected to a vacuum suction system and adapted to hold a portion of mucosa (15) of the intestinal wall (10) tight against the attachment region (57),
- a guide channel (59) formed in the tissue manipulation head (56) and adapted to slidingly receive a piercing wire (60), the guide channel forming an exit section (61) which opens into the tissue attachment region (57) at an angle that directs the piercing wire (60) in a planned submucosal space.

17. A system for submucosal tunneling an intestinal wall (10), the system comprising a multi-needle injector (23) having:

- an injection head (24),
- an injection needle array (26) with at least one line of injection needles protruding laterally outward from the injection head (24) and connected to an injection fluid feeding system, the needle array (26) being arranged in an elongate cavity (27) adapted to receive a bleb of the intestinal wall (10) created by the needle injection.

18. Method for diverting biliopancreatic juices from a physiological fluid flow path (5) to a target location in the intestine distal to the duodenal papilla of Vater (8), said method comprising the steps of:

- extending a catheter (9) from the physiological fluid flow path (5) to said target location in the intestine;
- anchoring the catheter (9) to an intestinal wall (10) along at least a prevalent portion of its length, said prevalent portion being greater than halve of the entire catheter length.

19. Method according to claim 18, comprising:

- creating a submucosal conduit path (12) in the intestinal wall (10); and
- extending the catheter (9) from the physiological fluid flow path (5) through the submucosal conduit path (12) to the target location (13) in the intestine.

20. Method according to claim 19, comprising:

- endoluminally creating a proximal otomy (14) through the thickness of the mucosa (15) in the duodenal wall (10) near the ampulla of Vater (8);
- endoluminally inserting a submucosal tunneling device through the proximal otomy (14)

in the duodenal wall (10) and advancing the tunneling device distally to the target portion of intestine, thereby creating the submucosal conduit path (12);

- creating a distal otomy through the thickness of the mucosa (15) to open the submucosal conduit path (12) into the target portion of intestine;
- endoluminally advancing the catheter (9) to the proximal otomy (14);
- inserting the catheter (9) through the proximal otomy (14) into the submucosal conduit path (12) so that a proximal end portion (11) of the catheter (9) emerges from the proximal otomy (14) into the duodenum (2) near the papilla of Vater (8) and a distal end portion (19) of the catheter (9) emerges from the distal otomy into the target portion (13) of the intestine;
- inserting the proximal end portion (11) of the catheter (9) endoluminally through the papilla of Vater (8) into the biliary tree (5).

21. Method according to claim 19, comprising:

- inserting an endoscope transorally to a target zone in the stomach (1) and creating a first otomy through the thickness of the mucosa (15) in the gastric wall;
- inserting a submucosal tunneling device through the first otomy in the gastric wall and advancing the tunneling device distally to the target portion of intestine, thereby creating the submucosal conduit path (12) in the intestinal wall (10);
- creating a distal otomy through the thickness of the mucosa (15) to open the submucosal conduit path (12) into the target portion of intestine;
- endoluminally advancing the catheter (9) to the first otomy; and
- inserting the catheter (9) through the first otomy in the submucosal conduit path (12) so that a distal end portion (19) of the catheter (9) emerges from the distal otomy into the target portion (13) of the intestine;
- creating a proximal otomy (14) through the thickness of the mucosa (15) into the conduit path (12) in the duodenal wall (10) near the ampulla of Vater (8);
- pulling a proximal end portion (11) of the catheter (9) through the proximal otomy (14) out of the submucosal conduit path (12) into the duodenum (2); and
- inserting said proximal end portion (11) through the papilla of Vater (8) into the biliary tree (5).

22. Method according to claim 19, comprising:

- creating a sequence of spaced submucosal tunnels (20) in the intestinal wall 10; and
- inserting the catheter (9) in the sequence of submucosal tunnels (20).

23. Method according to claim 18, comprising:

- endoluminally positioning a plurality of anchoring rings (21) inside the intestine and

connecting the anchoring rings (21) to the intestinal wall (10);

- endoluminally inserting the catheter (9) through annular seats of the anchoring rings (21).

24. Method according to claim 20 or 21, in which the step of creating the otomy for accessing the submucosal space comprises:

- creating a submucosal bleb by injecting a fluid in the interface between the mucosa and the submucosa of the intestinal wall;

- piercing into the created submucosal bleb.

25. Method according to claim 19, in which the step of creating the submucosal conduit path (12) comprises:

- creating a smaller size submucosal path advancing a guide wire in the interface between the mucosa and the submucosa; and,

- dilating the smaller size submucosal path to the desired dimensions by advancing a catheter with at least one dilating portion through the smaller size submucosal path.

26. Method according to claim 19, in which the step of creating the submucosal conduit path (12) comprises:

- syringe injecting a dilating fluid in the submucosal space along the planned extension of the submucosal conduit path (12).

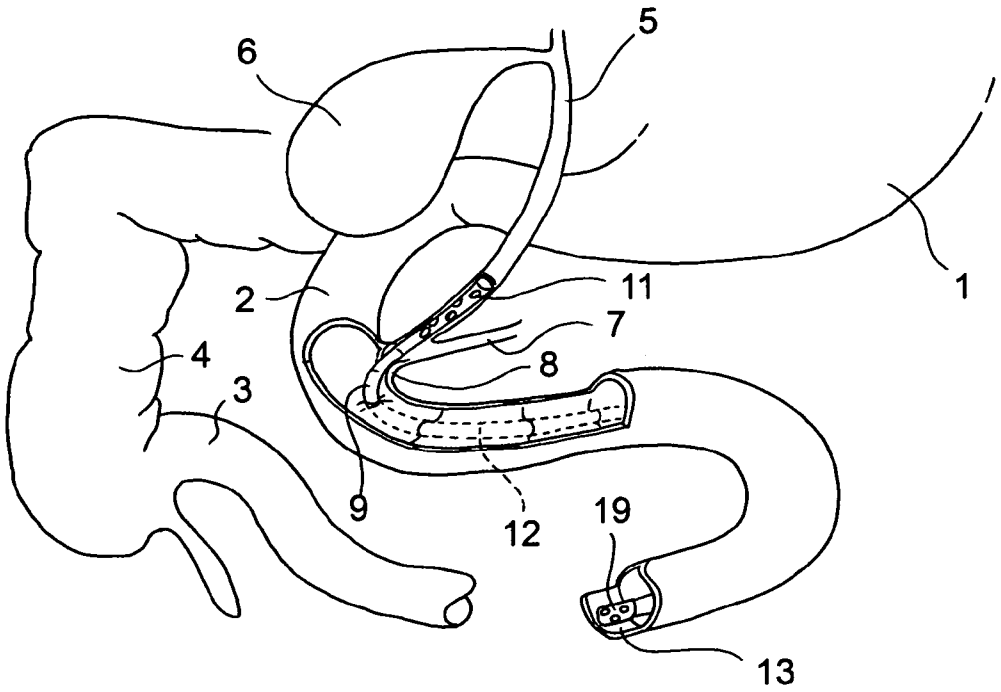

FIG. 1

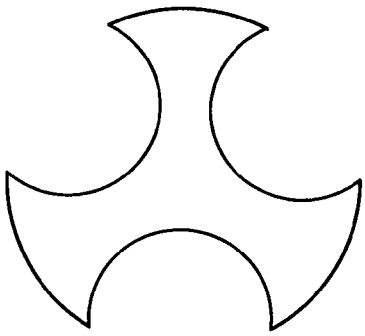

FIG. 2

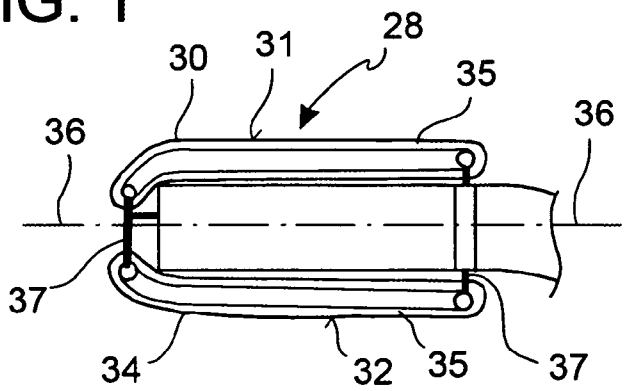

FIG. 3

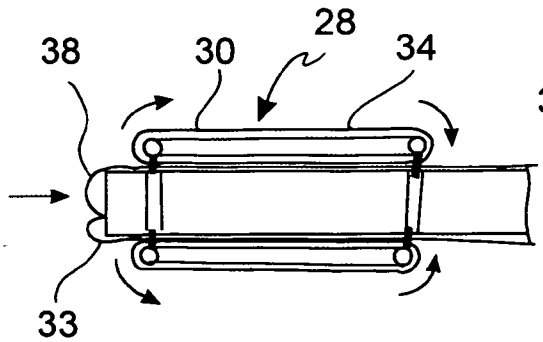

FIG. 4

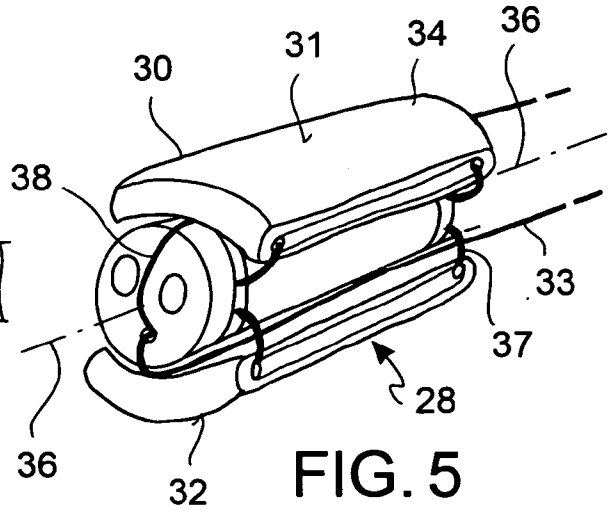

FIG. 5

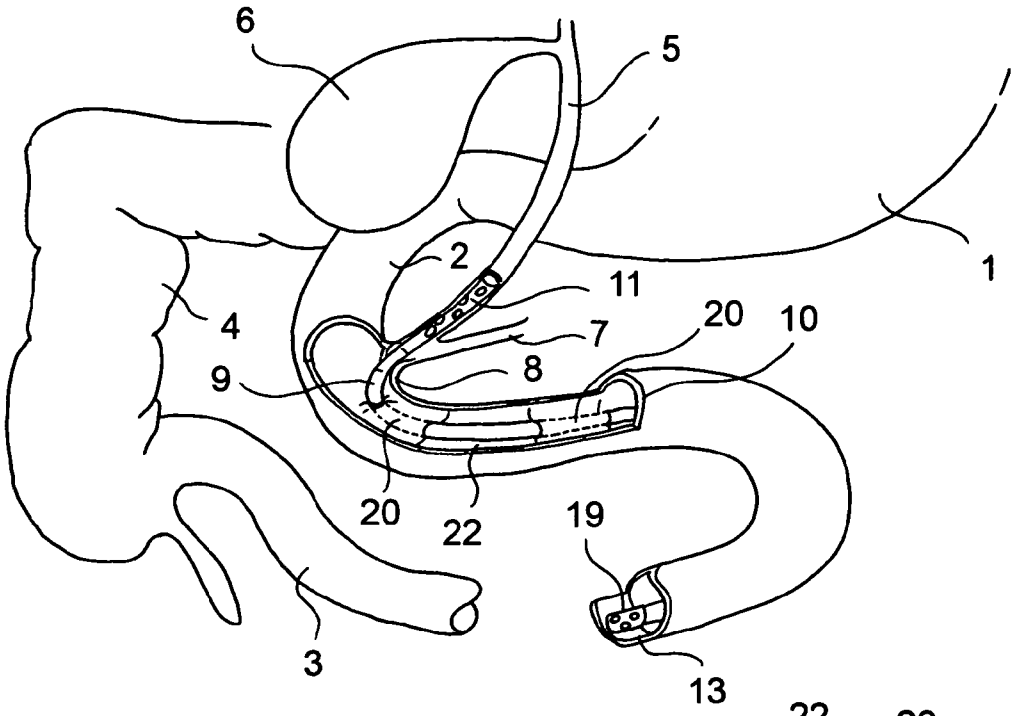

FIG. 6

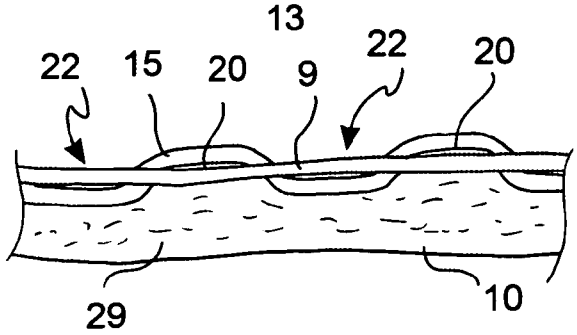

FIG. 6A

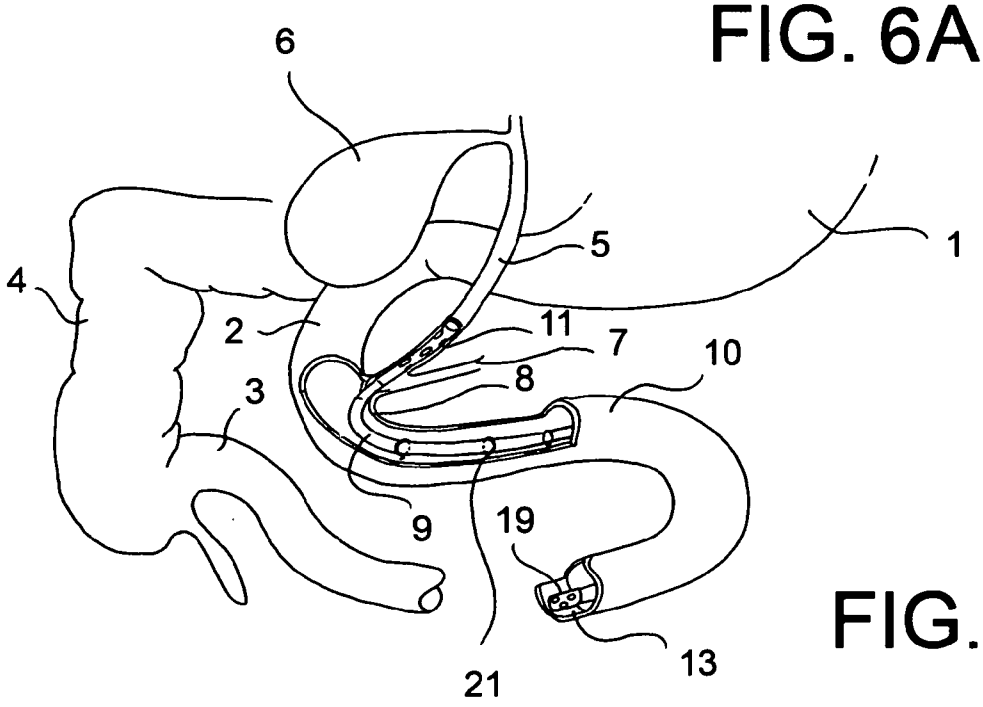

FIG. 7

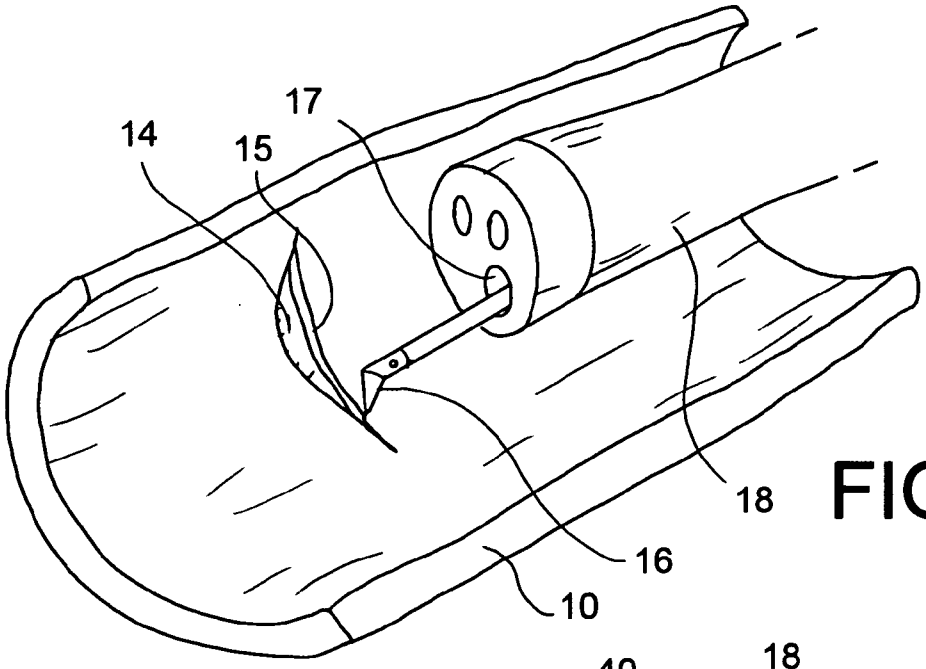

FIG. 8

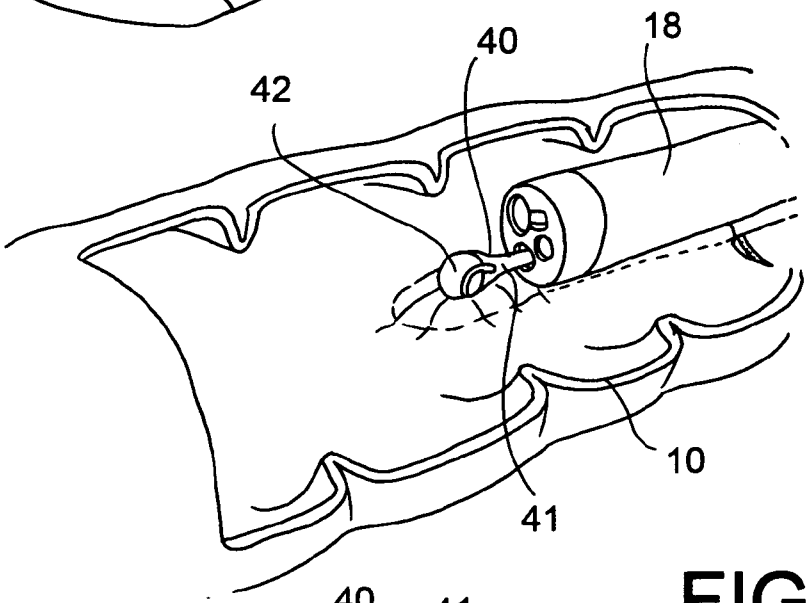

FIG. 9

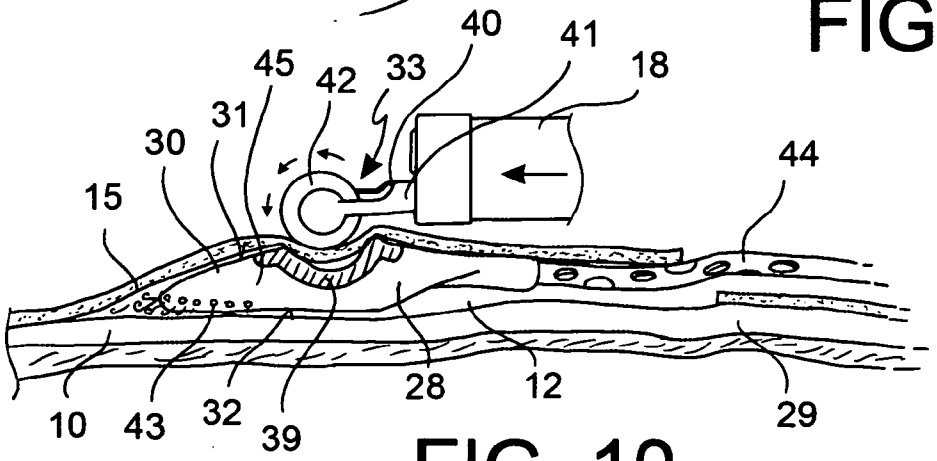

FIG. 10

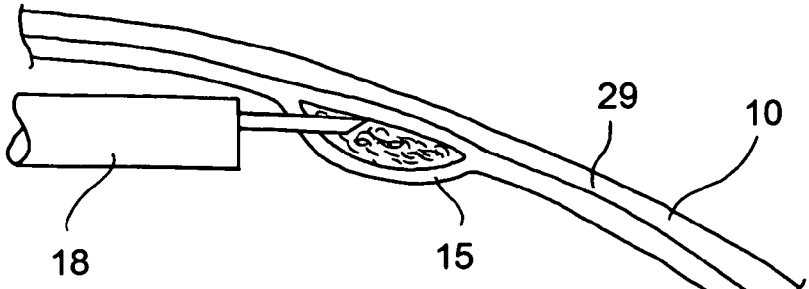

FIG. 11

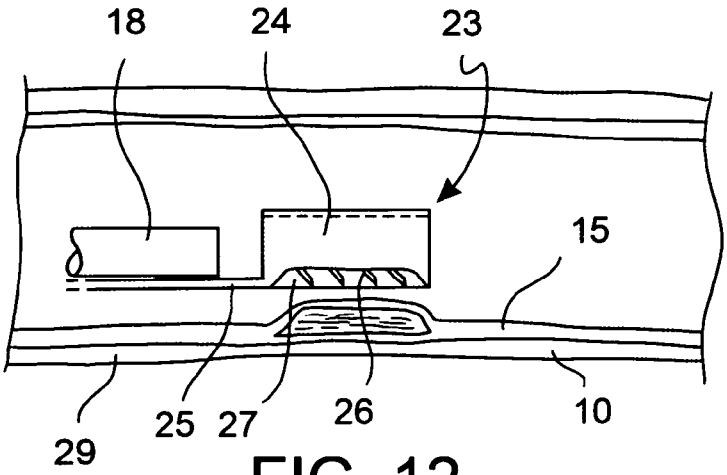

FIG. 12

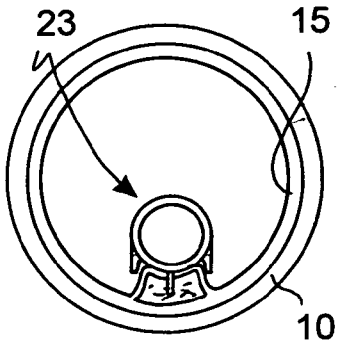

FIG. 13

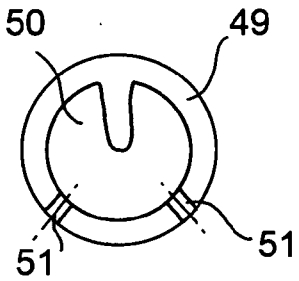

FIG. 14

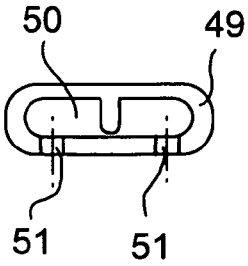

FIG. 15

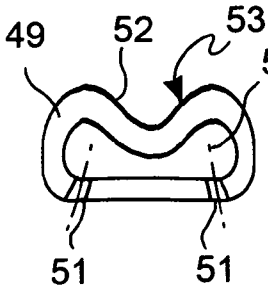

FIG. 16

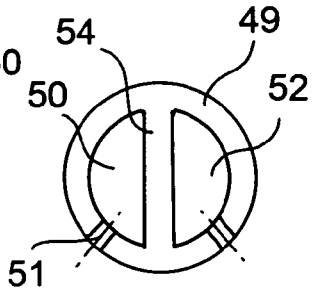

FIG. 17

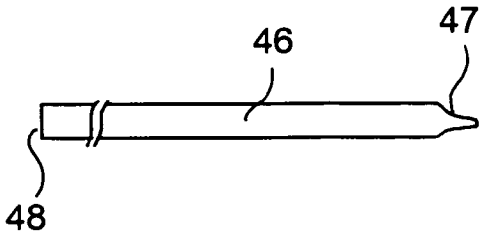

FIG. 18

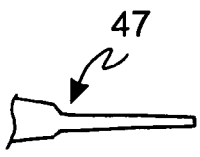

FIG. 19

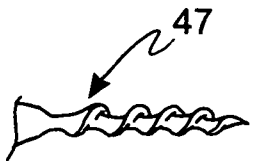

FIG. 20

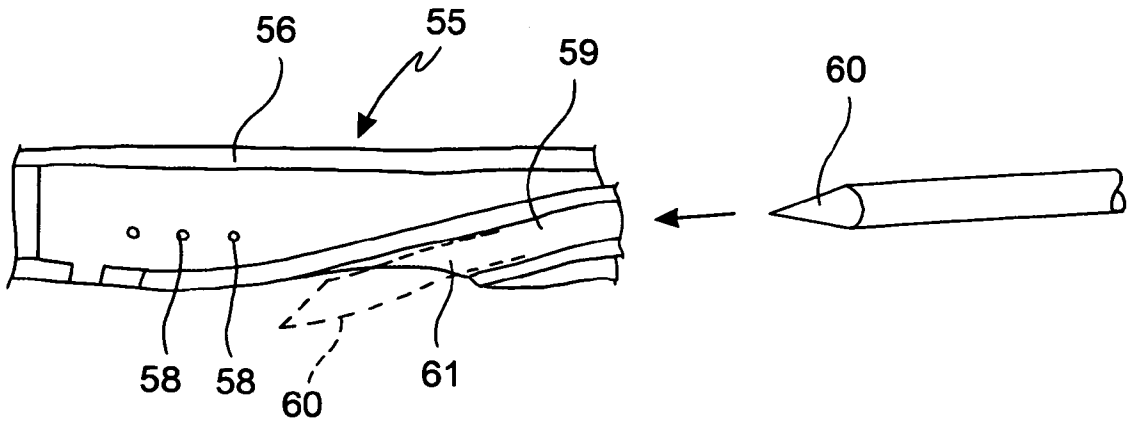

FIG. 21

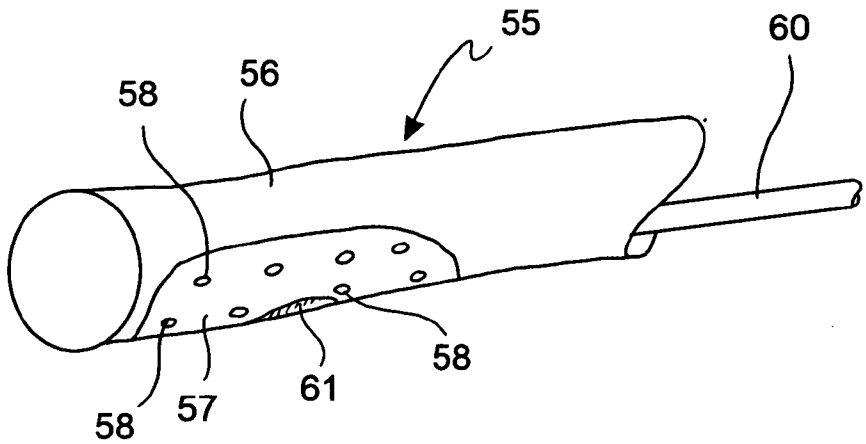

FIG. 22

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/061132

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/3203 A61B17/32 A61F5/00 A61F2/04
ADD. A61B17/00 A61B17/34 A61B17/20 A61B19/00 A61B17/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/018602 A1 (MITELBERG VLADIMIR [US] ET AL) 15 January 2009 (2009-01-15) paragraph [0095] - paragraph [0101]; figures 14-24D	1-7
Y	US 5 571 114 A (DEVANABOYINA UDAYA-SANKAR [US]) 5 November 1996 (1996-11-05) column 1, line 65 - column 2, line 14; figures 1-3 column 5, line 62 - column 7, line 12	1-7
A	US 2008/242940 A1 (STEFANCHIK DAVID [US]) 2 October 2008 (2008-10-02) abstract; figures 1-3, 8, 13, 14	1

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 June 2011	20/06/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Moers, Roelof

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/061132

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/225305 A1 (EWERS RICH [US] ET AL EWERS RICHARD C [US] ET AL) 11 November 2004 (2004-11-11) paragraph [0135] - paragraph [0136]; figures 18A,B	1,3,4
A	US 2004/092892 A1 (KAGAN JONATHAN [US] ET AL) 13 May 2004 (2004-05-13) paragraph [0318] - paragraph [0335]; figures 33-35	1
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/061132

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2010/061132

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18-26
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7

   A system for submucosal tunneling comprising first and second layer guides arranged for diverging the layers.

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2. claims: 8-12

   A system for submucosal tunneling comprising a magnetically susceptible coupling seat and a pusher with a magnetic roller.

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3. claims: 13-15

   A system for submucosal tunneling comprising injection fluid channel and concave drainage channel.

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4. claim: 16

   A system for submucosal tunneling comprising tissue manipulation head with suction openings and guide channel for piercing wire.

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5. claim: 17

   A system for submucosal tunneling comprising multi-needle injector.

INTERNATIONAL SEARCH REPORT

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PCT/EP2010/061132

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