(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 January 2012 (19.01.2012)

PCT

(10) International Publication Number
WO 2012/007045 A1

(51) **International Patent Classification:**
A61F 2/04 (2006.01)

(21) **International Application Number:**
PCT/EP20 10/060269

(22) **International Filing Date:**
16 July 2010 (16.07.2010)

(25) **Filing Language:** English

(26) **Publication Language:** English

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(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available):* AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available):* ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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(54) Title: A DEVICE AND METHOD FOR SUBCUTANEOUS DIVERSION OF BILE

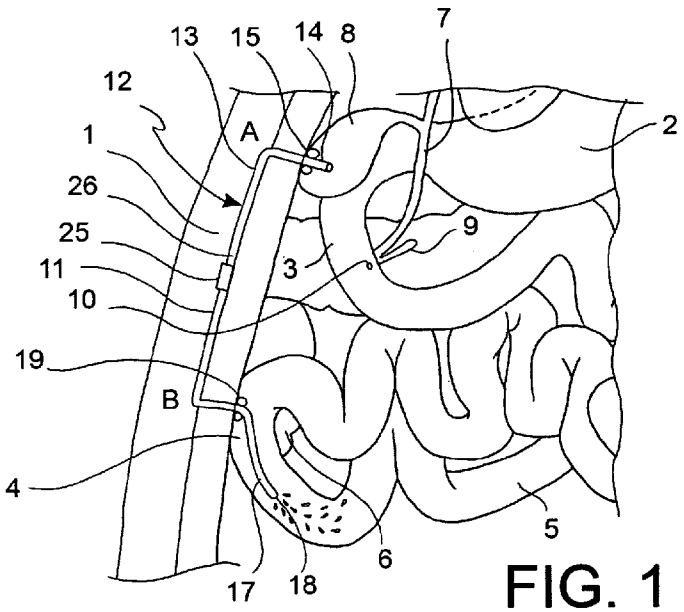

FIG. 1

(57) Abstract: A device (11) for diverting biliary fluid from a biliary fluid flow path (7, 8, 21) to a target location in the intestine (4) comprises a catheter (13) with a conduit section (26) extending between a proximal end portion (14) and a distal end portion (17), wherein the proximal end portion (14) is adapted for percutaneous placement in the biliary fluid flow path (7, 8, 21) and the distal end portion (17) is adapted for transcutaneous tunnelization, through the abdominal wall (1), and for percutaneous insertion in a target section of small intestine. The device comprises further distal fixating means (19, 20) connected to the distal end portion (17) and adapted to immobilize the target section of small intestine with respect to the abdominal wall (1) and to the catheter distal end portion (17).

WO 2012/007045 A1

Published:

— *with international search report (Art. 21(3))*

"A DEVICE AND METHOD FOR SUBCUTANEOUS DIVERSION OF BILE"

DESCRIPTION

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.

Moreover, the known conduit can divert only the amount of bile which has been released through the sphincter of ODDI and the flow rate of bile through the known conduit would not be sufficient to obtain a significant acceleration of the bile cycling compared to the natural entero-hepatic bile cycling velocity.

In view of the drawbacks of the known art, there is a need to provide a minimally invasive device and method of diverting bile from the biliary tree including the gallbladder into a section of the small intestine distally to the papilla of Vater, which obviate undesired relocations of the bile conduit from the target location.

There is a further need to increase the flow rate of the diverted bile towards the target location in the small intestine.

At least part of the above identified needs are met by a method for diverting biliary fluid from a biliary fluid flow path to a point distal to a duodenal papilla of Vater, the method comprising the steps of creating a flow path in an abdominal wall and extending a catheter from the biliary fluid flow path through the abdominal wall flow path to a location in the gastrointestinal tract distal to the duodenal papilla of Vater.

This makes it possible to extend a section of the catheter outside the small intestine so that it is not subject to peristalsis, thereby obviating the risk of bundling up and undesired relocation of the catheter.

In accordance with an aspect of the invention, a proximal end of the catheter is arranged within a gallbladder and the gallbladder is anastomosed to a layer of the abdominal wall.

This makes it possible to capture the biliary fluid directly from inside the gallbladder and to reliably fixate the relative position of the gallbladder with respect to the proximal catheter end.

In accordance with a further aspect of the invention, a proximal end of the catheter is arranged within a hepatic duct (right or left or common hepatic duct), thereby obviating the risk of trauma to the common bile duct which is very delicate and fragile.

In accordance with a yet further aspect of the invention, a pump is arranged in the biliary fluid flow path in the abdominal wall and connected with the catheter to accelerate a bile flow to the location in the gastrointestinal tract distal to the duodenal papilla of Vater.

At least part of the above identified needs are also met by a device for diverting biliary fluid from a biliary fluid flow path to a point distal to a duodenal papilla of Vater, the device comprising:

- a catheter having a proximal end portion and a distal end portion and a conduit section extending between the proximal end portion and the distal end portion,

wherein the proximal end portion is adapted for percutaneous placement, across an abdominal

wall, in a biliary fluid flow path,

wherein the distal end portion is adapted for transcutaneous tunnelization, through the abdominal wall, and for percutaneous insertion, across the abdominal wall, in a target section of small intestine,

- distal fixating means connected to the distal end portion and adapted to immobilize the target section of small intestine with respect to the abdominal wall and to the catheter distal end portion.

In accordance with an aspect of the invention, the device comprises proximal fixating means connected to the proximal end portion and adapted to immobilize the biliary fluid flow path with respect to the abdominal wall and to the catheter proximal end portion.

The biliary fluid flow path can be the gallbladder or a hepatic duct.

In accordance with a further aspect of the invention, the device comprises a pump for accelerating a bile flow in the catheter, the pump being connected to the conduit section and adapted to be arranged in a subcutaneous space in the abdominal wall.

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 device and method for a subcutaneous diversion of bile in accordance with an embodiment of the invention;
- Figure 2 illustrates a surgical procedure and method for a subcutaneous diversion of bile in accordance with a further embodiment;
- Figure 3 illustrates a device and method for a subcutaneous diversion of bile in accordance with a further embodiment of the invention;
- Figure 4 illustrates a detail of the device and method step for a subcutaneous diversion of bile in accordance with a further embodiment of the invention;
- Figure 5 illustrates a detail of the device in figures 1 to 3 in accordance with an embodiment;
- Figure 6 illustrates a pump for accelerating bile in accordance with an embodiment;
- Figure 7 illustrates a pump for accelerating bile or clearing the device in accordance with a further embodiment;
- Figure 8 illustrates a method in accordance with a yet further embodiment of the invention;
- Figures 9 to 16 illustrate a sequence of a method and devices for a subcutaneous diversion of bile in accordance with a further embodiment of the invention;

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 abdominal wall 1 with the following layers (from superficial to deep): skin - fascia - muscle - fascia transversalis - peritoneum, the stomach 2, duodenum 3, jejunum 4, ileum 5, colon 6, as well as the biliary tree 7 with gall bladder 8, the pancreatic duct 9 and the mayor duodenal papilla of Vater 10 through which the bile and pancreatic fluid normally enter the duodenum 3. Figure 1 shows further a method and a device 11 for diverting biliary fluid from the biliary fluid flow path, particularly from the gall bladder 8, to a target location in the intestine distal of the papilla of Vater 10.

In accordance with a general inventive idea, the method comprises the steps of creating a flow path 12 in the abdominal wall 1 and extending a catheter 13 from the biliary fluid flow path 7, 8 through the abdominal wall flow path 12 to a location in the gastrointestinal tract distal to the duodenal papilla of Vater 10.

This makes it possible to extend a section of the catheter 13 outside the small intestine 3, 4, 5 so that it is not subject to peristalsis, thereby obviating the risk of bundling up and undesired relocation of the catheter 13.

In accordance with an embodiment, a proximal end portion 14 of the catheter 13 is arranged within the gallbladder 8 and the gallbladder 8 may be anastomosed to an internal layer of the abdominal wall 1.

In this manner, it becomes possible to capture the biliary fluid directly from inside the gallbladder 8 and to reliably fixate the relative position of the gallbladder 8 with respect to the proximal catheter end portion 14.

A possible procedure for deploying the subcutaneous catheter 13 (Figures 1 and 2) may include the selection and marking of a proximal abdominal wall site "A" and a distal abdominal wall site "B" and local anesthetization of proximal site "A" and distal site "B". Then, visualization of the gallbladder 8 is gained by abdominal ultrasonic imaging, radiography or fluoroscopy. Once the position and orientation of the gallbladder 8 is known, the abdominal wall 1 is opened at the proximal site "A" and a percutaneous cholecystostomy of the gallbladder 8 is performed through the abdominal wall 1 at the proximal site "A". Then, the proximal end portion 14 of the catheter 13 is inserted through the abdominal wall 1 and the cholecystostomy into the gallbladder 8 and fixated with respect to the gallbladder 8 and with respect to the abdominal wall 1 at the proximal site "A".

The fixation of the proximal end portion 14 of the catheter 13 can involve a first proximal expandable collar 15 connected to the proximal end portion 14 and inserted together with the

proximal end portion 14 through the abdominal wall and through the gallbladder wall inside the gallbladder 8.

The first proximal expandable collar 15 may comprise an inflatable balloon collar or an elastically or temperature dependent expandable collar.

After the proximal end portion 14 with the first proximal expandable collar 15 are placed inside the gallbladder 8, the collar 15 is expanded, e.g. by insufflating a balloon collar, thereby covering and possibly sealing the previously created cholecystotomy from inside the gallbladder 8. Then the catheter 13 is pulled distally so that the proximal catheter end portion 14 together with the gallbladder 8 is approximated to and pressed against an internal layer, i.e. the peritoneum, of the abdominal wall 1 to allow anastomosis therebetween. The compression between the gallbladder 8 and the abdominal wall 1 at the proximal site "A" can be maintained by a second proximal collar 16 connected to the proximal end portion 14 distal to the first collar 15 and adapted to hold the gallbladder wall and at least an internal layer (e.g. peritoneum or peritoneum and muscle layer) of the abdominal wall 1 between the first and second proximal collars 15, 16.

The second proximal collar 16 may comprise an inflatable balloon collar or an elastically or temperature dependent expandable collar or an annular disk shaped collar.

In accordance with an embodiment, the second proximal collar 16 is adapted to slide along the catheter 13 and can be locked to the catheter 13 in a desired position to prevent further relative translation between the catheter 13 and the collars 15, 16, thereby assuring the intended compression between the gallbladder 8 wall and the abdominal wall 1 as well as the fixation of the catheter 13 at the proximal abdominal wall site "A".

Then, a distal end portion 17 of the catheter 13 is subcutaneously "tunnelized" from the proximal site "A" to the distal site "B", that means the distal end portion 17 is pierced in a subcutaneous layer of the abdominal wall 1 at proximal site "A" and advanced beneath the patient's skin to the distal site "B", at which a distal end 18 of the distal end portion 17 is brought outside the body ("externalization" of the catheter end).

For this purpose the device 11 may comprise a needle (not illustrated) securely fixed to the distal catheter end 18 and intended to be separated from the latter after "tunnelization".

Then, the abdominal wall 1 is opened at the distal site "B" and a percutaneous enterostomy (e.g. a jejunostomy) is performed through the abdominal wall 1 at the distal site "B". Then, the distal end portion 17 of the catheter 13 is inserted through the abdominal wall 1 and the enterostomy into the small intestine, e.g. in the jejunum 4, and fixated with respect to the intestine and with respect to the abdominal wall 1 at the distal site "B".

The fixation of the distal end portion 17 of the catheter 13 can involve a first distal expandable collar 19 connected to the distal end portion 17 and inserted together with the distal end portion 17 through the abdominal wall 1 and through the enterostomy inside the intestine 4.

The first distal expandable collar 19 may comprise an inflatable balloon collar or an elastically or temperature dependent expandable collar.

After the distal end portion 17 with the first distal expandable collar 19 are placed inside the intestine 4, the collar 19 is expanded, e.g. by insufflating a balloon collar, thereby covering and possibly sealing the previously created enterostomy from inside the intestine. Then the distal end portion 17 of catheter 13 is pulled proximally so that the intestine 4 is approximated to and pressed against an internal layer, i.e. the peritoneum, of the abdominal wall 1 to allow anastomosis therebetween. The compression between the intestine and the abdominal wall 1 at the distal site "B" can be maintained by a second distal collar 20 connected to the distal end portion 17 proximal to the first distal collar 19 and adapted to hold the intestinal wall (particularly the enterostomy of the jejunum wall) and at least an internal layer (e.g. peritoneum or peritoneum and muscle layer) of the abdominal wall 1 between the first and second distal collars 19, 20.

The second distal collar 20 may comprise an inflatable balloon collar or an elastically or temperature dependent expandable collar or an annular disk shaped collar.

In accordance with an embodiment, the second distal collar 16 is adapted to slide along the catheter 13 and can be locked to the catheter 13 in a desired position to prevent further relative translation between the catheter 13 and the collars 19, 20, thereby assuring the intended compression between the enterostomy and the abdominal wall 1 as well as the fixation of the catheter 13 at the distal abdominal wall site "B".

Then, the skin at the proximal site "A" and at the distal site "B" can be sutured.

In an embodiment illustrated in figure 1, the catheter comprises only one expandable proximal collar 15 and only one expandable distal collar 19 adapted to approximate the gallbladder and the intestine to the abdominal wall, wherein the position and compression is assured by additional sutures and/or by the longitudinal tensional resistance of the catheter 13.

In accordance with a further embodiment (Figure 3), a proximal end 23 of the catheter 13 is arranged within a hepatic duct 21, i.e. within the right or left or common hepatic duct.

In this case the abdominal wall 1 is opened at the proximal site "A" and a percutaneous transhepatic cholangiography (PTC) is performed with deployment of the proximal catheter end portion 14 through the abdominal wall 1 at the proximal site "A".

For this purpose, a thin needle is inserted through the skin (percutaneous) at the proximal site

"A" and through the liver 22 (transhepatic) into a bile duct 7. Then contrast media is injected, and the bile duct system is outlined, wherein imaging may be performed by fluoroscopy. Following the initial injection of contrast media (x-ray dye) into the bile duct during the PTC, a small guide wire is guided through the needle, into the hepatic duct 21 and possibly but not necessarily into the common bile duct (Figure 4) while watching the wire and ducts on x-ray. Over this guide wire, the proximal catheter end portion 14 is then inserted and fixated in the hepatic duct 21 to allow the bile to be drained from the liver, thereby avoiding manipulation of the very delicate and fragile common bile duct. The proximal catheter end 23 may be fixated in the hepatic duct 21 by means of an anchoring member 24 connected to the proximal catheter end portion 14, such as for example a metal stent, an inflatable balloon or a barbed anchoring portion (Figure 3).

In accordance with an alternative embodiment, the proximal catheter end 23 may be fixated in the biliary duct 7 by means of the same anchoring member 24 connected to the proximal catheter end portion 14.

The remaining method steps and device features are substantially identical to those previously described in connection with the embodiments of figures 1 and 2 and are not repeated for the sake of clarity.

In accordance with a further embodiment, the catheter 13 may be "tunnelized" and extended intramurally in the abdominal wall 1, i.e. between the parietal pleuramembrane and the fascia (preferably closer to the pleuramembrane), rather than subcutaneously.

In accordance with a further embodiment of the invention, a pump 25 is arranged in the biliary fluid flow path in the abdominal wall 1 and connected with the catheter 13 to accelerate the bile flow to the location in the gastrointestinal tract distal to the duodenal papilla of Vater 10. The pump 25 is connected to a conduit section 26 of the catheter 13 and can be preferably arranged in a subcutaneous space. The pump 25 may comprise an onboard power source 27 with an inductive recharging unit 28 adapted to be energized by an extracorporeal charging station 29 configured to operate a transcutaneous energy transfer (Figure 6).

In accordance with an alternative embodiment (Figure 7), the pump 25 comprises a pumping member 30, e.g. an elastically deformable hollow bulb or bellows, adapted to be deformable by muscular contractions of the abdominal wall, which occur for instance during standing up, sitting down and walking. In order to convert the compression of the pumping member 30 in an unidirectional flow of the bile in the distal direction, one way valves 31 can be arranged in the pump 25 or in the catheter 13 proximal and distal to the pumping member 30. Such a muscle powered valve is completely independent from any external energy source.

In accordance with an embodiment, the pumping operation is automatically or manually controlled and activated by means of an extracorporeal magnetic pump controller 36 which may be integrated in the above described charging station 29 or distinct from the latter. The pump controller 36 is adapted to generate and transmit to the pump 25 a control signal by magnetic induction in a near-field propagation mode and the pump 25 is adapted to pump the bile in response to and in accordance with the control signal.

In accordance with a further embodiment, an additional therapeutic agent is delivered to the distal target location in the intestine by injecting or dispensing the additional therapeutic agent into the catheter 13. For this purpose, the device 11 may comprise an injection port 32 adapted to be deployed in a subcutaneous space. The injection port 32 comprises a proportioning device 33 which is fluid connected with the catheter 13 and an injection septum 34 adapted to be pierced through by a syringe to receive the therapeutic agent.

In accordance with an embodiment (Figure 6) the injection port 32 may be integrated in the valve 25.

In order to prevent clogging or contamination of the catheter due to an undesired retro-flow of chime from the intestine, it is contemplated to inject a flushing agent, such as physiological saline solution, in the injection port 32 and to flush the catheter 13 when deemed necessary or at given time intervals.

Alternatively or in addition, manual clearing of the catheter 13 can be accomplished, e.g. by manually pressing the pumping member 30.

In order to easily locate the pump 25 and the injection port 32 from outside the body, the pump 25 may contain radio-opaque material and the pump position may be marked by means of a surface tattoo on the patient's abdominal skin.

Figure 8 illustrates a further exemplary embodiment, in which a harvested tubular organ 35, such as a saphenous vein is used instead of the catheter 13.

In accordance with a further embodiment (Figures 9 to 16), the device 11 comprises a hollow external needle 37 having a sharp pointed proximal end 38 adapted to penetrate through the abdominal wall 1 and a blunt tip portion 39 connected to the proximal end 38 and movable between a first position in which the blunt tip portion 39 exposes the pointed distal end 38 and a second position in which the blunt tip portion 39 covers the pointed distal end 38, thereby protecting the surrounding tissue from trauma.

A suction device 40 is slidably received inside the hollow external needle 37 and movable distally out of the hollow needle proximal end 38. The suction device 40 comprises a suction tube 41 and a suction cap 42 connected to a proximal end of the suction tube 41 and adapted

to hold an organ, particularly the gallbladder 8, by suction.

The device 11 may further comprise a tubular perforation needle 43 attached to the suction device 40 and adapted to perforate the organ, especially the gallbladder 8, held by the suction cap 42. The perforation needle 43 may be received slidably, and possibly rotatably, inside the suction tube 41 or suction cap 42 and operable to advance proximally, and possibly rotate, to perforate the wall of the organ held by the suction cap 42.

In this embodiment, the catheter 13 can be slidingly delivered through an internal channel 44 of the tubular perforation needle 43 or through the suction tube 41, so that the proximal end portion 14 of the catheter 13 emerges inside the held and perforated organ, particularly gallbladder 8.

For pulling the gallbladder 8 to the abdominal wall 1, the catheter 13 may comprise the above described first proximal expandable collar 15 connected to the proximal end portion 14 and insertible together with the proximal end portion 14 through the tubular perforation needle 43 or through the suction tube 41 inside the gallbladder 8.

The first proximal expandable collar 15 may comprise an inflatable balloon collar or an elastically or temperature dependent expandable collar.

After the proximal end portion 14 with the first proximal expandable collar 15 are placed inside the gallbladder 8, the collar 15 is expanded, e.g. by insufflating a balloon collar, thereby covering and possibly sealing the previously created cholecystotomy from inside the gallbladder 8. Then the catheter 13 is pulled distally (i.e. towards the abdominal wall 1) so that the proximal catheter end portion 14 together with the gallbladder 8 is approximated to and pressed against an internal layer, i.e. the peritoneum, of the abdominal wall 1 to allow anastomosis therebetween. The compression between the gallbladder 8 and the abdominal wall 1 at the proximal site "A" can be maintained by a second proximal collar 16 connected to the proximal end portion 14 distal to the first collar 15 and adapted to hold the gallbladder wall and at least an internal layer (e.g. peritoneum or peritoneum and muscle layer) of the abdominal wall 1 between the first and second proximal collars 15, 16.

The second proximal collar 16 may comprise an inflatable balloon collar or an elastically or temperature dependent expandable collar or an annular disk shaped collar. As best seen in figure 16, the first and second proximal collars can also be configured to seal the interstice between the catheter and the gallbladder wall to avoid leakage of bile into the abdominal space.

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 method for diverting biliary fluid from a biliary fluid flow path (7, 8, 21) to a target location in the intestine (4) distal to a duodenal papilla of Vater (10), the method comprising the steps of:

- creating a flow path in an abdominal wall (1) and extending a catheter (13) from the biliary fluid flow path (7, 8, 21) through the abdominal wall (1) flow path to said target location in the intestine (4) distal to the duodenal papilla of Vater (10).

2. A method according to claim 1, comprising the step of arranging a proximal end (23) of the catheter (13) within a gallbladder (8).

3. A method according to claim 2, comprising the step of anastomosing the gallbladder (8) to a layer of the abdominal wall (1).

4. A method according to claim 2, comprising the steps of:

- selection and marking of a proximal abdominal wall site (A) and a distal abdominal wall site (B);
- local anesthetization of proximal site (A) and distal site (B);
- gaining visualization of the gallbladder (8);
- performing a percutaneous cholecystostomy of the gallbladder (8) through the abdominal wall (1) at the proximal site (A);
- inserting a proximal end portion (14) of the catheter (13) through the abdominal wall (1) and the cholecystostomy into the gallbladder (8);
- immobilizing said proximal end portion (14) with respect to the gallbladder (8) and with respect to the abdominal wall (1) at the proximal site (A).

5. A method according to claim 4, comprising the steps of:

- providing a first proximal expandable collar (15) at the proximal end portion (14);
- inserting the first proximal expandable collar (15) together with the proximal end portion (14) through the abdominal wall and through the cholecystostomy inside the gallbladder (8);
- expanding the first proximal collar (15) inside the gallbladder (8);
- pulling the catheter (13) distally to press the gallbladder (8) against an internal layer of the abdominal wall (1) to allow anastomosis therebetween.

6. A method according to claim 5, comprising the steps of:

- holding the gallbladder wall and at least an internal layer of the abdominal wall (1) at the proximal site (A) between said first proximal collar (15) and a second proximal collar (16), said second proximal collar (16) being connected to the proximal end portion (14) distal to the first collar (15).

7. A method according to claim 6, comprising the steps of:

- sliding the second proximal collar (16) along the catheter (13) to a desired position; and

- locking the second proximal collar (16) to the catheter (13) in said desired position.

8. A method according to claim 1, comprising the steps of:

- arranging a proximal end (23) of the catheter (13) within a hepatic duct (21).

9. A method according to claim 8, comprising the steps of:

- performing a percutaneous transhepatic cholangiography (PTC) with deployment of a proximal catheter end portion (14) through the abdominal wall (1) at the proximal site (A);

- fixating a proximal catheter end (23) in the hepatic duct (21).

10. A method according to any one of the preceding claims, comprising the steps of:

- tunnelizing a distal end portion (17) of the catheter (13) subcutaneously from the proximal site (A) to the distal site (B);

- bringing the distal end portion (17) outside the body at said distal site (B);

- performing a percutaneous enterostomy through the abdominal wall (1) at the distal site (B);

- inserting the distal end portion (17) of the catheter (13) through the abdominal wall (1) and the enterostomy into the small intestine; and

- immobilizing said distal end portion (17) with respect to the intestine (4) and with respect to the abdominal wall (1) at the distal site (B).

11. A method according to claim 10, comprising the steps of:

- providing a first distal expandable collar (19) at the distal end portion (17);

- inserting the first distal expandable collar (19) together with the distal end portion (17) through the abdominal wall and through the enterostomy inside the intestine (4);

- expanding the first distal collar (19) inside the intestine (4);

- pulling the distal end portion (17) of the catheter (13) distally to press the intestine (4) against an internal layer of the abdominal wall (1) to allow anastomosis therebetween.

12. A method according to claim 11, comprising the steps of:

- holding the intestinal wall and at least an internal layer of the abdominal wall (1) at the distal site (B) between said first distal collar (19) and a second distal collar (20), said second distal collar (20) being connected to the distal end portion (14) proximal to the first collar (19).

13. A method according to claim 12, comprising the steps of:

- sliding the second distal collar (20) along the catheter (13) to a desired position; and

- locking the second distal collar (20) to the catheter (13) in said desired position.

14. A method according to claim 1, comprising the step of extending the catheter (13) intramurally in the abdominal wall (1).

15. A method according to claim 1, comprising the step of arranging a pump (25) is arranged in the biliary fluid flow path in the abdominal wall (1) and connected to the catheter (13) to accelerate the bile flow to the target location.

16. A method according to claim 1, comprising the step of using a harvested tubular organ (35) as a the catheter (13).

17. A device (11) for diverting biliary fluid from a biliary fluid flow path (7, 8, 21) to a target location in the intestine (4) distal to a duodenal papilla of Vater (10), the device (11) comprising:

- a catheter (13) having a proximal end portion (14) and a distal end portion (17) and a conduit section (26) extending between the proximal end portion (14) and the distal end portion (17),

wherein the proximal end portion (14) is adapted for percutaneous placement, across an abdominal wall (1), in said biliary fluid flow path (7, 8, 21),

wherein the distal end portion (17) is adapted for transcutaneous tunnelization, through the abdominal wall (1), and for percutaneous insertion, across the abdominal wall (1), in a target section of small intestine,

- distal fixating means (19, 20) connected to the distal end portion (17) and adapted to immobilize the target section of small intestine with respect to the abdominal wall (1) and to the catheter distal end portion (17).

18. A device (11) according to claim 17, wherein said distal fixating means (19, 20) comprise a first distal expandable collar (19) connected to the distal end portion (17).

19. A device (11) according to claim 18, wherein said distal fixating means (19, 20) comprise a second distal collar (20) connected to the distal end portion (17) proximal to said first distal collar (19) and adapted to hold the intestinal wall and at least an internal layer of the abdominal wall (1) between said first and second distal collars (19, 20).

20. A device (11) according to claim 19, wherein said second distal collar (20) is slidable along the catheter (13) and lockable to the catheter (13) in a desired position.

21. A device (11) according to claim 17, comprising proximal fixating means (15, 16) connected to the proximal end portion (14) and adapted to immobilize the biliary fluid flow path (8) with respect to the abdominal wall (1) and to the catheter proximal end portion (14).

22. A device (11) according to claim 21, wherein said proximal fixating means (15, 16) comprise a first proximal expandable collar (15) connected to the proximal end portion (14).

23. A device (11) according to claim 22, wherein said proximal fixating means (15, 16) comprise a second proximal collar (16) connected to the proximal end portion (14) distal to the first proximal collar (15) and adapted to hold a gallbladder wall and at least an internal layer of

the abdominal wall (1) between said first and second proximal collars (15, 16).

24. A device (11) according to claim 23, wherein said second proximal collar (16) is slidable along the catheter (13) and lockable to the catheter (13) in a desired position.

25. A device (11) according to claim 17, comprising a pump (25) for accelerating a bile flow in the catheter (13), the pump (25) being connected to the conduit section (26) and adapted to be arranged in a subcutaneous space in the abdominal wall (1).

26. A device (11) according to claim 25, wherein said pump (25) comprises an onboard power source (27) with an inductive recharging unit (28) adapted to be energized by an extracorporeal charging station (29) configured to operate a transcutaneous energy transfer.

27. A device (11) according to claim 25, wherein said pump (25) comprises:

- an elastically deformable hollow pumping member (30) adapted to be deformable by muscular contractions of the abdominal wall,
- one way valves (31) arranged proximal and distal to the pumping member (30).

28. A device (11) according to claim 25, comprising an extracorporeal magnetic pump controller (36) adapted to generate and transmit to the pump (25) a control signal by magnetic induction in a near-field propagation mode, wherein the pump (25) is adapted to pump the bile in response to said control signal.

29. A device (11) according to claim 17, comprising an injection port (32) integrated in the valve (25), said injection port (32) comprising a proportioning device (33) fluid connected with the catheter (13).

30. A device (11) for diverting bodily fluid from an organ (7, 8, 21) to a target location, the device (11) comprising:

- a hollow external needle (37) having a sharp pointed proximal end (38) adapted to penetrate through an abdominal wall (1) and a blunt tip portion (39) connected to the proximal end (38) and movable between a first position in which the blunt tip portion (39) exposes the pointed distal end (38) and a second position in which the blunt tip portion (39) covers the pointed distal end (38),
- a suction device (40) slidably received inside the hollow external needle (37), said suction device (40) comprising a suction tube (41) and a suction cap (42) adapted to hold an organ (8) by suction.
- a tubular perforation needle (43) attached to the suction device (40) and adapted to perforate the organ (8) held by the suction cap (42).
- a catheter (13) adapted to be delivered through the suction tube (41), so that a proximal end portion (14) of the catheter (13) emerges inside the held and perforated organ (8).

31. A device (11) according to claim 30, wherein the perforation needle (43) is received slidably and rotatably inside the suction tube (41) and operable to advance proximally and rotate the organ held by the suction cap (42).

32. A device (11) according to claim 30 or 31, wherein said catheter (13) is adapted to be delivered through an internal channel (44) of the tubular perforation needle (43).

33. A device (11) according to any one of claims 30 to 32, comprising a first proximal expandable collar (15) connected to the proximal end portion (14).

34. A device (11) according to claim 33, comprising a second proximal collar (16) connected to the proximal end portion (14) distal to the first proximal collar (15) and adapted to hold a gallbladder wall and at least an internal layer of the abdominal wall (1) between said first and second proximal collars (15, 16).

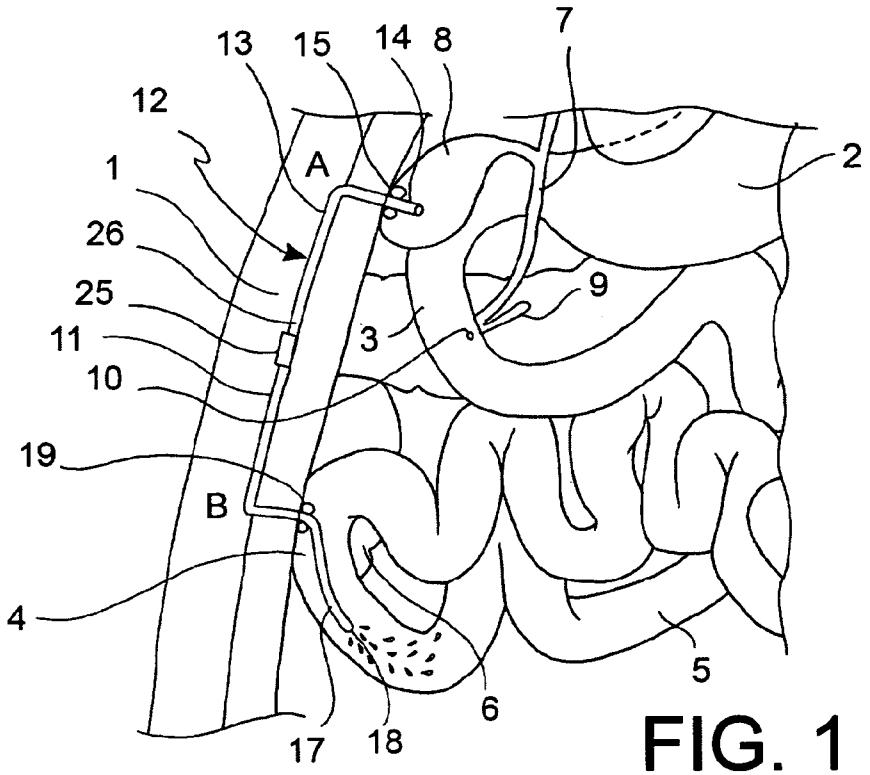
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FIG. 1

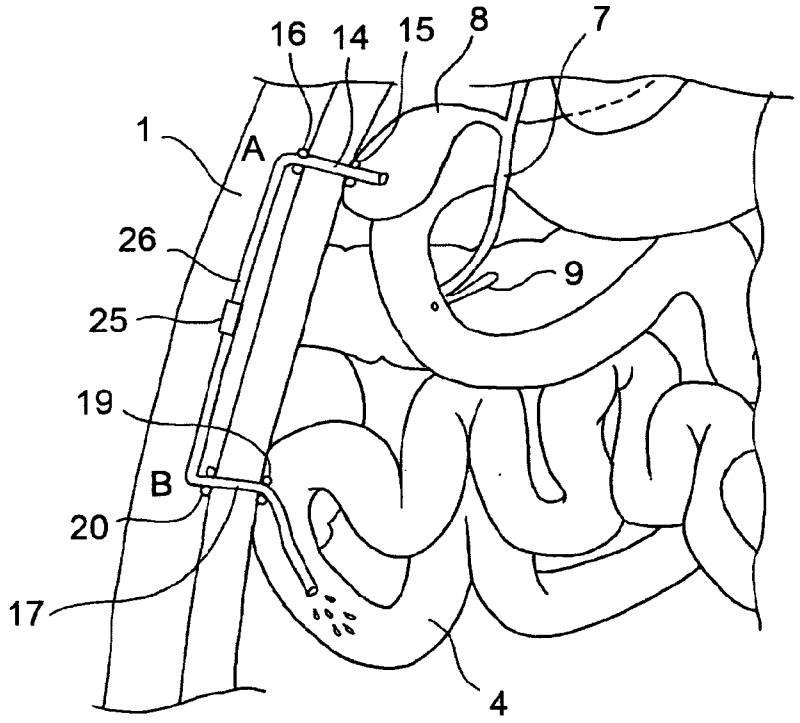
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FIG. 2

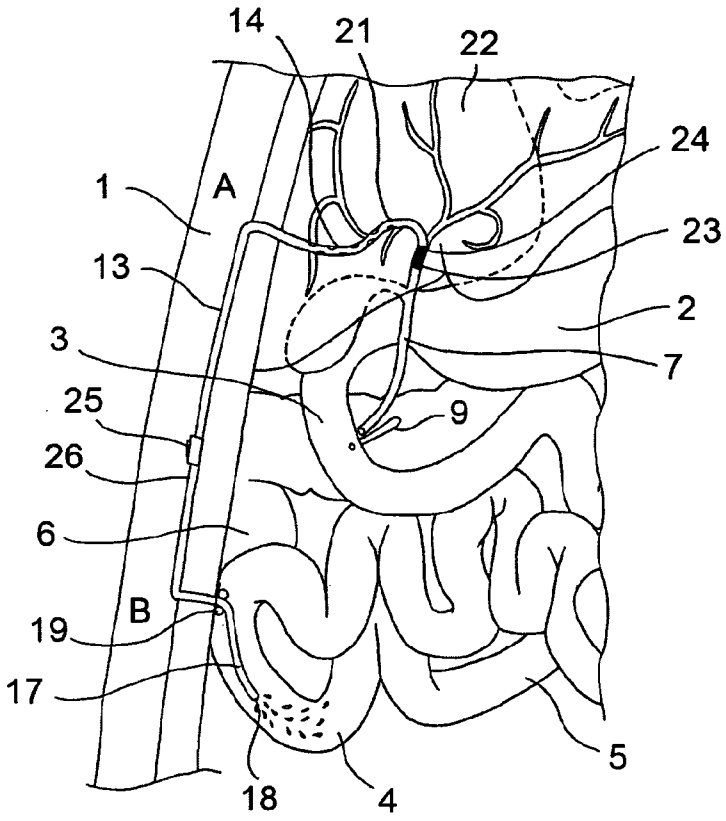


FIG. 3

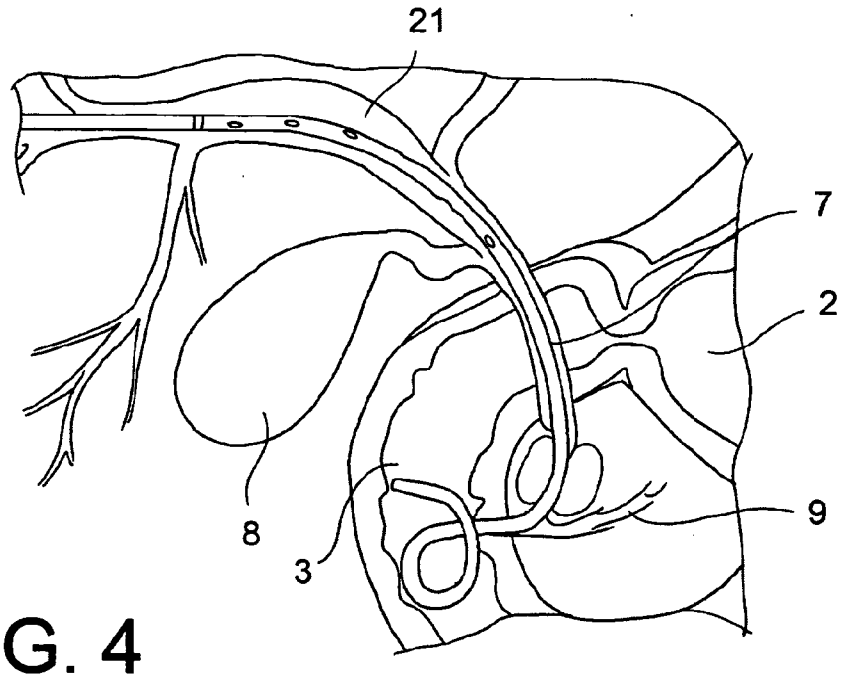


FIG. 4

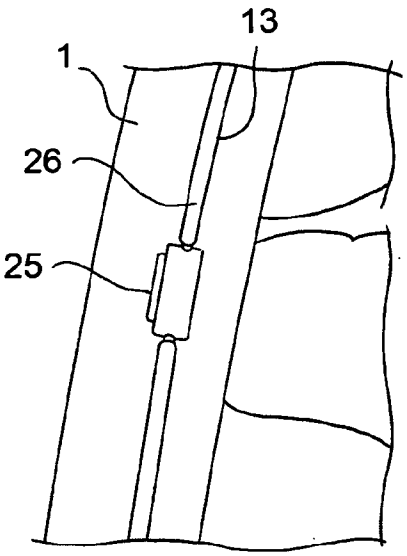


FIG. 5

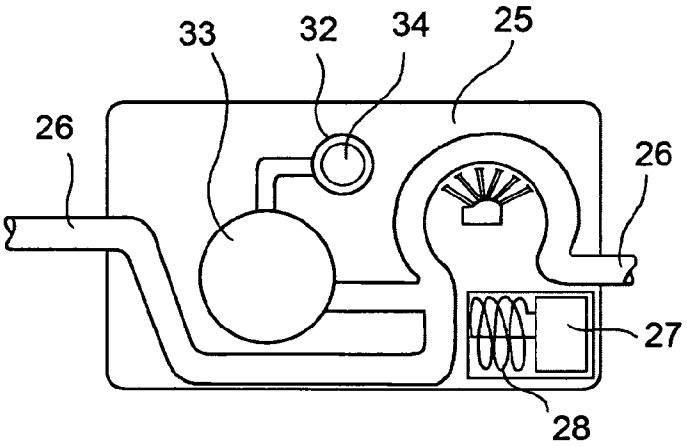
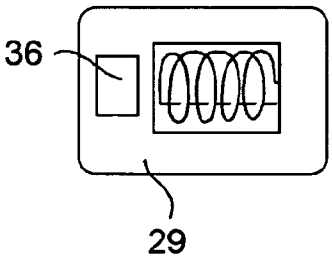


FIG. 6



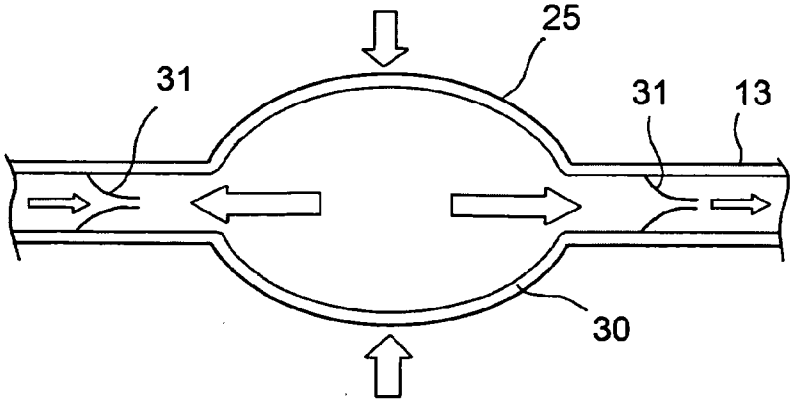


FIG. 7

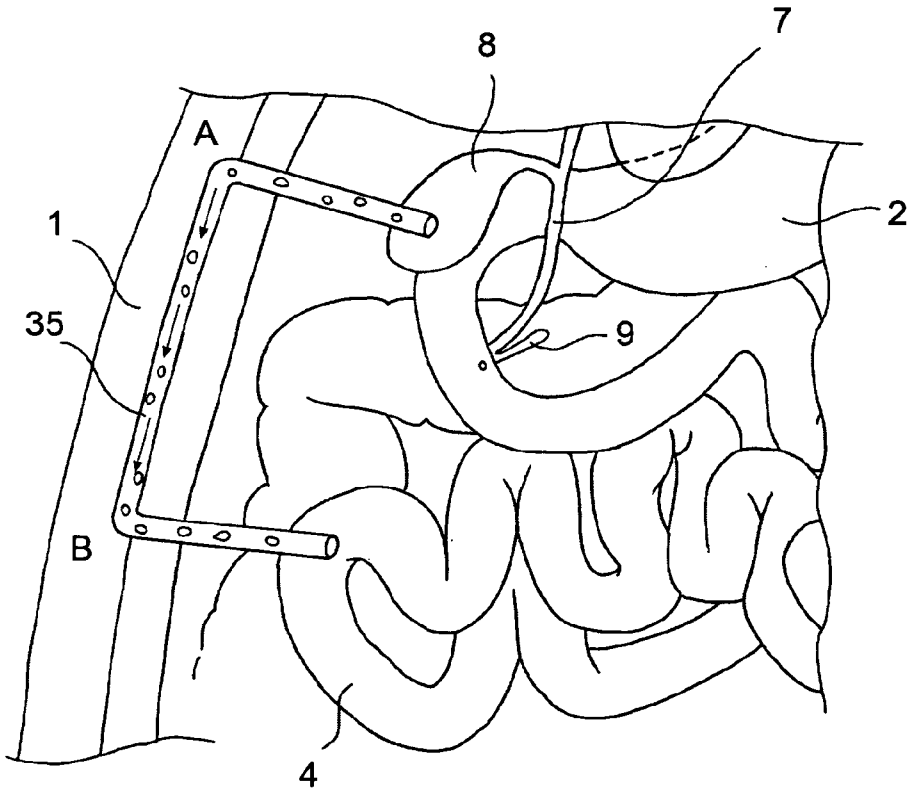


FIG. 8

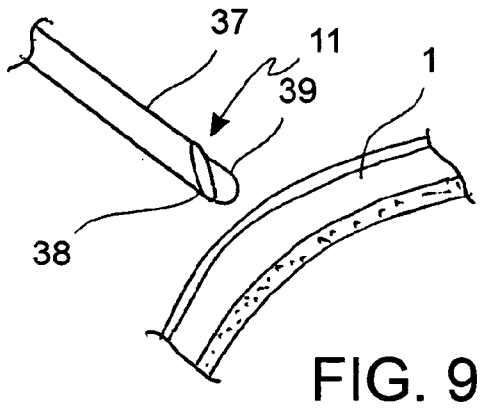


FIG. 9

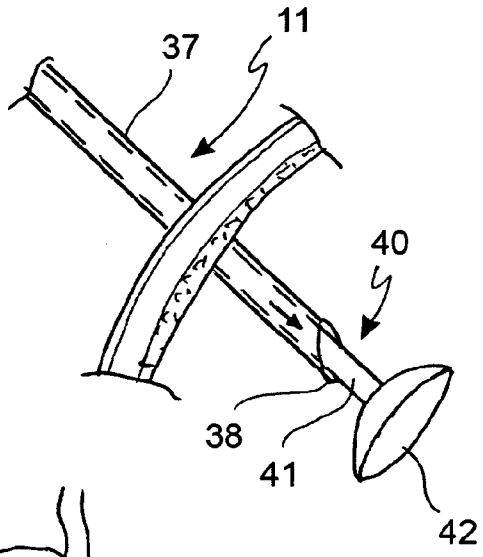


FIG. 10

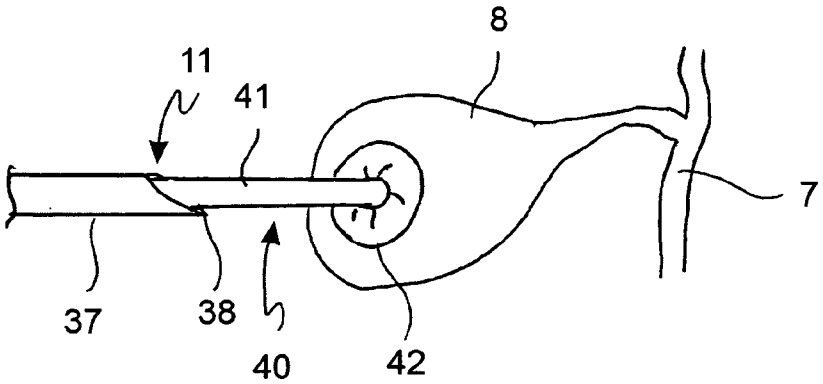


FIG. 11

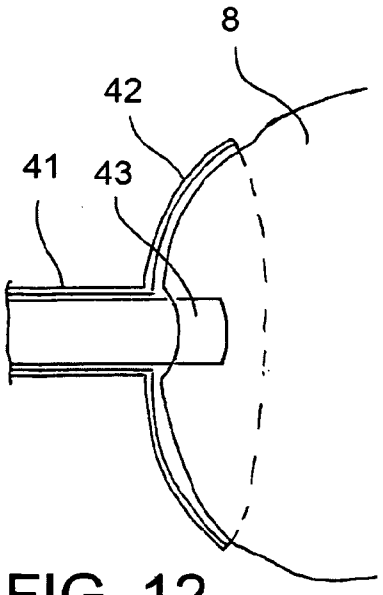


FIG. 12

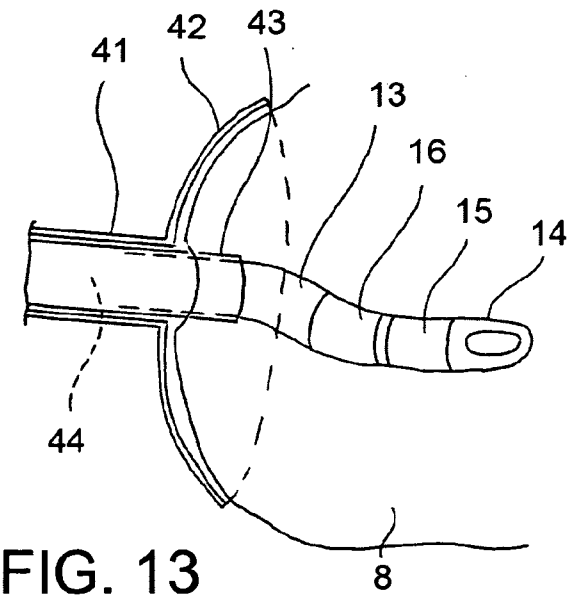


FIG. 13

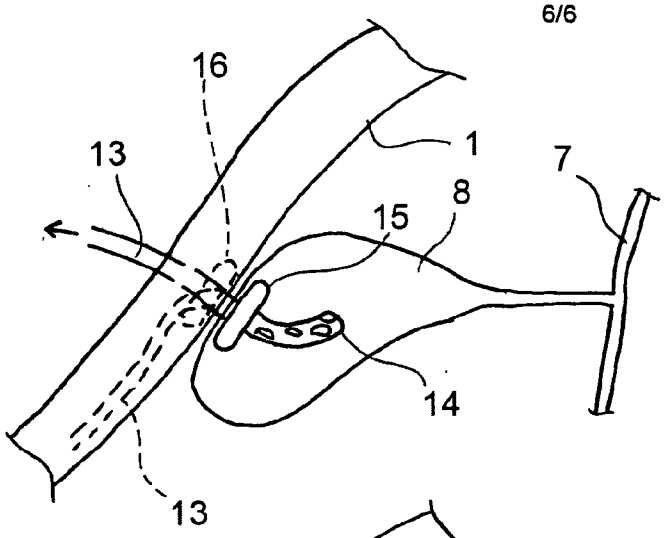


FIG. 14

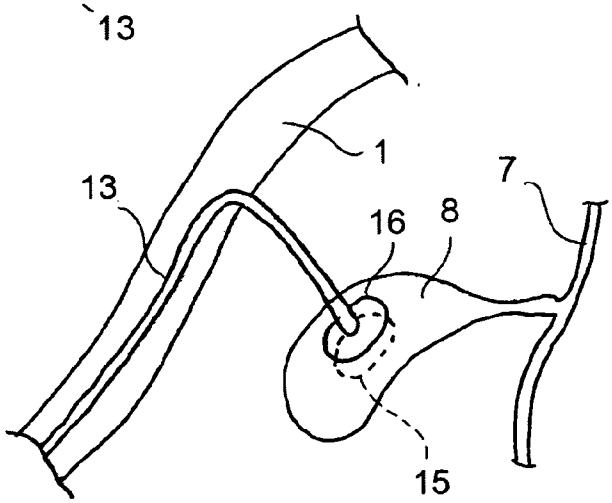


FIG. 15

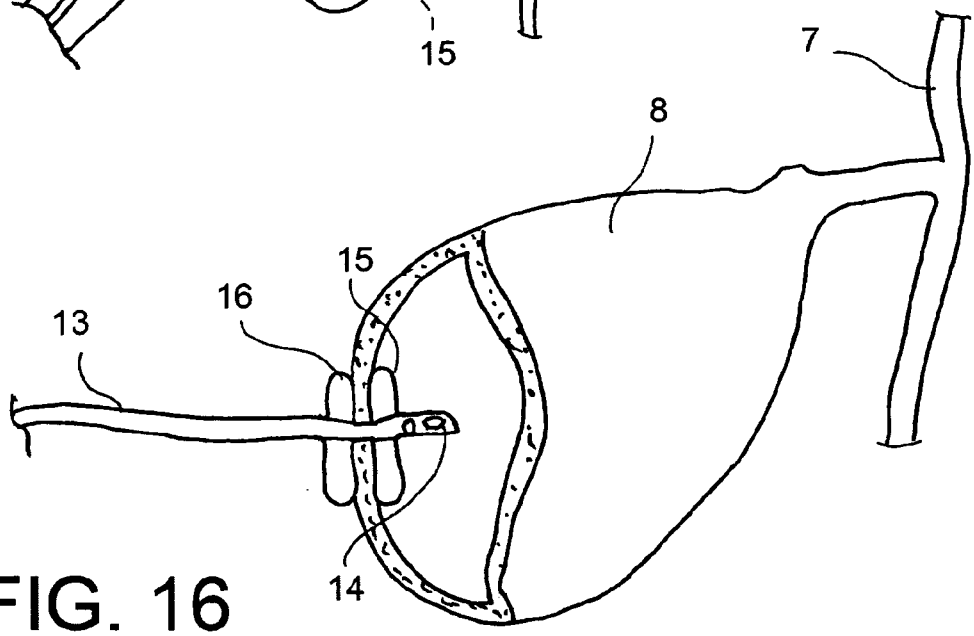


FIG. 16

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP201Q/06Q269

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/Q4
ADD.

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)
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.
A	US 2005/020963 Al (GABAL ABDELWAHAB M [US]] 27 January 2005 (2005-01-27) the whole document	17 ,30

☐ Further documents are listed in the continuation of Box C.

☒ 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
13 Apri l 2011	26/04/2011

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	Smi th, Col i n

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP201Q/06Q269

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.: 1-16
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:

1. [ ] 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.

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP201Q/06Q269

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005020963 Al	27-01-2005	NONE	