

AperTO - Archivio Istituzionale Open Access dell'Università di Torino

A DEVICE FOR TRANSLUMENAL DIVERSION OF BILE

This is the author's manuscript

Original Citation:

Availability:

This version is available <http://hdl.handle.net/2318/129180> since

Terms of use:

Open Access

Anyone can freely access the full text of works made available as "Open Access". Works made available under a Creative Commons license can be used according to the terms and conditions of said license. Use of all other works requires consent of the right holder (author or publisher) if not exempted from copyright protection by the applicable law.

(Article begins on next page)



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

(21) International Application Number:
PCT/EP2010/060268

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

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant (for all designated States except US):
ETHICON ENDO-SURGERY, INC. [US/US]; 4545
Creek Road, Cincinnati, Ohio 45242-2839 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **PASTORELLI, Alessandro** [IT/IT]; Via Francesco Sivori, 5, I-00136 Roma (IT). **HESS, Christopher J.** [US/US]; 1704 East McMillan St, Cincinnati, Ohio 45206 (US). **ORTIZ, Mark Steven** [US/US]; 1145 Glen Echo Ln, Milford, Ohio 45150 (US). **BILOTTI, Federico** [IT/IT]; Via Bernina, 18, I-04011 Aprilia (IT). **AREZZO, Alberto** [IT/IT]; Via San Fermo, 3, I-10133 Torino (IT).

(74) Agents: **LEIHKAU, Steffen Falk** et al.; c/o Jacobacci & Partners S.p.A., Via Senato, 8, I-20121 Milano (IT).

(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).

Published:

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

(54) Title: A DEVICE FOR TRANSLUMENAL DIVERSION OF BILE

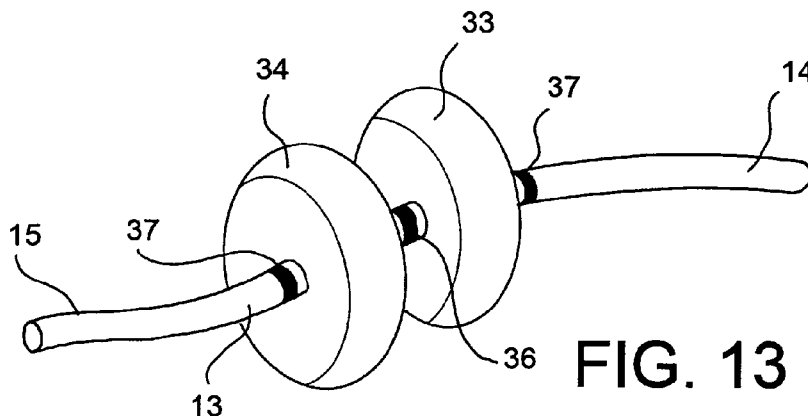


FIG. 13

(57) Abstract: A device (6) for diverting biliary fluid comprises a catheter (13) and an anastomotic coupler (32) connected to the catheter (13), the anastomotic coupler (32) having an expandable first compression portion (33) and an expandable second compression portion (34) adapted to clamp a first portion (17) of a hollow organ and a target portion (18) of the intestine to each other to cause anastomosis of the first portion (17) and the target portion (18), thereby immobilizing the catheter (13) with respect to the anastomosis.

WO 2012/007044 A1

DESCRIPTION

A DEVICE FOR TRANSLUMENAL DIVERSION OF BILE

5 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.

10 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
15 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
20 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
25 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
30 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 extend inside the intestine and 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, in order to follow the winding path of the intestine, the known endoluminal conduit must have a significant length which undesirably increases the flow resistance and decreases the flow rate of the bile to the distal target location in the GI tract. Accordingly, the known conduit is not suitable 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, an aim of the invention is to provide a minimally invasive device and method of diverting bile from the biliary tree including the gallbladder into a section of the intestine distally to the papilla of Vater, which obviate undesired relocations of the bile conduit from the target location.

A further aim of the invention is to increase the flow rate of the diverted bile towards the target location in the small intestine.

At least part of the above identified aims are achieved by a method for diverting biliary fluid from a biliary fluid flow path to a target location in the intestine distal to a duodenal papilla of Vater, the method comprising the steps of:

- a) creating a firstotomy at a first portion of a hollow organ;
- b) creating a secondotomy at a target portion of the intestine, said target portion being distal to the papilla of Vater;
- c) placing a proximal end portion of a catheter within a biliary fluid flow path;
- d) extending the catheter from the biliary fluid flow path, through the firstotomy and the secondotomy, to said target location in the intestine;
- e) placing a distal end portion of the catheter in said target location in the intestine.

Thanks to the extension of a transluminal catheter from the biliary fluid flow path to the target location in the intestine, at least part of the duodenum can be bypassed and the bypass length can be minimized. Moreover, by extending the catheter through anotomy at the target portion of the intestine, the distal catheter end portion cannot bundle up and cannot be dislocated away from the intended target location.

The target portion of the intestine may be a portion of the small intestine, e.g. a distal portion of duodenum, a portion of jejunum or ileum or a portion of the large intestine, such as for example the transverse or sigmoid colon.

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

- creating the firstotomy at a first portion of the intestine; and

- anastomosing the first portion of the intestine to the target portion of the intestine.

The entero-entero anastomosis creates a lumen continuity which obviates the risk of leakage of bowel contents in the abdominal space through the interstices between the catheter and the otomies.

5 Moreover, thanks to the entero-entero anastomosis, it is possible to extend the catheter from the biliary duct through the first otomy out of the duodenum and directly into the target portion of intestine, thereby creating a very short bypass path.

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

- creating the first otomy at a first portion of a gallbladder; and

10 - anastomosing the first portion of the gallbladder to the target portion of the intestine.

By creating a cholecystoenterostomy instead of an enteroenterostomy, the proximal catheter end portion is extended through the gallbladder wall, thereby avoiding an insertion of the catheter through the papilla of Vater in the very delicate common bile duct.

In accordance with a yet further aspect of the invention, the method comprises the step of
15 creating the first otomy at a first portion of a common bile duct.

This allows to place the proximal catheter end portion in the biliary fluid flow path without entering the papilla of Vater and without manipulating the gallbladder.

At least part of the above identified aims are further achieved by a device for diverting biliary fluid from a biliary fluid flow path to a target location in the intestine distal to a
20 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,

- an anastomosis device connected to the catheter, the anastomosis device having an expandable first compression portion and an expandable second compression portion,

25 wherein the first and second compression portions are adapted to clamp a first portion of a hollow organ and a target portion of intestine to each other to cause anastomosis of the first portion and the target portion and to immobilize the catheter with respect to the anastomosis.

This allows to place the catheter and create the anastomosis in a single step and to fixate
30 the catheter with respect to the anastomosis so that the catheter cannot be withdrawn from the anastomosis site.

In accordance with an aspect of the invention, the catheter comprises an external tubular wall and the anastomosis device comprises a first inflatable ring shaped balloon formed in the external wall and a second inflatable ring shaped balloon formed in the external wall at

a distance from the first balloon.

In accordance with a further aspect of the invention, the distance between the first and second balloon is adjustable.

5 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.

- 10 - Figure 1 illustrates a device and method for a transluminal diversion of bile in accordance with an embodiment of the invention;
- Figure 2 illustrates an enlarged detail of figure 1;
- Figure 3 illustrates a method for a transluminal diversion of bile in accordance with a further embodiment of the invention;
- Figure 4 illustrates an enlarged detail of figure 3;
- 15 - Figure 5 illustrates a method and device for a transluminal diversion of bile in accordance with a further embodiment of the invention;
- Figures 6 to 9 illustrate method steps, a device and instrumentation for a transluminal diversion of bile in accordance with an embodiment of the invention;
- Figure 10 illustrates an anastomosis device applier used in the method in figures 6 to 9;
- 20 - Figure 11 illustrate an anastomosis device after deployment and withdrawal of the applier in figure 10;
- Figure 12 illustrates a device for a transluminal diversion of bile in accordance with a further embodiment of the invention, wherein the device is in a first collapsed configuration;
- 25 - Figure 13 illustrates the device of figure 12 in a second expanded configuration;
- Figure 14 illustrates a method for a transluminal diversion of bile using the device of figures 12 and 13;
- Figure 15 illustrates a device for a transluminal diversion of bile in accordance with a further embodiment of the invention, wherein the device is shown in a first collapsed configuration (continuous line) and in a second expanded configuration (broken line);
- 30 - Figure 16 illustrates a device for a transluminal diversion of bile in accordance with a yet further embodiment of the invention, wherein the device is shown in a first collapsed configuration (continuous line) and in a second expanded configuration (broken line);
- Figure 17 illustrates a method and devices for a transluminal 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 stomach 1, duodenum 2, jejunum 3, ileum 4 and colon 5, 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 2. Figure 1 shows further a method and a device 6 for diverting biliary fluid translumenally from a biliary fluid flow path, defined by the biliary tree 7 and the gallbladder 8, to a target location in the intestine distal of the papilla of Vater 10.

10 In accordance with a general inventive idea, the method comprises the steps of:

- creating a firstotomy 11 at a first portion 17 of a hollow organ;
- creating a secondotomy 12 at a target portion 18 of the intestine 2,3,4,5, said target portion 18 being distal to the papilla of Vater 10;
- placing a proximal end portion 14 of a catheter 13 within a biliary fluid flow path;
- 15 - extending the catheter 13 from the biliary fluid flow path, through the firstotomy 11 and the secondotomy 12, to the target location in the intestine 2, 3, 4, 5;
- placing a distal end portion 15 of the catheter 13 in the target location in the intestine.

Thanks to the extension of a transluminal catheter 13 from the biliary fluid flow path to the target location in the intestine, at least part of the duodenum can be bypassed and the bypass length can be minimized. Moreover, by extending the catheter 13 through an

20

otomy at the target portion 18 of the intestine, the distal catheter end portion 15 cannot bundle up and cannot be dislocated away from the intended target location.

The target portion 18 of the intestine may be a portion of the small intestine, e.g. a distal portion of duodenum 2, a portion of jejunum 3 or ileum 4 or a portion of the large intestine

25

5, such as for example the transverse or sigmoid colon.

The proximal end portion 14 of the catheter 13 can be anchored inside the biliary tree 7, e.g. inside the common bile duct, by means of a metallic stent 16 or alternative anchoring means connected to the proximal end portion 14.

In accordance with an embodiment (figures 1, 2, 5), the firstotomy 11 is created at a first

30

portion 17 of the intestine, particularly at the duodenum 2 near the papilla of Vater 10, and the first portion 17 of the intestine is anastomosed to the target portion 18 of the intestine. Such an entero-entero anastomosis creates a lumen continuity which obviates the risk of leakage of bowel contents in the abdominal space through the interstices between the catheter 13 and the otomies 11, 12. In this embodiment, the catheter 13 can be extended

from the biliary tree 7 through the papilla of Vater 10 and the firstotomy 11 out of the duodenum 2 and directly into the target portion 18 of intestine, thereby creating a very short bypass path (Figure 2).

In order to place the catheter 13, an endoscope is inserted in the intestine to visualize the duodenum 2 near the sphincter of Oddi and to identify the first portion 17 of intestine for the firstotomy 11. The same endoscope may be used to identify the target portion 18 of intestine for the secondotomy 12 distal to the papilla of Vater 10 and distal to the firstotomy 11. Then, the first portion 17 of intestine and the target portion 18 of intestine are approximated to each other and an enteroenterostomy is formed therebetween. For the sake of clarity, it should be understood that the enteroenterostomy includes a patent lumen formed by the first and secondotomies 11, 12 which might be performed before or after approximation and connection of the first portion 17 and the target portion 18 of the intestine.

The creation of the enteroenterostomy may involve a laparoscopic deployment of an anastomotic ring device using an applier and an anastomosis device described in the commonly owned US 7,452,363 whose entire content is herein enclosed by reference.

After creation of the enteroenterostomy, the proximal end portion 14 of the catheter 13 with the stent 16 is introduced through the papilla of Vater 10 in the common bile duct, using e.g. an ERCP (Endoscopic Retrograde Cholangio Pancreatography) like technique. The ERCP procedure involves passing a flexible endoscope through the mouth, esophagus, and stomach into the duodenum 2 near the papilla of Vater 10. The doctor then passes the catheter 13 through an instrument channel in the endoscope and out into view in the duodenum 2 and inserts it into the papilla of Vater 10.

After the proximal catheter end portion 14 is positioned in the intended location in the common bile duct, the stent 16 or other anchoring means is activated to connect to the bile duct and to anchor the catheter 13 thereto.

Then, the endoscope is withdrawn to an extent that the distal end portion 15 of the catheter 13 emerges from the instrument channel or the distal end portion 15 of the catheter 13 is expelled from the instrument channel so that it can be grasped by means of an endoscopic grasper and introduced through the enteroenterostomy in the target portion 18 of the intestine.

In accordance with an embodiment, the catheter 13 may be additionally fixated to the anastomosis device or to the entero-entero anastomosis, thereby immobilizing the catheter 13 with respect to the target portion 18 of the intestine. Then the endoscope can

be withdrawn from the body of the patient. The resulting situation is illustrated in figures 1 and 2.

In order to prevent retrograde infection of the biliary tree 7 or pancreatitis, the catheter 13 may comprise an antimicrobial coating 19 containing e.g. silver.

5 In accordance with a further embodiment (Figure 9), the firstotomy 11 is created at a first portion 17 of the gallbladder 8 and the first portion 17 of the gallbladder 8 is anastomosed to the target portion 18 of the intestine 2, 3, 4, 5. In this embodiment, a cholecystoenterostomy is created instead of an enteroenterostomy and the proximal end portion 14 of the catheter 13 is extended through the gallbladder wall, thereby avoiding an
10 insertion of the catheter 13 through the papilla of Vater in the very delicate common bile duct.

In this embodiment, the gallbladder 8 can be approximated to the target portion 18 of the intestine through a percutaneous introduction of a grasping instrument into the abdominal space and grasping the gallbladder 8 by means of the grasping instrument and pulling the
15 gallbladder 8 towards and against the target portion 18 of the intestine. The grasping instrument may comprise opposing jaws connected to a rigid shaft or, alternatively, the grasping instrument may comprise an inflatable balloon connected to a distal end of a rigid shaft and having an inflated shape adapted to engage the gallbladder 8 and push it towards and against the target portion 18 of the intestine. For this purpose, a distal tip of
20 the grasping instrument together with the inflatable balloon may be percutaneously introduced into the gallbladder 8 and the balloon is inflated inside the gallbladder to engage the latter.

After approximation of the first portion 17 of the gallbladder and the target portion 18 of the intestine, the cholecystoenterostomy is created by laparoscopic deployment of an
25 anastomotic ring device using an applier and an anastomosis device described in the commonly owned US 7,452,363 whose entire content is herein enclosed by reference. The anastomosis device may be completely bioabsorbable or biofragmentable or only a proximal (gallbladder side) compression portion of the anastomosis device may be bioabsorbable or biofragmentable so that the anastomosis device can be expelled
30 together with the stool.

After the creation of the cholecystoenterostomy, the proximal end portion 14 of the catheter 13 with the stent 16 is introduced through the cholecystoenterostomy (i.e. through the second and firstotomy) in the gallbladder 8 and, possibly, run up into the cystic duct. This can be advantageously accomplished by a modified ERCP (Endoscopic

Retrograde Cholangio Pancreatography) like procedure which involves passing a flexible side viewing scope through the rectum and colon into the target portion 18 of the intestine 2, 3, 4, 5 or, alternatively, passing the flexible side viewing scope transorally into the target portion 18 of the intestine and, then passing the catheter 13 through an instrument

5 channel in the endoscope and out into view in the target portion 18 of the intestine and inserting the proximal catheter end portion 14 through the cholecystoenterostomy in the gallbladder 8 and, possibly, guiding it up into the cystic duct.

After the proximal catheter end portion 14 is positioned in the intended location, the stent 16 or other anchoring means is activated to anchor the catheter 13 in the gallbladder 8 or

10 in the cystic duct.

Then, the side view scope is withdrawn to an extent that the distal end portion 15 of the catheter 13 emerges from the instrument channel or the distal end portion 15 of the catheter 13 is expelled from the instrument channel in the target portion 18 of the intestine.

15 If a total bile diversion is desired, a plug 20 may be deployed in the common bile duct distal of the proximal catheter end (Figure 9).

The catheter 13 may be additionally fixated to the anastomosis device or to the cholecystoentero-anastomosis, thereby immobilizing the catheter 13 with respect to the target portion 18 of the intestine. Then the endoscope can be withdrawn from the body of

20 the patient. The resulting situation is illustrated in figure 9.

In accordance with an embodiment, both the cholecystoenterostomy and the placement of the transluminal catheter 13 can also be accomplished using a laparoscopic approach, as illustrated in figures 6 to 11.

Figure 11 shows an exemplary anastomosis ring device 22 having proximal 23, center 24, and distal rings 25 connected respectively by proximal and distal hinged arms, the ring device 22 having a generally cylindrical shape when unactuated and a rivet shape when actuated. Figure 10 illustrates an exemplary applier 21 for the anastomosis ring device 22. The applier 21 comprises an elongate implement portion 26, a handle 27 connected to the implement portion 26, an actuating member internally engaged to a selected one of the

25 rings of the anastomosis device 22, an arresting member internally engaged to a selected second of the rings of the anastomosis device 22 and a control coupled to the handle 27 and configured to cause movement of the actuating member, and thus the engaged ring, toward the arresting member, and thus the selected second ring, causing actuating the interposed hinged arms of the ring device 22. Such an anastomosis device and applier

30

have been described in the above mentioned US 7,452,363.

The applier 21 together with the ring device 22 is introduced in the abdominal space through a laparoscopic access port and placed through the first and second otomies 11, 12 which are intended to be anastomosed. The applier 21 can have a distal pointed tip 28 adapted to create the otomies when being forced through the wall of the intestine and or
5 gallbladder. Alternatively, the first and second otomies 11, 12 may be created with a standard laparoscopic cutting instrument.

As shown in figure 6, the applier 21 may be inserted through a third otomy 29 in a portion of the intestine distal to the target portion 18 and subsequently advanced proximally to the
10 target portion 18. Then the distal ring 25 of the anastomosis device 22 is inserted through the previously created second otomy 12, while the proximal hinged arms of the anastomosis device 22 are actuated to expand radially so that the device 22 cannot completely slip through the second otomy 12. By pushing the applier 21 towards the gallbladder 8, the target portion 18 of the intestine is approximated to the first portion 17 of
15 the gallbladder 8. Then the distal ring 25 of the anastomosis device 22 is inserted through the previously created first otomy 11 inside the gallbladder 8 and the distal hinged arms are activated to expand radially, thereby clamping the first portion 17 of the gallbladder 8 against the target portion 18 of the intestine to allow anastomosis therebetween (Figure 7). Then, the applier 21 can be withdrawn through the third otomy 29 and the catheter 13
20 can be inserted through the third otomy 29 and the second and first otomies 12, 11 at the cholecystoenterostomy into the gallbladder 8 and, possibly, into the cystic duct (Figure 8). After the proximal catheter end portion 14 is positioned in the intended location, the stent 16 or other anchoring means may be activated to anchor the catheter 13 in the gallbladder 8 or in the cystic duct (Figure 9). Additionally, the catheter 13 can be fixated to the
25 anastomosis device 22 to immobilize the catheter distal end portion 15 with respect to the target portion 18 of the intestine.

The resulting bypass allows to divert the bile originating from the liver to the target location in the intestine.

In accordance with a further embodiment (Figures 3, 17), the first otomy 11 is created at a
30 first portion 18 of the common bile duct. This allows to place the proximal catheter end portion 14 in the biliary fluid flow path without entering the papilla of Vater 10 and without manipulating the gallbladder 8.

In the embodiment of figure 17, the bile is caused to bypass part of the small intestine 2, 3 by placing the catheter 13 so that the proximal catheter end portion 14 is positioned in the

common bile duct and the distal catheter end portion 15 is positioned in the jejunum 3 or ileum 5.

In the embodiment of figure 3, the bile is caused to completely bypass the small intestine 2, 3, 4 by placing the catheter 13 in a transcolonic approach, so that the proximal catheter end portion 14 is positioned in the common bile duct and the distal catheter end portion 15 is positioned in the large bowel 5, for example in the transverse bowel.

In a possible laparoscopic procedure, a laparoscopic access port is created and a laparoscopic cutting instrument is inserted through the access port in the abdominal space to perform the firstotomy 11 at the bile duct 7 and the secondotomy 12 at the colon 5.

Then the cutting instrument is withdrawn and the catheter 13 is inserted through the access port in the abdominal space. The proximal end portion 14 of the catheter 13 is inserted through the firstotomy 11 in the bile duct 7 in retrograde direction (against the direction of the natural flow of the bile) and the stent 16 or other anchoring means is deployed to anchor the proximal catheter end portion 14 in the bile duct 7. Then a purse string suture is applied to the firstotomy 11 around the catheter 13 to seal the firstotomy 11.

The distal end portion 15 of the catheter 13 is inserted through the secondotomy 12 in the colon 5 and a purse string suture is applied to the secondotomy 12 around the catheter 13 to seal the secondotomy 12. Then the instrumentation is withdrawn from the patient's body and the access ports are removed and the apertures in the abdominal wall are sutured.

By bypassing the entire small bowel, the absorption of lipids will be significantly reduced due to the absence of bile.

Undesired backflow of stool or chime from the intestine can be prevented by arranging an unidirectional valve 30 (illustrated in Figure 17), such as a collapsible low pressure flapper valve at the distal end of the catheter 13. The valve 17 closes when intestinal or colonic peristalsis tend to push chime or stool into the catheter 13 and opens when bile flows down the catheter and the internal bile pressure exceeds the external pressure at a distal catheter outlet opening.

In order to reduce the risk of peritonitis and retrograde infection due to the transfer of chime or stool into the bile duct, a transhepatic introduction of the catheter 13 through the liver into the bile duct 7 is contemplated. In this case the distal catheter end portion 15 is fed through the firstotomy 11 out of the bile duct 7 towards a transilluminated target portion 18 of the colon 5 and through the secondotomy 12 into the colon 5.

In accordance with a further embodiment, the catheter 13 is inserted transhepatically through the liver into the bile duct 7 and the distal catheter end portion 15 is fed through the papilla of Vater 10 into the duodenum 2 and through a previously created firstotomy 11 in the duodenal wall out of the duodenum 2 towards a transilluminated target portion 18 of the colon 5 and through the secondotomy 12 into the colon 5.

These embodiments require purse string sutures at the first and secondotomies 11, 12 to seal the latter with respect to the catheter 13 in order to prevent leakage of bowel contents into the abdominal space.

Such a chronic trauma of the intestinal wall can be obviated through re-establishing the intestinal lumen continuity by means of a duodeno-colono-anastomosis between the first and secondotomies 11, 12 and extending the catheter 13 from inside the bile duct 7 through the papilla of Vater 10 and through the duodeno-colono-anastomosis into the target portion 18 of the colon 5 (Figure 5). For this purpose, the devices and methods which have been described above in connection with the entero-entero-anastomoses and cholecysto-entero-anastomosis may be used. Alternatively, the duodeno-colono-anastomosis can also be accomplished using an anastomosis device and applier as described in US 7,618,427 whose entire content is incorporated herein by reference.

Figures 12 to 16 illustrate further embodiments of the device 6 for diverting biliary fluid from the biliary fluid flow path 7, 8 to the target location in the intestine distal to a duodenal papilla of Vater 10.

In the embodiment of figures 12 and 13, the device 6 comprises the catheter 13 with its proximal end portion 14 and distal end portion 15 and a conduit section 31 extending between the proximal end portion 14 and the distal end portion 15, as well as an anastomotic coupler 32 connected to the catheter 13. The anastomotic coupler 32 comprises a first expandable compression portion 33 and a second expandable compression portion 34, wherein the first and second compression portions 33, 34 are adapted to clamp the first portion 17 of a hollow organ and the target portion 18 of the intestine to each other to cause anastomosis of the first portion 17 and the target portion 18 and to immobilize the catheter 13 with respect to the resulting anastomosis.

This allows to place the catheter 13 and create the anastomosis in a single step and to fixate the catheter 13 with respect to the anastomosis so that the catheter cannot be withdrawn from the anastomosis site.

In a collapsed and radially retracted state, the compression portions 33, 34 allow for endoscopic or laparoscopic placement of the catheter 13 through the first and second

otomies 11, 12.

In accordance with an embodiment, the catheter 13 comprises an external tubular wall 35 and the anastomotic coupler 32 comprises a first inflatable ring shaped balloon formed in the external wall 32 and a second inflatable ring shaped balloon formed in the external wall 32 at a distance from the first balloon.

In accordance with an embodiment, a first marker 36 which can be visualized, for instance a radio opaque region, is provided at the catheter tract between the compression portions 33, 44 and further markers 37 may be provided adjacent to the compression portions 33, 44 opposite the first marker 36. The markers 36, 37 help localization of the compression portions 33, 44 and facilitate a correct positioning of the catheter 13.

Figure 14 illustrates an exemplary non limiting use of the device 6 for creating a cholecystoenterostomy and extending the catheter 13 through the anastomotic lumen, e.g. in one of the methods described above in connection with figure 9.

In accordance with a further embodiment, the distance between the first and second compression portions 33, 34 is adjustable to regulate the compression force acting on the first portion 17 and the target portion 18 in the anastomosis site. For this purpose a threaded adjustment coupling 38 (Figure 15) or a ratcheting adjustment coupling 39 (Figure 16) may be provided in the catheter 13 between the first and second compression portions 33, 34. The ratcheting adjustment coupling 39 may further comprise a pulling string 40 having a first end connected to a first ratcheting portion of two engaging ratcheting portions and a second end emerging from the catheter 13 on the side opposite the first ratcheting portion and adapted to be grasped and pulled to further approximate the ratcheting portions.

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) to a target location in the intestine (3,4,5) distal to a duodenal papilla of Vater (10), the method comprising the steps of:

- 5 - creating a firstotomy (11) at a first portion (17) of a hollow organ;
- creating a secondotomy (12) at a target portion (18) of the intestine (2,3,4,5), said target portion (18) being distal to the papilla of Vater (10);
- placing a proximal end portion (14) of a catheter (13) within the biliary fluid flow path (7, 8);
10 - extending the catheter (13) from the biliary fluid flow path (7, 8), through the firstotomy (11) and the secondotomy (12), to the target location in the intestine (2, 3, 4, 5).

2. Method according to claim 1, comprising the step of anchoring the proximal end portion (14) of the catheter (13) inside the biliary tree (7).

3. Method according to claim 1 or 2, comprising the steps of:

- 15 - creating the firstotomy (11) at a first portion (17) of the duodenum (2) near the papilla of Vater (10); and
- anastomosing the first portion (17) of the duodenum (2) to the target portion (18) of the intestine.

4. Method according to claim 3, comprising the steps of:

- 20 - inserting an endoscope in the intestine to visualize the duodenum (2) near the sphincter of Oddi; and
- identifying the first portion (17) of intestine for the firstotomy (11) using said endoscope;
- identifying the target portion (18) of intestine for the secondotomy (12) using said endoscope;
25 - approximating the first portion (17) of duodenum (2) and the target portion (18) of intestine to each other and forming an enteroenterostomy therebetween;
- inserting the proximal end portion (14) of the catheter (13) with a stent (16) through the papilla of Vater (10) in the common bile duct by passing a flexible endoscope through the mouth, esophagus, and stomach into the duodenum (2) near the papilla of Vater (10) and
30 passing the catheter (13) through an instrument channel of the endoscope in the duodenum (2) and into the papilla of Vater (10).
- deploying the stent (16) to anchor the catheter (13) to the bile duct.
- grasping, by means of an endoscopic grasper, a distal end portion (15) of the catheter (13) and introducing the distal end portion (15) through the enteroenterostomy in the

target portion (18) of the intestine.

5. Method according to claim 3, comprising the step of fixating the catheter (13) to the anastomosis, thereby immobilizing the catheter (13) with respect to the target portion (18) of the intestine.

5 **6.** Method according to claim 1, comprising the steps of:

- creating the firstotomy (11) at a first portion (17) of the gallbladder (8); and
- anastomosing the first portion (17) of the gallbladder (8) to the target portion (18) of the intestine (2, 3, 4, 5).

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

- 10
- percutaneous introduction of a grasping instrument into the abdominal space; and
 - grasping the gallbladder (8) by means of the grasping instrument and pulling the gallbladder (8) towards and against the target portion (18) of the intestine.

8. Method according to claim 7, comprising the steps of:

- 15
- providing an inflatable balloon connected to a distal end of said grasping instrument;
 - introducing the distal end of the grasping instrument together with the inflatable balloon into the gallbladder (8); and
 - grasping the gallbladder by inflating the balloon inside the gallbladder.

9. Method according to claim 6, comprising the steps of:

- 20
- creating a cholecystoenterostomy by laparoscopic deployment of an anastomotic ring device.

10. Method according to claim 6, comprising the steps of:

- 25
- after the creation of the cholecystoenterostomy, inserting the proximal end portion (14) of the catheter (13) and a stent (16) through said cholecystoenterostomy in the gallbladder (8) by passing a flexible side viewing scope into the target portion (18) of the intestine and passing the catheter (13) through an instrument channel of the endoscope in the target portion (18) of the intestine and inserting the proximal catheter end portion (14) through the cholecystoenterostomy in the gallbladder (8);
 - activating the stent (16) to anchor the catheter (13) in the gallbladder (8).

11. Method according to claim 6, comprising the step of fixating the catheter (13) to the anastomosis, thereby immobilizing the catheter (13) with respect to the target portion (18) of the intestine.

12. Method according to claim 6, comprising the steps of:

- 30
- creating a laparoscopic access port;
 - creating a thirdotomy in the intestine near the secondotomy;

15

- introducing a laparoscopic applier (21) together with a ring device (22) through said laparoscopic access port and said thirdotomy into the target portion of intestine;
- placing the ring device (22) into the secondotomy (12) and pushing the target portion (18) having the secondotomy (12) towards the first portion (17) having the firstotomy (11) and, then, placing the ring device (22) into the firstotomy (11);
- deploying the ring device (22) to anastomose the first portion (17) to the target portion (18);
- withdrawing the applier (21) through the thirdotomy (29); and
- inserting the catheter (13) through the thirdotomy (29) and the second and firstotomies (12, 11) at the cholecystoenterostomy into the gallbladder (8).

13. Method according to claim 2, comprising the step of creating said firstotomy (11) at a common bile duct.

14. Method according to claim 13, comprising the steps of placing the proximal catheter end portion (14) in the common bile duct and placing the distal catheter end portion (15) in the small intestine distal to the duodenum (2).

15. Method according to claim 13, comprising the steps of placing the proximal catheter end portion (14) in the common bile duct and placing the distal catheter end portion (15) in the colon (5).

16. Method according to claim 15, comprising the steps of:

- creating a laparoscopic access port;
- inserting a laparoscopic cutting instrument through the access port in the abdominal space and performing the firstotomy (11) at the bile duct (7) and the secondotomy (12) at the colon (5), using said cutting instrument;
- withdrawing the cutting instrument;
- inserting the catheter (13) through the access port in the abdominal space; and
- inserting the proximal end portion (14) of the catheter (13) and a stent (16) through the firstotomy (11) in the bile duct (7) in retrograde direction; and
- anchoring the proximal end portion (14) by deploying the stent (16) in the bile duct (7);
- sealing the firstotomy (11) by applying a purse string suture to the firstotomy (11) around the catheter (13);
- inserting the distal end portion (15) of the catheter (13) through the secondotomy (12) in the colon (5);
- sealing the secondotomy (12) by applying a purse string suture to the secondotomy (12) around the catheter (13).

17. Method according to claim 1, comprising the step of arranging an unidirectional valve (30) at the distal end (15) of the catheter (13).

18. Method according to claim 13, comprising the steps of:

- transhepatic introduction of the catheter (13) through the liver into the bile duct (7);
- 5 - transilluminating the target portion (18) of the colon (5);
- feeding the distal catheter end portion (15) through the firstotomy (11) out of the bile duct (7) towards the transilluminated target portion (18) and through the secondotomy (12) into the colon (5).

19. Method according to claim 1, comprising the steps of:

- 10 - transhepatic introduction of the catheter (13) through the liver into the bile duct (7);
- transilluminating the target portion (18) of the colon (5);
- feeding the distal catheter end portion (15) through the papilla of Vater (10) into the duodenum (2) and through a previously created firstotomy (11) in the duodenal wall out of the duodenum (2) towards the transilluminated target portion (18) and through the second
- 15 -otomy (12) into the colon (5).

20. A device (6) for diverting biliary fluid from a biliary fluid flow path (7, 8) to a target location in the intestine (3,4,5), the device (6) comprising:

- 20 - a catheter (13) having a proximal end portion (14) and a distal end portion (15) and a conduit section (31) extending between the proximal end portion (14) and the distal end portion (15),
- an anastomotic coupler (32) connected to the catheter (13), said anastomotic coupler (32) having an expandable first compression portion (33) and an expandable second compression portion (34),

said first and second compression portions (33, 34) being adapted to clamp a first portion (17) of a hollow organ and a target portion (18) of the intestine to each other to cause anastomosis of the first portion (17) and the target portion (18), thereby immobilizing the catheter (13) with respect to said anastomosis.

21. Device (6) according to claim 20, in which the catheter (13) comprises an external tubular wall (35) and the anastomotic coupler (32) comprises a first inflatable ring shaped balloon formed in the external wall (32) and a second inflatable ring shaped balloon formed in the external wall (32) at a distance from the first balloon.

22. Device (6) according to claim 20, in which the catheter (13) comprises a visualizable marker (36, 37) positioned at a catheter tract near the compression portions (33, 44).

23. Device (6) according to claim 22, in which said marker (36,37) comprises a radio-

opaque substance.

24. Device (6) according to claim 20, in which the distance between the first and second compression portions (33, 34) is adjustable.

5 **25.** Device (6) according to claim 24, wherein a threaded adjustment coupling (38) is arranged in the catheter (13) between the first and second compression portions (33, 34).

26. Device (6) according to claim 24, wherein a ratcheting adjustment coupling (39) is arranged in the catheter (13) between the first and second compression portions (33, 34).

10 **27.** Device (6) according to claim 26, wherein said ratcheting adjustment coupling (39) comprises a pulling string (40) having a first end connected to a first ratcheting portion of two engaging ratcheting portions and a second end emerging from the catheter (13) on the side opposite the first ratcheting portion and adapted to be grasped and pulled to approximate said two engaging ratcheting portions.

28. Device (6) according to any one of claims 20 to 27, comprising an anchoring stent (16) connected to the proximal end portion (14) of the catheter (13).

15 **29.** Device (6) according to any one of claims 20 to 28, in which said catheter (13) comprises an antimicrobial coating (19).

30. Device (6) according to any one of claims 20 to 29, comprising an unidirectional valve (30) arranged at a distal end of the catheter (13).

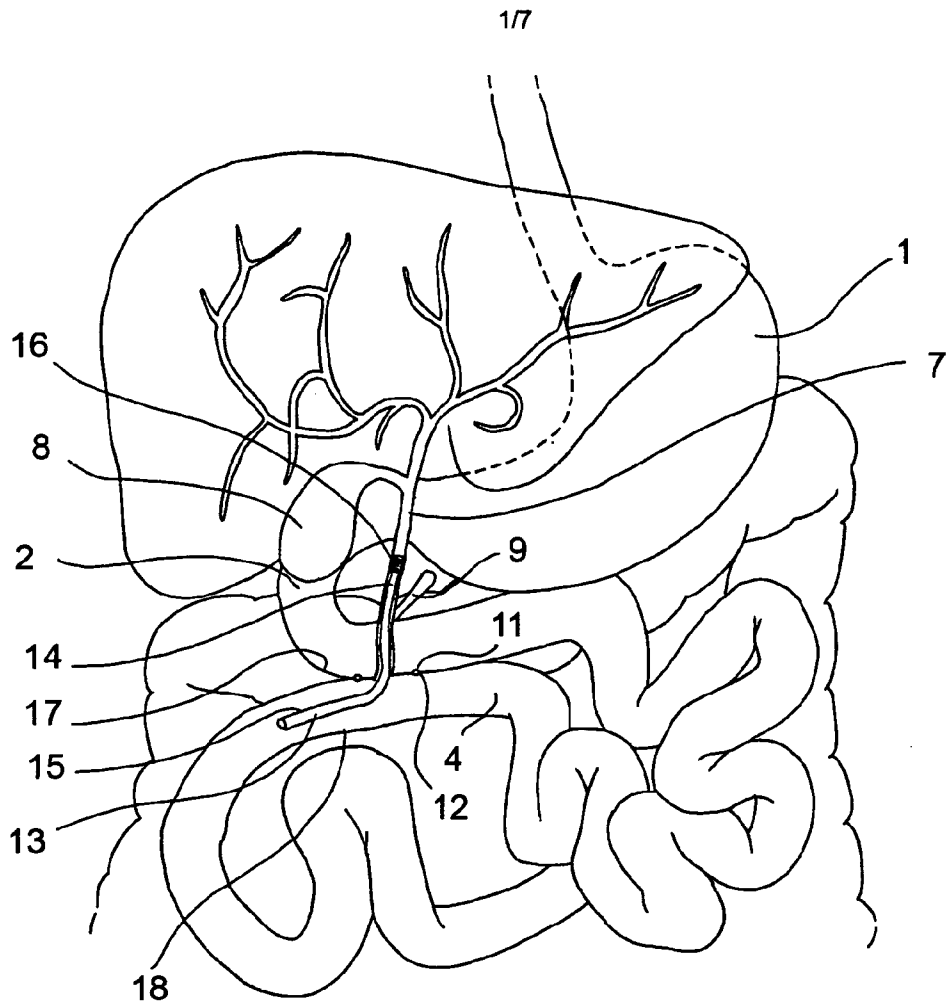


FIG. 1

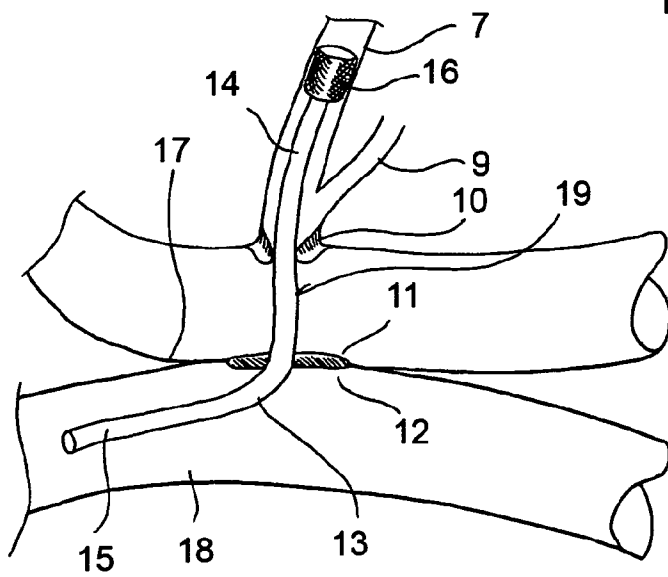


FIG. 2

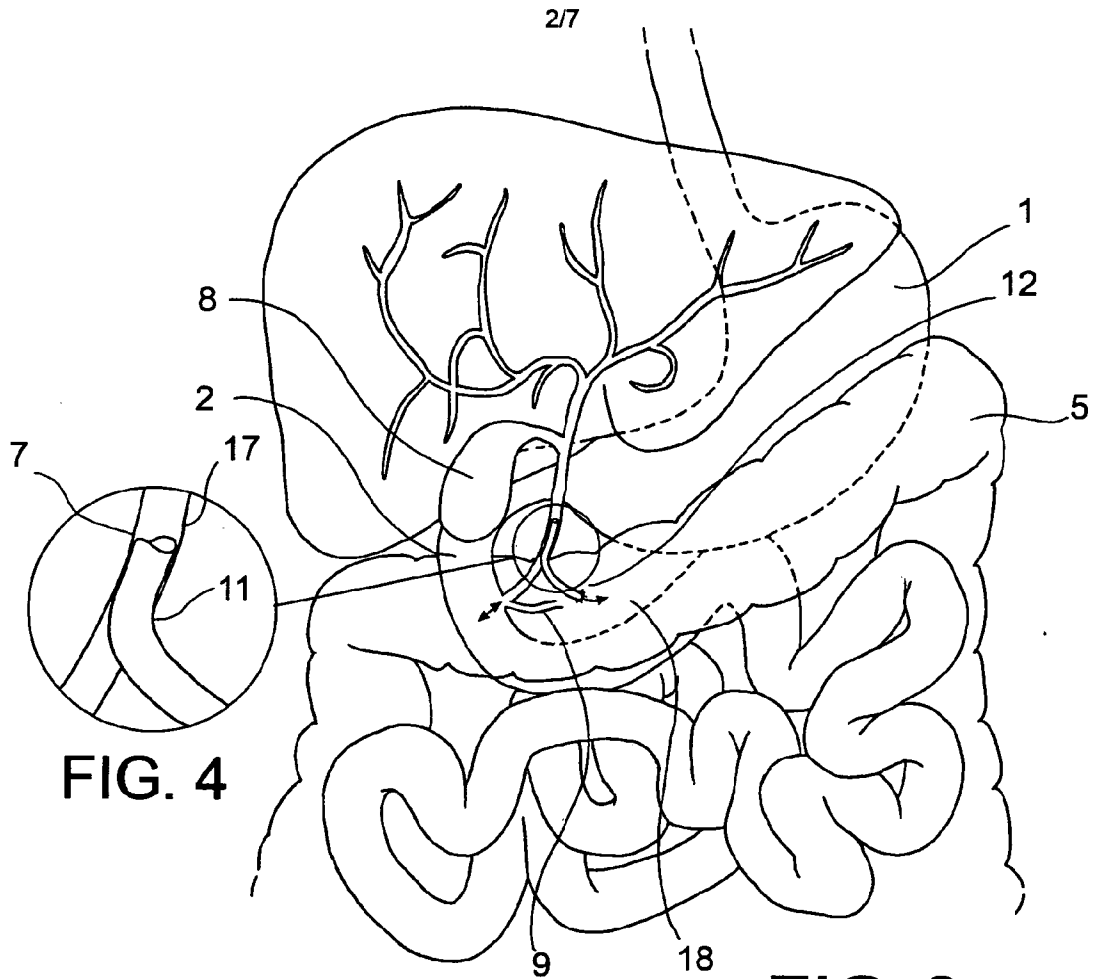


FIG. 4

FIG. 3

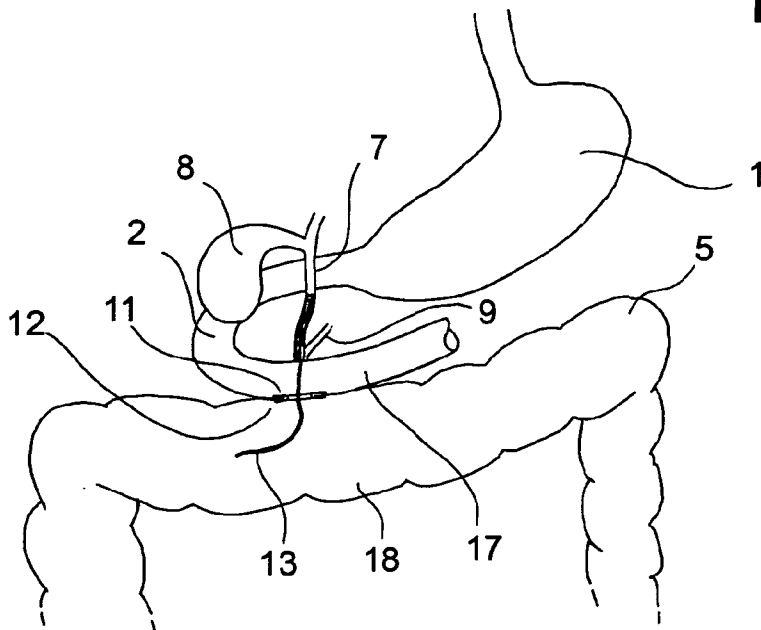


FIG. 5

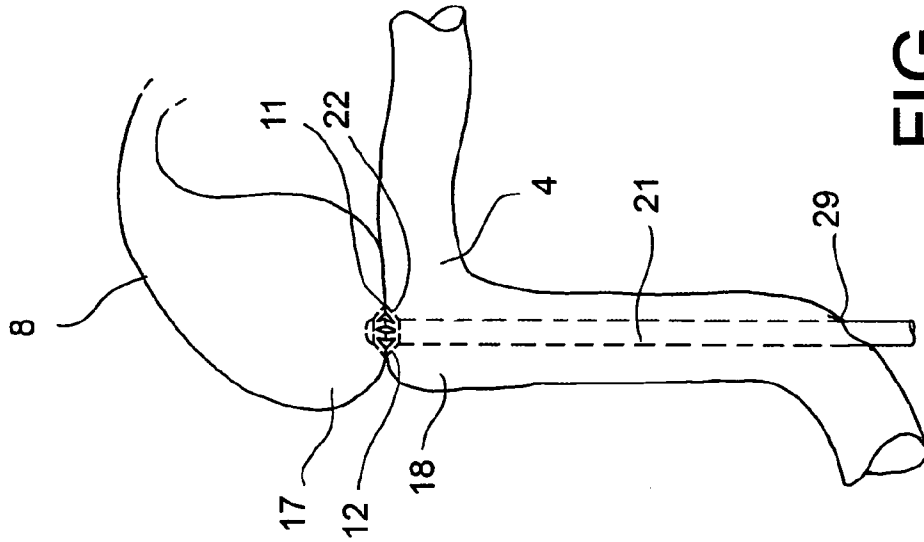


FIG. 7

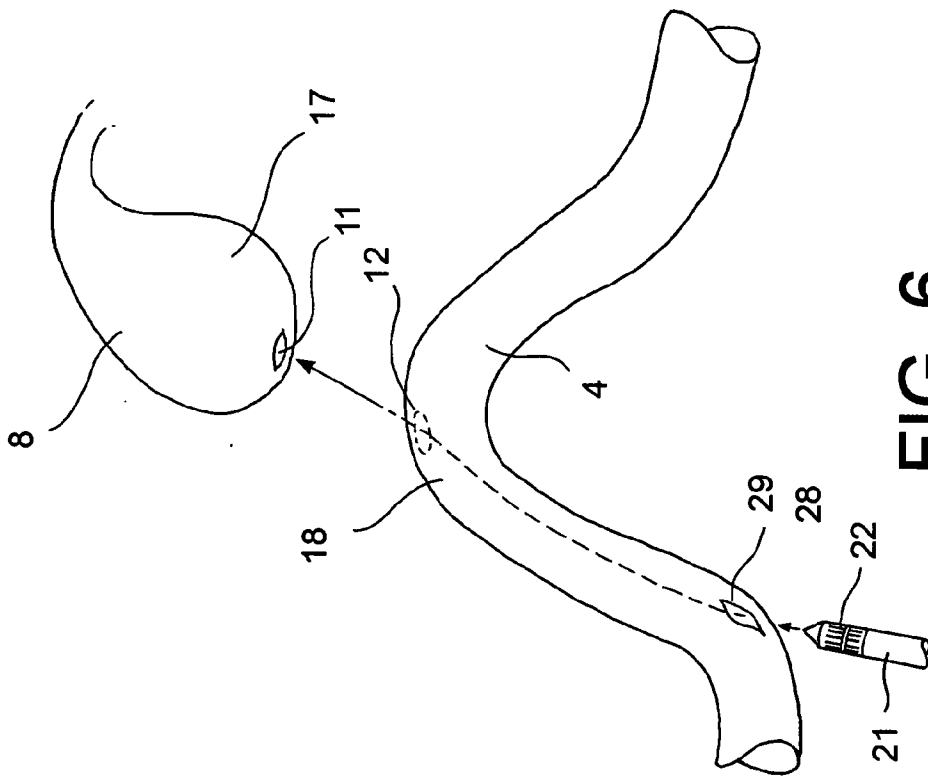


FIG. 6

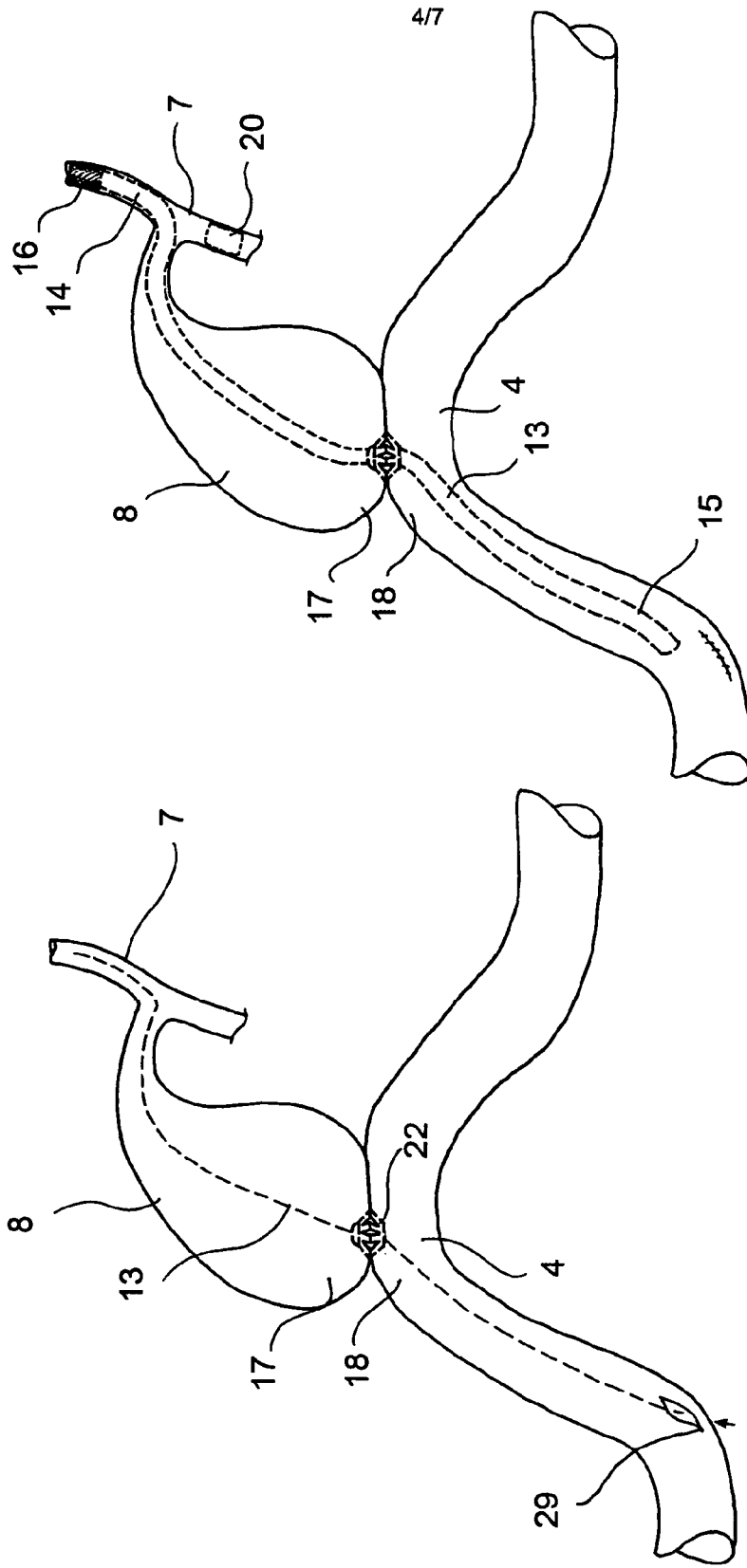


FIG. 9

FIG. 8

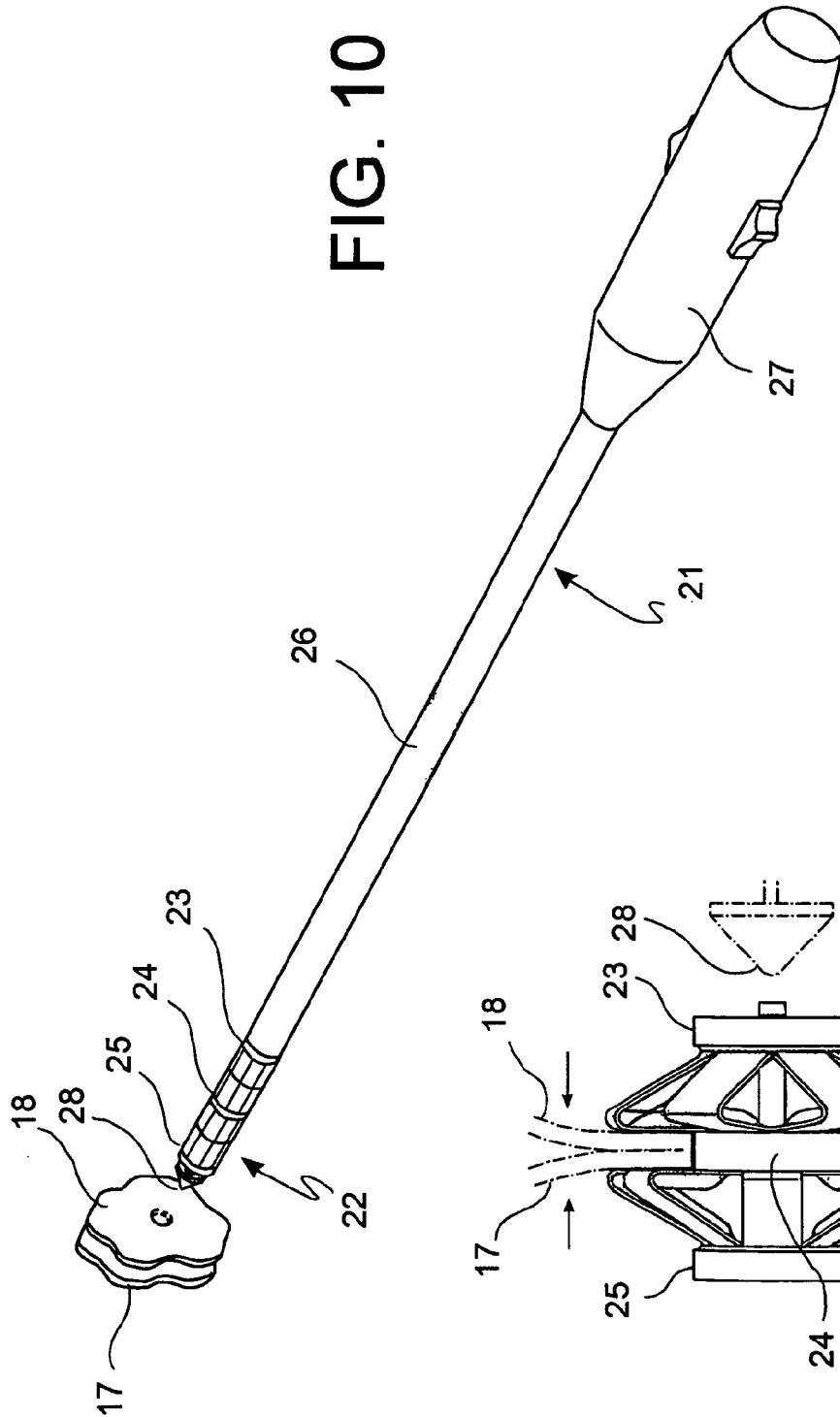


FIG. 10

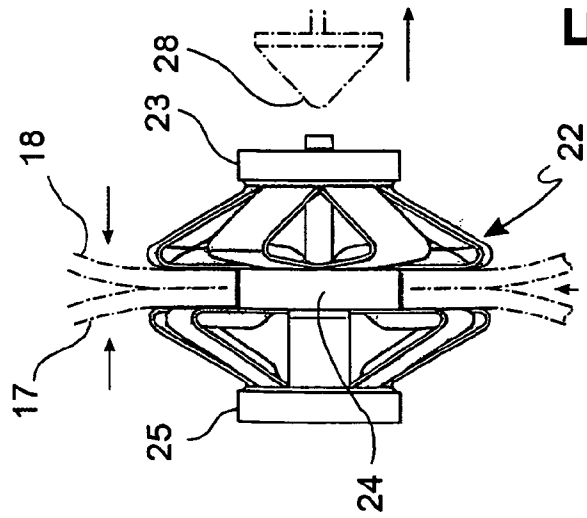


FIG. 11

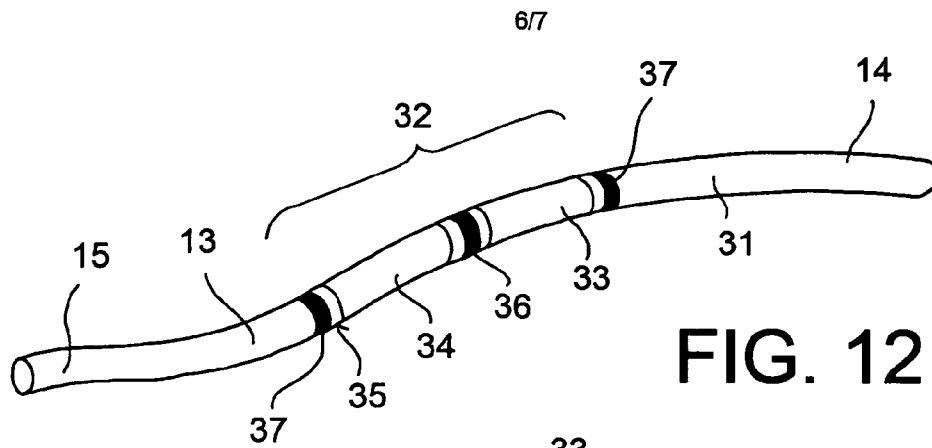


FIG. 12

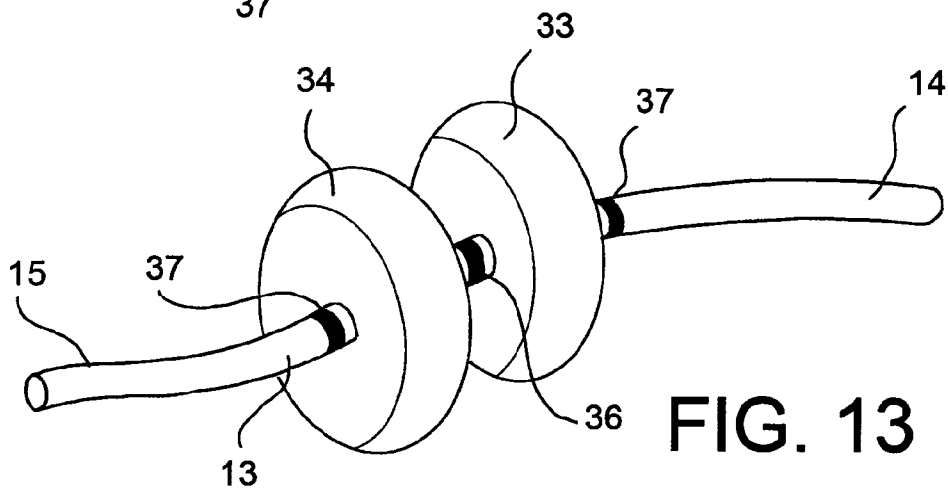


FIG. 13

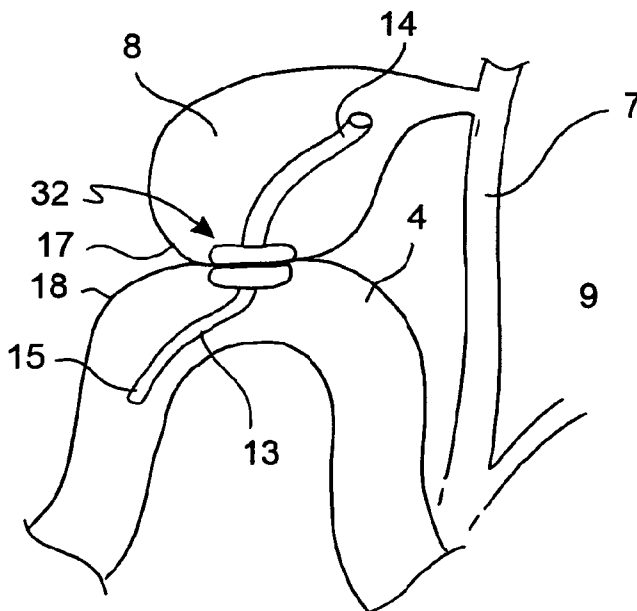
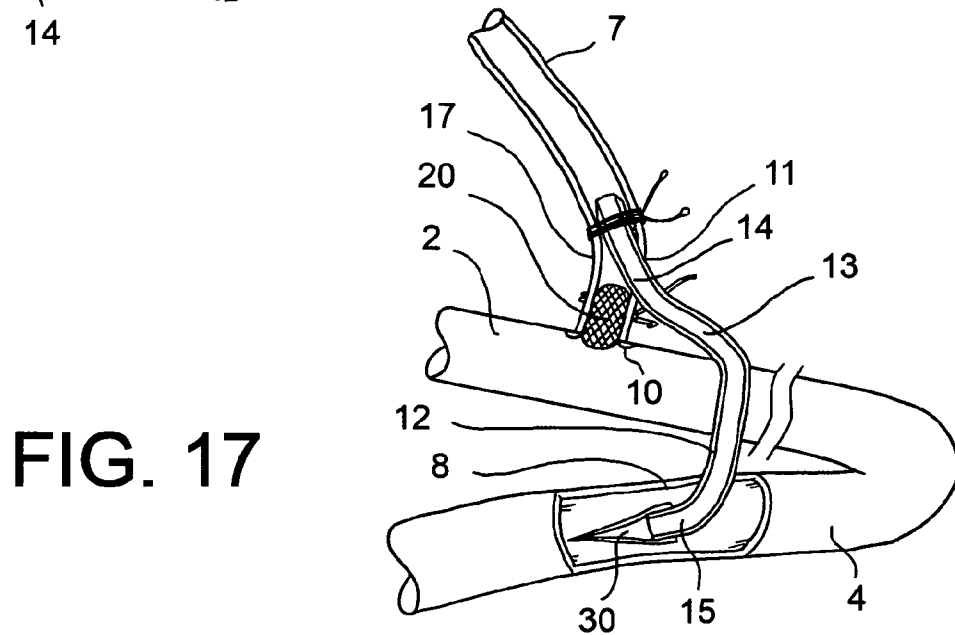
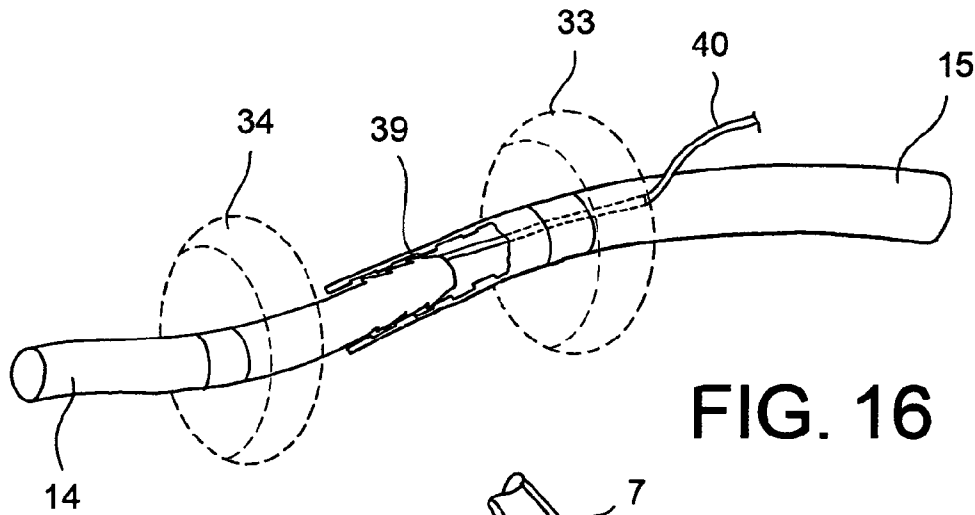
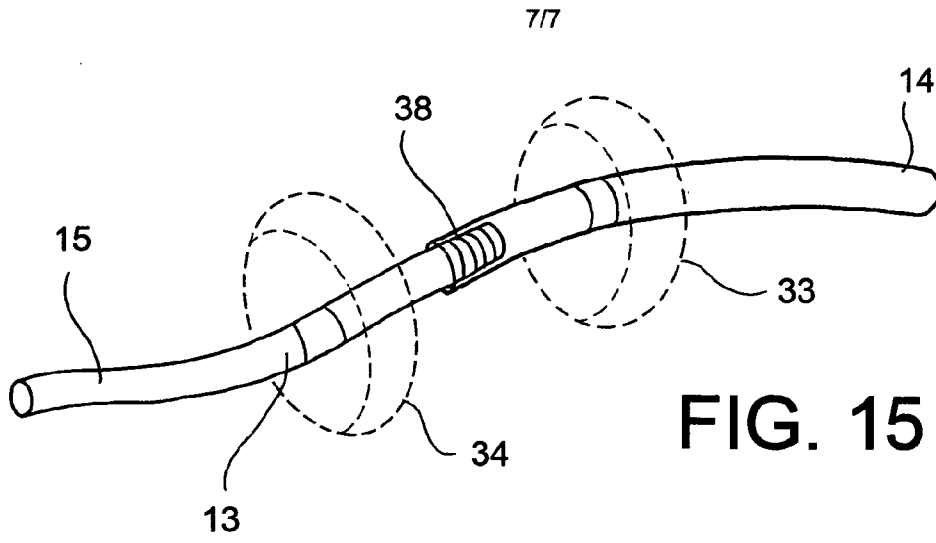


FIG. 14



INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2010/060268

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/04

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.
X	GB 2 460 287 A (TREUS MEDICAL INC [US]) 25 November 2009 (2009-11-25)	20,28-30
Y	paragraphs [0027], [0028], [0053], [0079]; figures 16,18	21-27
Y	----- WO 2004/086984 A1 (UCL BIOMEDICA PLC [GB]; SWAIN CHRISTOPHER PAUL [GB]; MOSSE CHARLES ALE) 14 October 2004 (2004-10-14)	21
A	page 7, lines 9-17; figure 8	20,22-30
Y	----- WO 2005/011788 A1 (WILSON COOK MEDICAL INC [US]; DEAL STEPHEN E [US]; CARTER MATTHEW P [U]) 10 February 2005 (2005-02-10)	22,23
A	paragraph [0124]; figure 21	20,21, 24-30
	----- -/--	

 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

4 March 2011

Date of mailing of the international search report

14/03/2011

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Lee, Ronan

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/060268

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	WO 02/094108 A2 (UNIV LONDON [GB]; QUEEN MARY & WESTFIELD COLLEGE [GB]; SWAIN CHRISTOPH) 28 November 2002 (2002-11-28) page 8, lines 4-10; figures 11,12	24,26,27 20-23, 25,28-30
Y A	----- US 2006/276871 A1 (LAMSON THEODORE C [US] ET AL LAMSON THEODORE CHARLES [US] ET AL) 7 December 2006 (2006-12-07) figure 18 -----	25 20-24, 26-30

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2010/060268

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. Claims Nos.: **1-19**
because they relate to subject matter not required to be searched by this Authority, namely:

The subject-matter of claims 1-19 appears to constitute a surgical procedure on the human body, and therefore under Rule 39.1(iv) PCT (Method for treatment of the human or animal body by surgery), these claims have not been searched; the subject-matter being deemed non-patentable.
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/EP2010/060268

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2460287	A	25-11-2009	NONE

WO 2004086984	A1	14-10-2004	AU 2004226692 A1 14-10-2004
			BR PI0409193 A 11-04-2006
			CN 1787783 A 14-06-2006
			EP 1610694 A1 04-01-2006
			JP 2006521855 T 28-09-2006
			US 2006167482 A1 27-07-2006

WO 2005011788	A1	10-02-2005	EP 1653884 A1 10-05-2006
			EP 1660164 A1 31-05-2006
			EP 1660165 A1 31-05-2006
			JP 2007500553 T 18-01-2007
			JP 2007500554 T 18-01-2007
			JP 4611301 B2 12-01-2011
			JP 2007500555 T 18-01-2007
			US 2005143770 A1 30-06-2005
			US 2005070794 A1 31-03-2005
			US 2005059990 A1 17-03-2005
			US 2005070821 A1 31-03-2005
			US 2005059890 A1 17-03-2005
			WO 2005011530 A1 10-02-2005
			WO 2005011790 A1 10-02-2005

WO 02094108	A2	28-11-2002	AT 443476 T 15-10-2009
			CA 2447514 A1 28-11-2002
			EP 1392179 A2 03-03-2004
			JP 4255288 B2 15-04-2009
			JP 2005508206 T 31-03-2005
			US 2004186514 A1 23-09-2004

US 2006276871	A1	07-12-2006	EP 1887976 A2 20-02-2008
			US 2009060977 A1 05-03-2009
			US 2008039874 A1 14-02-2008
			US 2008039894 A1 14-02-2008
			US 2008033232 A1 07-02-2008
			US 2008033488 A1 07-02-2008
			US 2009192439 A1 30-07-2009
			US 2009204128 A1 13-08-2009
			US 2008039889 A1 14-02-2008
			US 2009018523 A1 15-01-2009
			WO 2006127431 A2 30-11-2006
			WO 2007075981 A2 05-07-2007
