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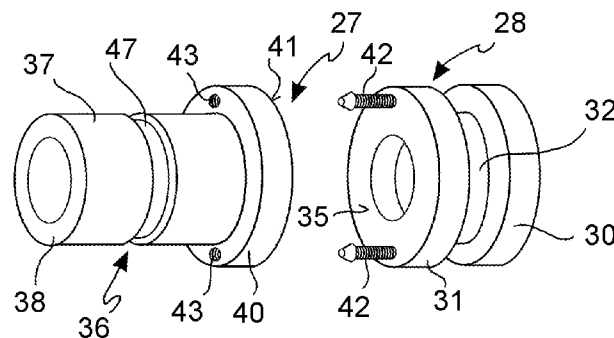
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(54) Title: A CONNECTING DEVICE FOR CREATING AN ANASTOMOSIS BETWEEN A HOLLOW ORGAN AND A CON-
 DUIT

**FIG. 1**

(57) Abstract: A connecting device (27) for creating an anastomosis between a hollow organ and a conduit comprises a ring con-
 nector (28) forming first and second ring walls (30, 31) defining an annular connecting seat (32) for receiving a hollow organ (34)
 wall, a tube connector (36) having a tubular wall (37) with a free end (38) insertable into a conduit (39) and a ring flange (40), as
 well as snap coupling means adapted to snap connect the ring flange of the tube connector (36) to the ring connector (28).

DESCRIPTION**A CONNECTING DEVICE FOR CREATING AN ANASTOMOSIS
BETWEEN A HOLLOW ORGAN AND A CONDUIT**

The present invention relates, in general, to devices and methods for surgically
5 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
15 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
20 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;
- 25 - 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
30 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 an
artificial 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 and method is not suitable to obtain a significant acceleration of the bile cycling compared to the natural entero-hepatic bile cycling velocity. Moreover, the known methods and devices bear an inherent risk of conduit obstruction and related harboring of bacteria which may lead to severe infections and require frequent substitutions of the artificial conduits.

In view of the drawbacks of the known art, an aim of the invention is to provide a method and device for diverting bile from the biliary tree including the gallbladder into a section of the intestine distally to the papilla of Vater, which addresses at least part of the problems described in relation with the prior art.

An aim of the invention is to provide devices and methods which obviate the risk of undesired relocations of the bile discharge point 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.

A yet further aim of the invention is to obviate the risk of obstruction and harboring of bacteria inside a bile diverting conduit.

A yet further aim of the invention is to provide devices and methods for improving the connection of a bile conduit to a target section of small intestine.

At least part of the above identified aims are achieved by a method for diverting biliary fluid from a natural 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 in a proximal target location in the natural biliary fluid flow path;
- b) creating a secondotomy in a distal target location of the natural biliary fluid flow path downstream the proximal target location, said distal target location being a section of intestine distal to the papilla of Vater,

c) extending a bile diverting conduit grafted from natural tissue from the first otomy to the second otomy, thereby bypassing the natural biliary flow path between the proximal target location and the distal target location,

d) anastomosing a proximal end of the conduit to the first otomy and anastomosing a distal end of the conduit to the second otomy.

Thanks to the extension of a natural tissue lumen from the proximal to the distal target location and anastomosis of the natural tissue lumen with the first and second otomies, at least part of the natural biliary flow path, e.g. part of the duodenum, can be bypassed without artificial conduits, thereby reducing the risk of obstruction and infection, as well as the risk of undesired dislocation away from the intended distal target location.

At least part of the above identified aims are also achieved by a method for diverting biliary fluid from a natural 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) detaching a proximal portion of the common bile duct at a proximal target location from the duodenum, thereby creating a proximal lumen stump in flow communication with the common hepatic duct and a distal lumen stump in flow communication with the duodenum,

b) creating an enterostomy in a distal target location of intestine distal to the papilla of Vater,

c) approximating and anastomosing the proximal lumen stump to the enterostomy, thereby bypassing the natural biliary flow path between the proximal target location and the distal target location.

At least part of the above identified aims are also achieved by a method for diverting biliary fluid from a natural 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) performing a cholecystectomy by transecting the cystic duct at a proximal target location, thereby creating a proximal lumen stump in flow communication with the common hepatic duct,

b) creating an enterostomy in a distal target location of intestine distal to the papilla of Vater,

c) approximating and anastomosing the proximal lumen stump to the enterostomy, thereby bypassing the natural biliary flow path between the proximal target location and the distal target location.

In accordance with a further aspect of the invention, the end of the conduit is anastomosed to one of the first and second otomies by means of a connecting device having a ring connector and a tube connector initially separate from the ring connector and connectable with the ring connector by snap fit, the method comprising the phases of:

- connecting the ring connector to one of the proximal and distal target locations of the natural biliary flow path,
- connecting the tube connector to the conduit,
- approximating and snap-connecting the ring connector to the tube connector.

This makes it possible to perform the anastomosis by separate, independent and time-shifted attachment of the tube connector to the conduit end and of the ring connector to the target location and subsequent snap engaging the tube connector with the ring connector. Splitting the anastomosis in the three independent phases (connecting the tubular connector to the conduit, connecting the ring connector to the hollow organ, snap connecting the tubular connector to the ring connector) obviates the necessity of contemporaneously holding, approximating and anastomosing the conduit and the intestine, thereby reducing the complexity of the entire operation and the level of dexterity needed.

At least part of the above identified aims are also achieved by an anastomosis connecting device comprising:

- a ring connector forming a passage opening and first and second ring walls defining therebetween an annular connecting seat adapted to receive and hold an edge of a tissue wall of a hollow organ, the second ring wall forming a first sealing surface facing away from the annular connecting seat,
- a tube connector having a tubular wall with a free end insertable into a conduit and a ring flange forming a second sealing surface complementary with the first sealing surface and facing away from the free end,
- snap coupling means adapted to snap connect the tube connector to the ring connector such that the first and second sealing surfaces are pressed together and the free end is put in flow communication with the passage opening.

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 connecting device for anastomosing a natural or artificial conduit to a hollow organ in accordance with an embodiment of the invention;
- Figure 2 illustrates an anastomosis between a natural conduit and a hollow organ
5 by means of the connecting device of figure 1;
- Figure 3 illustrates a connecting device for anastomosing a natural or artificial conduit to a hollow organ in accordance with a further embodiment of the invention;
- Figure 4 illustrates an anastomosis between a natural conduit and a hollow organ by means of the connecting device of figure 3;
- 10 - Figure 5 illustrates a connecting device for anastomosing a natural or artificial conduit to a hollow organ in accordance with a yet further embodiment of the invention;
- Figure 6 illustrates an anastomosis between a natural conduit and a hollow organ by means of the connecting device of figure 5;
- 15 - Figure 7 illustrates a method for diverting biliary fluid from a natural biliary fluid flow path to a target location in the intestine in accordance with an embodiment of the invention;
- Figure 8 illustrates a method for diverting biliary fluid from a natural biliary fluid flow path to a target location in the intestine in accordance with a further
20 embodiment of the invention;
- Figure 9 illustrates a method for diverting biliary fluid from a natural biliary fluid flow path to a target location in the intestine in accordance with a yet further embodiment of the invention;
- Figures 10 and 11 illustrate a method for diverting biliary fluid from a natural
25 biliary fluid flow path to a target location in the intestine in accordance with a further embodiment of the invention;
- Figures 12 and 13 illustrate a method for diverting biliary fluid from a natural biliary fluid flow path to a target location in the intestine in accordance with a further embodiment of the invention;
- 30 - Figure 14 illustrate a method for diverting biliary fluid from a natural biliary fluid flow path to a target location in the intestine in accordance with a further embodiment of the invention;
- Figure 15 illustrate a method for diverting biliary fluid from a natural biliary fluid flow path to a target location in the intestine in accordance with another

embodiment of the invention.

Referring to the drawings in which like numerals denote like anatomical structures and components throughout the several views, figures 7 through 14 illustrate methods for diverting biliary fluid from a natural biliary fluid flow path 1 to a target location in the intestine 2 distal to a duodenal papilla of Vater 3.

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

- a) creating a first otomy 4 in a proximal target location 5 in the natural biliary fluid flow path 1,
- b) creating a second otomy 6 in a distal target location 7 of the natural biliary fluid flow path 1 downstream the proximal target location 5, said distal target location 7 being a section of intestine 2 distal to the papilla of Vater 3,
- c) extending a bile diverting conduit 8 grafted from natural tissue from the first otomy 4 to the second otomy 6, thereby bypassing the natural biliary flow path 1 between the proximal target location 5 and the distal target location 7,
- d) anastomosing a proximal end 9 of the conduit 8 to the first otomy 4 and anastomosing a distal end 10 of the conduit 8 to the second otomy 6.

Thanks to the extension of a natural tissue lumen from the proximal to the distal target location and anastomosis of the natural tissue lumen with the first and second otomies, at least part of the natural biliary flow path, e.g. part of the duodenum, can be bypassed without artificial conduits, thereby reducing the risk of obstruction and infection, as well as the risk of undesired dislocation away from the intended distal target location.

The conduit 8 may be e.g. grafted from vein material, sections of small bowel (e.g. a piece of jejunum), sections of cystic duct or of common bile duct.

The distal target location 7 of the intestine 2 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 preferred embodiments, the distal end 10 of the conduit 8 is anastomosed to a distal target location 7 e.g. in the jejunum or in the ileum, thereby creating an ileum biliary drain branch which directs biliary fluid rapidly towards the terminal ileum where it is re-absorbed. In this way it is possible to achieve a considerable acceleration of the enterohepatic circulation (EHC).

In accordance with an embodiment (Figure 7), the method comprises performing an incision into the gallbladder 11 to create a cholecystomy and anastomosing the

proximal end 9 of the conduit 8 to the cholecystomy, in order for biliary fluid to be diverted from the natural biliary flow path 1 at the gallbladder.

In accordance with a further embodiment (Figure 9), the method comprises creating the first otomy 4 in the duodenal wall adjacent the sphincter of ODDI 3, in order for biliary fluid to be diverted from the natural biliary flow path 1 immediately downstream the sphincter of ODDI.

In accordance with a yet further embodiment (Figures 10, 11), the method comprises performing an incision into the gallbladder 11 to create a cholecystomy, transecting the jejunum, thereby creating a distal jejunal stump 12 and a proximal jejunal stump 13 (Figure 10), then anastomosing the distal jejunal stump 12 to the cholecystomy and anastomosing the proximal jejunal stump 13 to a second enterotomy 6 created in a section of intestine distal from the distal jejunal stump 12 (Figure 11). A Y-shaped bifurcation of the intestine 2 is thus created which diverts a flow of bile directly from the gallbladder 11 into the distal jejunal stump 12.

The method may be implemented by a laparoscopic procedure with endoluminal assistance. After having mobilized the interested target area, the distal jejunum or ileum is transected laparoscopically to create the above said distal and proximal stumps 12, 13. Then, the distal stump 12 is laparoscopically pulled to the gallbladder 11 and a side-to-side cholecystenterostomy 14 (Figure 13) or a front-to-side cholecystenterostomy 15 (Figure 11) is performed therebetween to create lumen continuity between the gallbladder 11 and the distal stump 12. Then, a flexible endoscope (not illustrated in the figures) with an instrument channel is introduced transanally and guided with laparoscopic assistance through the colon 16 and through the ileal cecal valve 17 into the small intestine (ileum or jejunum) to the distal target location 7. The intestinal wall at the distal target location 7 can now be perforated by a piercing instrument guided through the instrument channel of the endoscope. The thus created second otomy 6 can be dilated by means of a balloon dilator guided along the piercing instrument through the instrument channel of the endoscope. The proximal stump 13 can now be grasped and approximated to the second otomy 6 either laparoscopically and/or by an endoscopic grasper extended through the second otomy 6 into the abdominal space. Then, the proximal stump 13 and the second otomy 6 are anastomosed to re-establish intestinal lumen continuity. By this method an anatomical configuration is created which allows a first part of bile to flow from the gallbladder 11 directly in the ileum

or distal jejunum and a second part of bile to flow along its natural path 1 to the duodenum. This shortens the time it takes for the bile to contact the terminal ileum and, at the same time, provides bile inside the duodenum to trigger physiological signaling mechanisms related with the early phases of digestion.

- 5 Alternatively, the common bile duct 19 may be blocked or artificially obstructed downstream the junction of the hepatic duct 18 with the cystic duct 20 such that the entire biliary fluid produced by the liver 21 is diverted through the gallbladder 11 to the distal target location in the intestine.

10 In accordance with a further aspect of the invention an alternative method (Figures 8, 14) is proposed for diverting biliary fluid from a natural biliary fluid flow path to a target location in the intestine distal to a duodenal papilla of Vater, the alternative method comprising the steps of:

- a) detaching a proximal portion of the common bile duct 19 at a proximal target location from the duodenum, thereby creating a proximal lumen stump 22 in flow communication with the common hepatic duct 18 and a distal lumen stump 23 in flow communication with the duodenum,
- 15 b) creating an enterostomy 24 in a distal target location 7 of intestine distal to the papilla of Vater 3,
- c) approximating and anastomosing the proximal lumen stump 22 to the enterostomy 24, thereby bypassing the natural biliary flow path between the proximal target location and the distal target location.
- 20

This method allows to use at least part of the common bile duct directly as bile diverting conduit and obviates the attachment of an additional piece of artificial conduit or of conduit grafted from natural tissue. As can be readily understood from figures 8 and 14, in this case, the total amount of bile is diverted to the distal target location 7 of the intestine 2 and the distal lumen stump 23 must be closed and sealed in order to prevent leakage of intestinal contents and/or pancreatic juices in the abdominal space.

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In accordance with a preferred embodiment (Figure 14), the proximal portion of the common bile duct 19 is detached from the duodenum by a circumferential transection of the duodenal wall around the sphincter of ODDI 3. This can be accomplished laparoscopically by means of scissors or a hot knife and suture. The transected patch 25 of duodenal wall containing the sphincter of ODDI and attached to the common bile duct is then (preferably laparoscopically)

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approximated and anastomosed with the enterostomy 24 at the distal target location 7 of the intestine, e.g. by serosa to serosa apposition for better healing and by suturing, stapling or gluing. Thanks to the circumferential transection around the sphincter of ODDI, both the papilla of Vater and the sphincter of ODDI remain intact and within the biliary bypass path and can thus contribute to prevent backflow of chime and retrograde infection of the biliary tree or pancreatitis.

In accordance with a further embodiment (Figure 8), the proximal portion of the common bile duct 19 is detached from the duodenum by transecting the common bile duct 19.

In accordance with a further aspect of the invention an alternative method (Figure 15) is proposed for diverting biliary fluid from a natural biliary fluid flow path to a target location in the intestine distal to a duodenal papilla of Vater, the alternative method comprising the steps of:

- a) performing a cholecystectomy by transecting the cystic duct 20 at a proximal target location, thereby creating a proximal lumen stump 26 in flow communication with the common hepatic duct 18,
- b) creating an enterostomy 24 in a distal target location 7 of intestine 2 distal to the papilla of Vater 3,
- c) approximating and anastomosing the proximal lumen stump 26 to the enterostomy 24, thereby bypassing the natural biliary flow path 1 between the proximal target location and the distal target location.

This method allows to use part of the cystic duct directly as bile diverting conduit and obviates the attachment of an additional piece of artificial conduit or of conduit grafted from natural tissue. As can be readily understood from figure 15, in this case, only a partial flow of bile is diverted to the distal target location 7 of the intestine 2 and a residual flow of bile is discharged in the duodenum along the natural biliary flow path. Total bile diversion may be obtained by additionally blocking the common bile duct.

In the described methods, an end of the conduit 8 may be anastomosed to one of the proximal and distal target locations by a connecting device having a ring connector and a tube connector initially separate from the ring connector and connectable with the ring connector by snap fit. The anastomosis is performed by connecting the ring connector to one of the proximal and distal target locations 5, 7 of the natural biliary flow path 1, connecting the tube connector to the conduit 8

and, subsequently, approximating and snap connecting the ring connector to the tube connector.

This makes it possible to perform the anastomosis by separate, independent and time-shifted attachment of the tube connector to the conduit end and of the ring connector to the target location, e.g. to a section of intestine, and snap engaging the tube connector with the ring connector. The single operations can be performed laparoscopically or by open surgery. Splitting the anastomosis in the three independent phases (connecting the tubular connector to the conduit, connecting the ring connector to the hollow organ, snap connecting the tubular connector to the ring connector) obviates the necessity of contemporaneously holding, approximating and anastomosing the conduit and the intestine, thereby reducing the complexity of the entire operation and the level of dexterity needed.

More particularly, the connecting device 27 (figures 1 through 6) may comprise:

- a ring connector 28 forming a passage opening 29 and first and second ring walls 30, 31 defining therebetween an annular connecting seat 32 adapted to receive and hold an edge 33 of a tissue wall of a hollow organ 34, the second ring wall 31 forming a first sealing surface 35 facing away from the annular connecting seat 32,
- a tube connector 36 having a tubular wall 37 with a free end 38 insertable into a conduit 39 and a ring flange 40 forming a second sealing surface 41 complementary with the first sealing surface 35 and facing away from the free end 38,
- first snap coupling means adapted to snap connect the tube connector 36 to the ring connector 28 such that the first and second sealing surfaces 35, 41 are pressed together and the free end 38 is put in flow communication with the passage opening 29.

In accordance with an embodiment (Figure 1), the first snap coupling means comprise toothed pins 42 protruding from one of the first and second sealing surfaces 35, 41 and corresponding snap holes 43 formed in the other one of the first and second sealing surfaces 35, 41 and adapted to receive the pins 42 with snap fit.

The ring connector 28 may comprise an internal compression ring forming the first ring wall 30 and an external compression ring forming the second ring wall 31, as well as second snap coupling means adapted to snap connect the external ring to the internal ring to compress the tissue edge 33 therebetween. The second snap

coupling means may comprise toothed studs 42 protruding from one of the first and second ring walls 30, 31 and corresponding second holes 45 formed in the other one of the first and second ring walls 30, 31 and adapted to (adjustably) receive the studs 42 with snap fit.

- 5 In an embodiment (Figure 4) the toothed studs 42 protrude from the first ring wall 30 and are insertable by snap fit in through holes 45 of the second ring wall 31 such that a toothed free end of the stud 42 protrudes from the first sealing surface 35 and forms the above said pin 42 for the snap connection with the tube connector 36.
- 10 In an alternative embodiment, (Figure 5) the snap holes 43 may extend coaxially inside the toothed studs 42 and may be configured such that, by snap coupling the tube connector 36 with the ring connector 28, the toothed pins 42 penetrate the snap holes 43 inside the toothed studs 42 and lock the latter in the second holes 45 to prevent detachment of the compression rings.
- 15 The free end 38 can be inserted by interference fit in the conduit end and may have a circumferential groove 47 into which the conduit can be tightened by means of a suture loop 46.

The connection device 27 may be made of PET or titanium alloy and may comprise a unidirectional valve which prevents undesired backflow e.g. from the ring connector 28 to the tube connector 36.

- 20 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 connecting device (27) for creating an anastomosis between a hollow organ and a conduit, comprising:
- a ring connector (28) forming a passage opening (29) and first and second ring walls (30, 31) defining therebetween an annular connecting seat (32) adapted to receive and hold an edge (33) of a tissue wall of a hollow organ (34), the second ring wall (31) forming a first sealing surface (35) facing away from the annular connecting seat (32),
 - a tube connector (36) having a tubular wall (37) with a free end (38) insertable into a conduit (39) and a ring flange (40) forming a second sealing surface (41) complementary with the first sealing surface (35) and facing away from the free end (38),
 - first snap coupling means adapted to snap connect the tube connector (36) to the ring connector (28) such that the first and second sealing surfaces (35, 41) are pressed together and the free end (38) is put in flow communication with the passage opening (29).
2. A connecting device (27) according to claim 1, in which the first snap coupling means comprise toothed pins (42) protruding from one of the first and second sealing surfaces (35, 41) and snap holes (43) formed in the other one of the first and second sealing surfaces (35, 41) and adapted to receive the pins (42) by snap fit.
3. A connecting device (27) according to claim 1 or 2, in which said ring connector (28) comprises an internal compression ring forming the first ring wall (30) and an external compression ring forming the second ring wall (31), as well as second snap coupling means adapted to snap connect the external ring to the internal ring to compress the tissue edge (33) therebetween.
4. A connecting device (27) according to claim 3, in which said second snap coupling means comprise toothed studs (42) protruding from one of the first and second ring walls (30, 31) and second holes (45) formed in the other one of the first and second ring walls (30, 31) and adapted to receive the studs (42) by snap fit.
5. A connecting device (27) according to claim 4, in which the toothed studs (42) protrude from the first ring wall (30) and are insertable by snap fit in said holes (45) of the second ring wall (31) such that a toothed free end of the stud (42) protrudes

from the first sealing surface (35) and forms said pin (42) for the snap connection with the tube connector (36).

6. A connecting device (27) according to claim 4, in which the snap holes (43) extend coaxially inside the toothed studs (42).

5 **7.** A connecting device (27) according to claim 5, wherein the toothed pins (42) and the toothed studs (42) are configured such that, when the toothed pins (42) penetrate the snap holes (43) inside the toothed studs (42), the toothed studs (42) are non-detachably locked in the second holes (45).

8. A connecting device (27) according to any one of claims 1 to 7, wherein the free
10 end (38) forms a circumferential groove into which the conduit can be tightened by means of a suture loop (46).

9. A connecting device (27) according to any one of claims 1 to 8, comprising a unidirectional valve.

10. Method for diverting biliary fluid from a natural biliary fluid flow path (1) to a
15 target location in the intestine (2) distal to a duodenal papilla of Vater (3), the method comprising the steps of:

- creating a first otomy (4) in a proximal target location (5) in the natural biliary fluid flow path (1),
- creating a second otomy (6) in a distal target location (7) of the natural biliary fluid
20 flow path (1) downstream the proximal target location (5), said distal target location (7) being a section of intestine (2) distal to the papilla of Vater (3),
- extending a bile diverting conduit (8) grafted from natural tissue from the first otomy (4) to the second otomy (6),
- anastomosing a proximal end (9) of the conduit (8) to the first otomy (4) and
25 anastomosing a distal end (10) of the conduit (8) to the second otomy (6), thereby bypassing the natural biliary flow path (1) between the proximal target location (5) and the distal target location (7).

11. Method according to claim 10, comprising anastomosing the distal end (10) of the conduit (8) to a distal target location (7) in the ileum.

30 **12.** Method according to claim 10 or 11, comprising the steps of creating a cholecystomy and anastomosing the proximal end (9) of the conduit (8) to the cholecystomy.

13. Method according to claim 10 or 11, comprising the step of creating the first otomy (4) in the duodenal wall adjacent the sphincter of ODDI (3).

14. Method according to claim 10 or 11, comprising the steps of:

- creating a cholecystomy,
- transecting the jejunum, thereby creating a distal jejunal stump (12) and a proximal jejunal stump (13),
- 5 - creating said secondotomy (6) in a section of intestine distal from the distal jejunal stump (12),
- anastomosing the distal jejunal stump (12) to the cholecystomy,
- anastomosing the proximal jejunal stump (13) to the secondotomy (6).

15. Method according to claim 14, comprising the step of closing the common bile duct (19) downstream the junction of the hepatic duct (18) with the cystic duct (20).

16. Method according to claim 10, comprising the step of anastomosing an end of the conduit (8) to one of the proximal and distal target locations (5, 7) by a connecting device having a ring connector and a tube connector initially separate from the ring connector and connectable with the ring connector by snap fit,

15 comprising the phases of:

- connecting the ring connector to one of the proximal and distal target locations (5, 7) of the natural biliary flow path (1),
- connecting the tube connector to the conduit (8),
- approximating and snap-connecting the ring connector to the tube connector.

17. Method for diverting biliary fluid from a natural biliary fluid flow path (1) to a target location (7) in the intestine (2) distal to a duodenal papilla of Vater (3), the method comprising the steps of:

- detaching a proximal portion of the common bile duct (19) at a proximal target location from the duodenum, thereby creating a proximal lumen stump (22) in flow communication with the common hepatic duct (18) and a distal lumen stump (23) in flow communication with the duodenum,
- 25 - creating an enterostomy (24) in a distal target location (7) of intestine distal to the papilla of Vater (3),
- approximating and anastomosing the proximal lumen stump (22) to the enterostomy (24), thereby bypassing the natural biliary flow path (1) between the proximal target location and the distal target location.

18. Method according to claim 17, comprising the steps of:

- circumferentially transecting the duodenal wall around the sphincter of ODDI (3) to obtain a patch (25) of duodenal wall containing the sphincter of ODDI and being

15

attached to the common bile duct,

- anastomosing the patch (25) with the enterostomy (24) at the distal target location (7) of the intestine.

19. Method according to claim 17, comprising the steps of:

- 5 - detaching the proximal portion of the common bile duct (19) from the duodenum by transecting the common bile duct (19).

20. Method for diverting biliary fluid from a natural biliary fluid flow path (1) to a target location (7) in the intestine (2) distal to a duodenal papilla of Vater (3), the method comprising the steps of:

- 10 - performing a cholecystectomy by transecting the cystic duct (20) at a proximal target location, thereby creating a proximal lumen stump (26) in flow communication with the common hepatic duct (18),
 - creating an enterostomy (24) in a distal target location (7) of the intestine (2) distal to the papilla of Vater (3),
15 - approximating and anastomosing the proximal lumen stump (26) to the enterostomy (24), thereby bypassing the natural biliary flow path (1) between the proximal target location and the distal target location.

21. Method according to claim 20, comprising the step of additionally closing the common bile duct.

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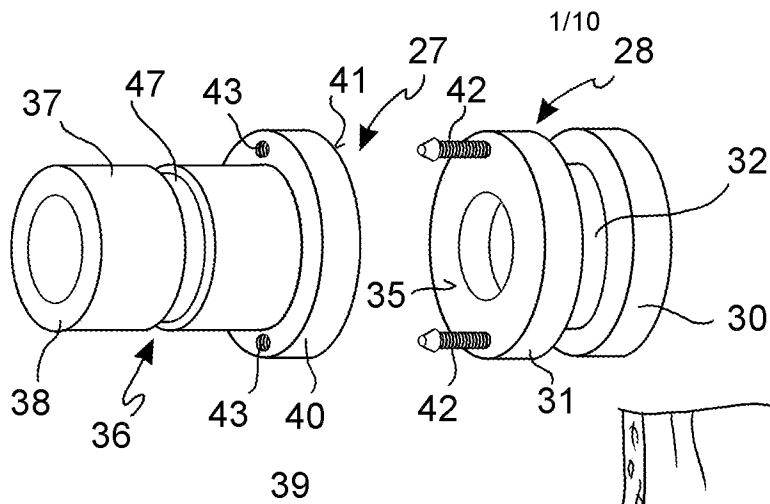


FIG. 1

FIG. 2

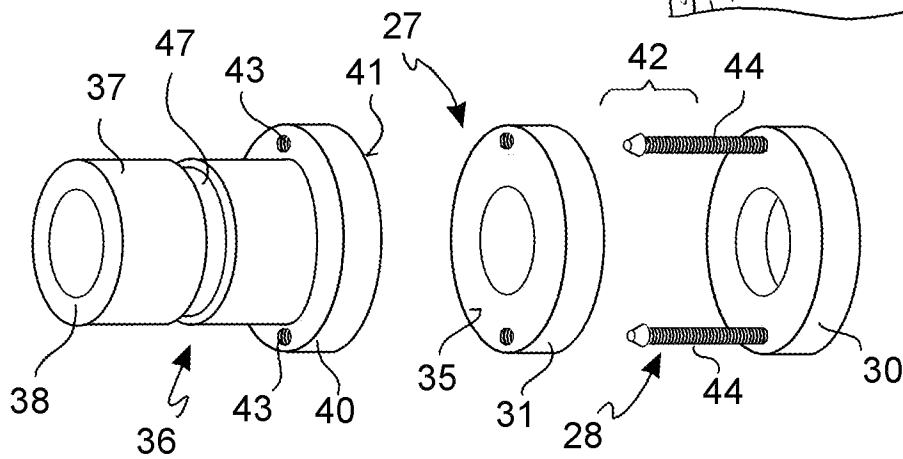
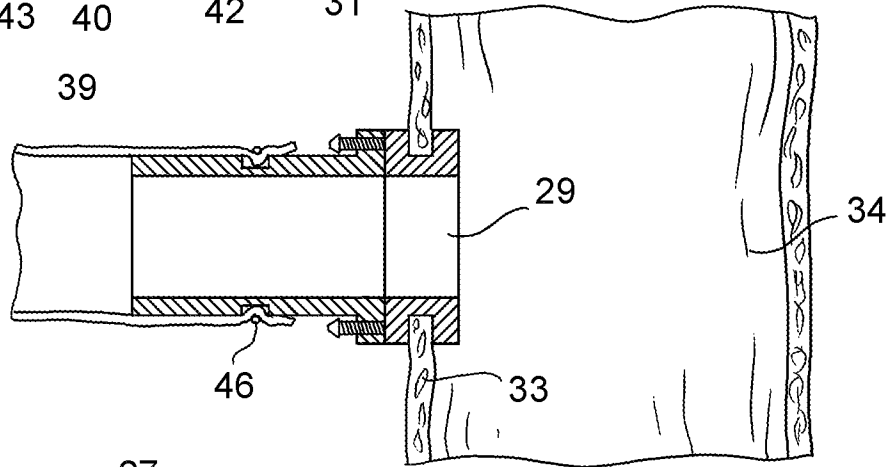
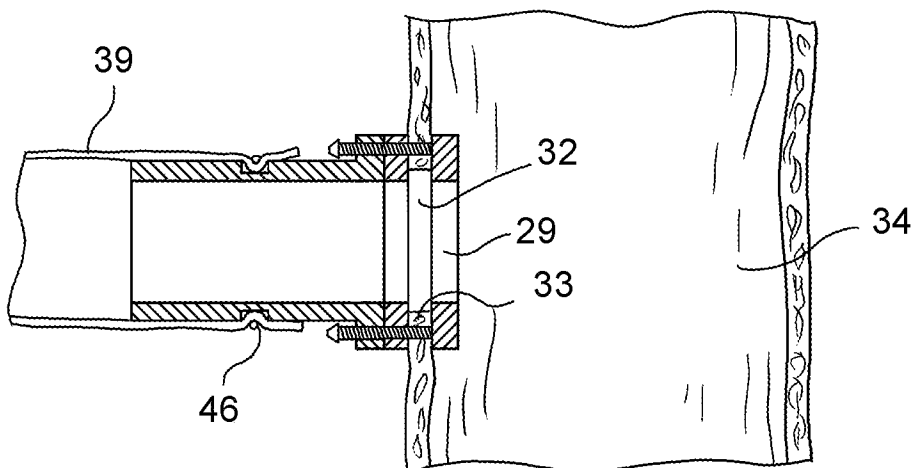


FIG. 3

FIG. 4



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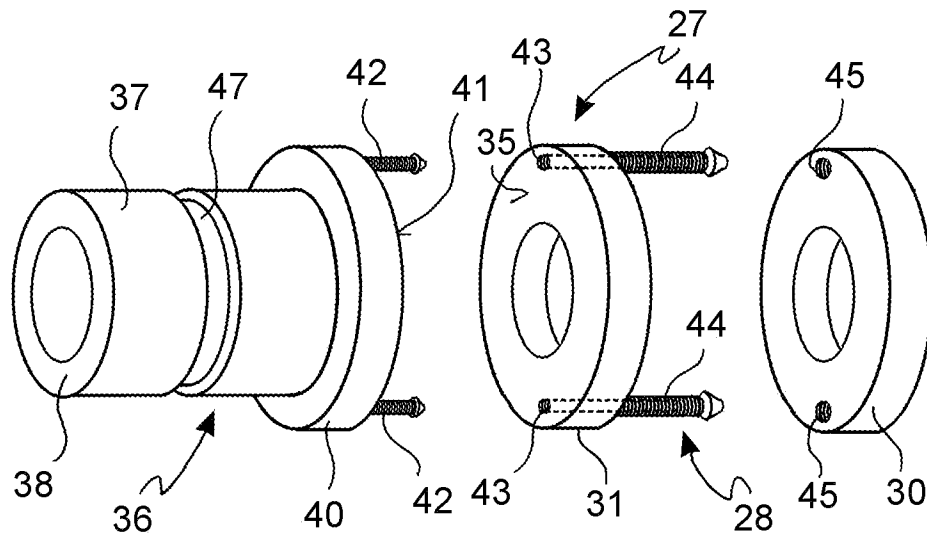


FIG. 5

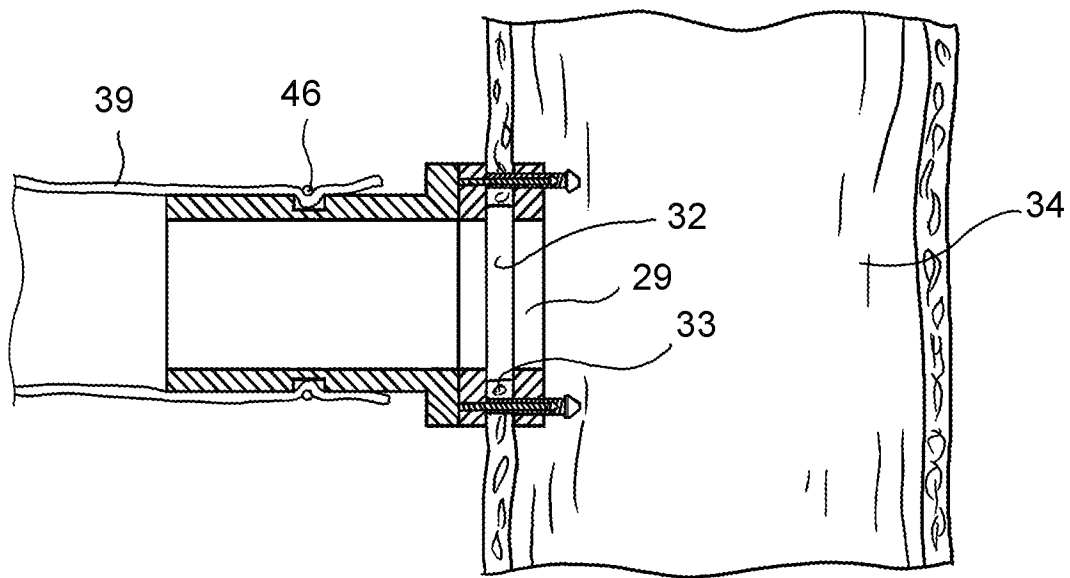


FIG. 6

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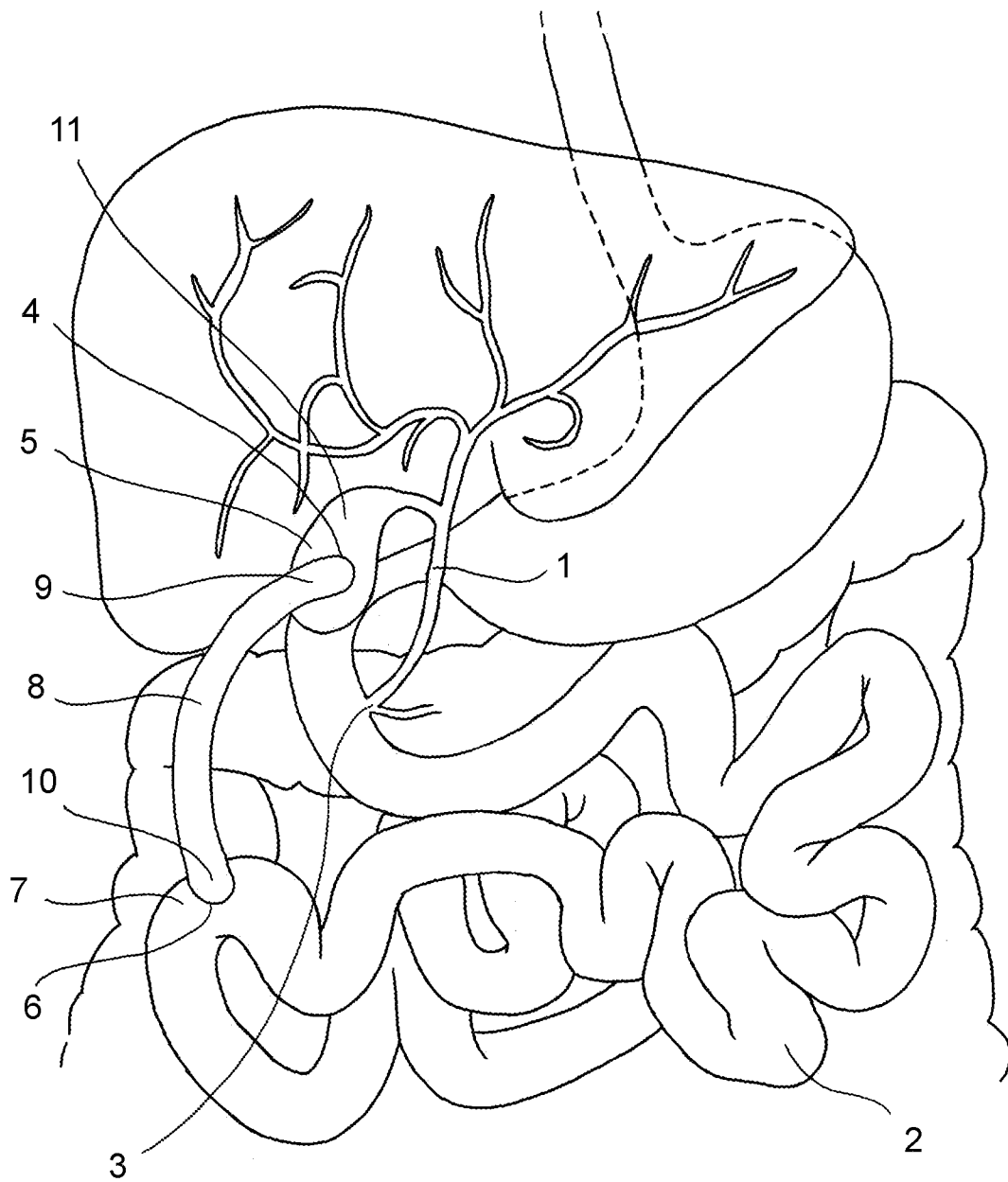


FIG. 7

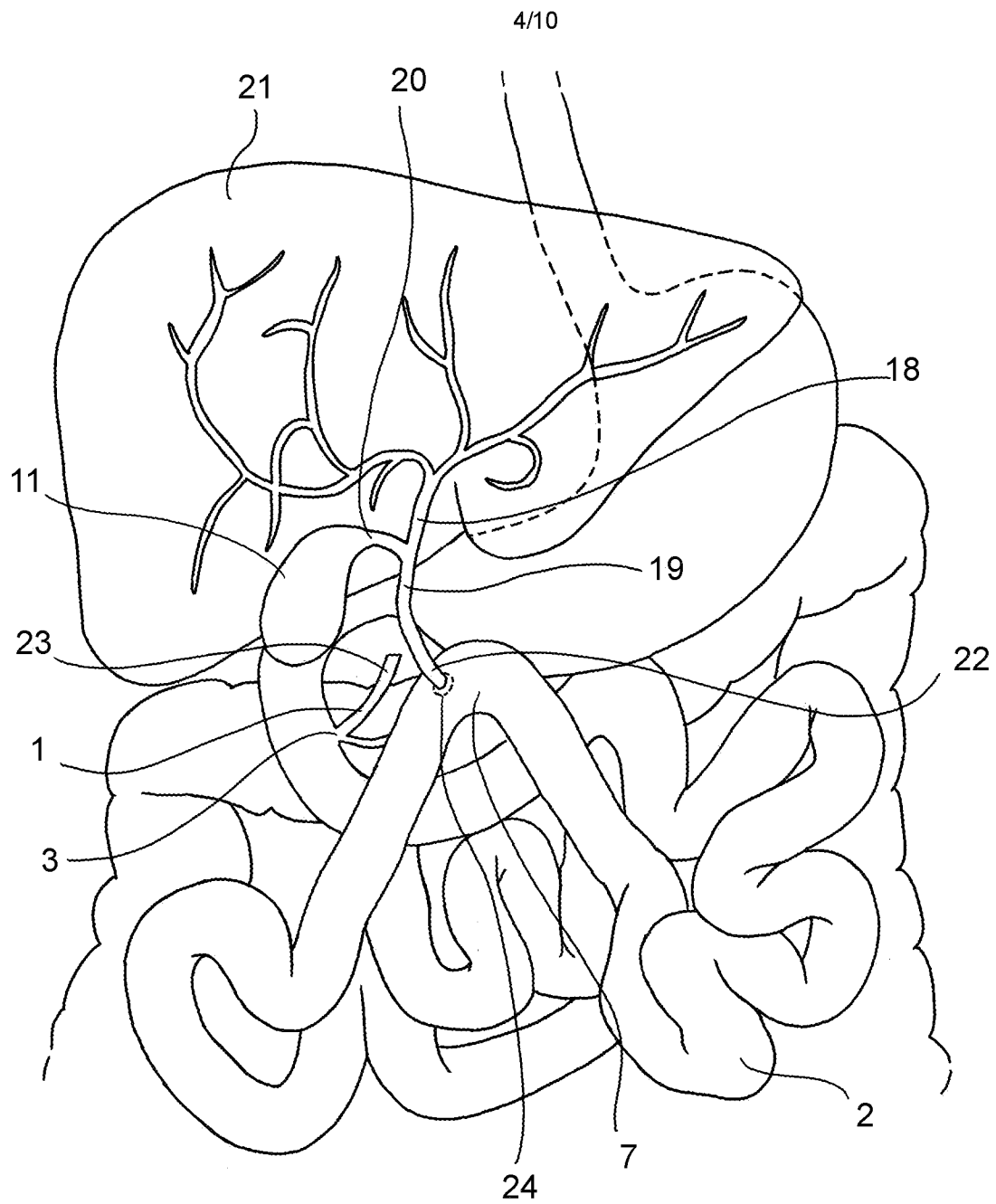


FIG. 8

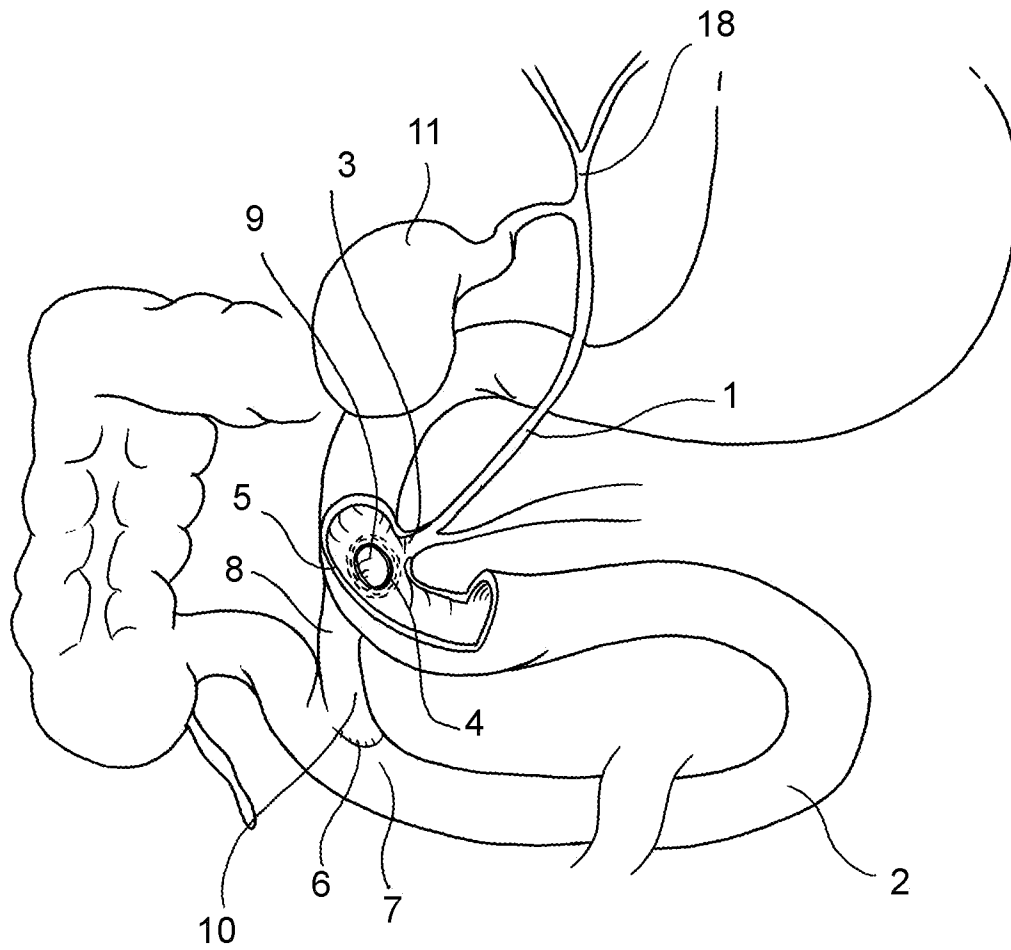


FIG. 9

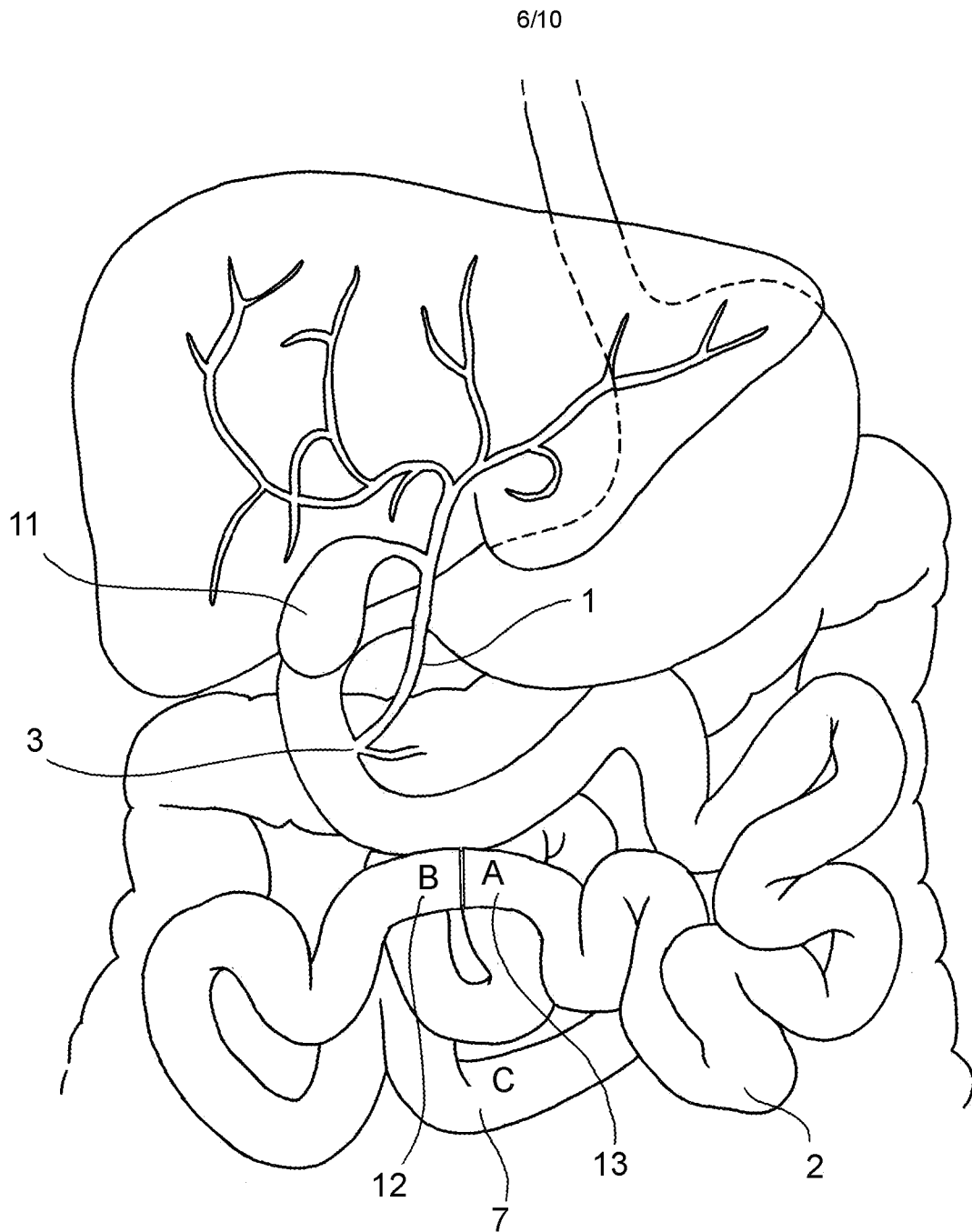


FIG. 10

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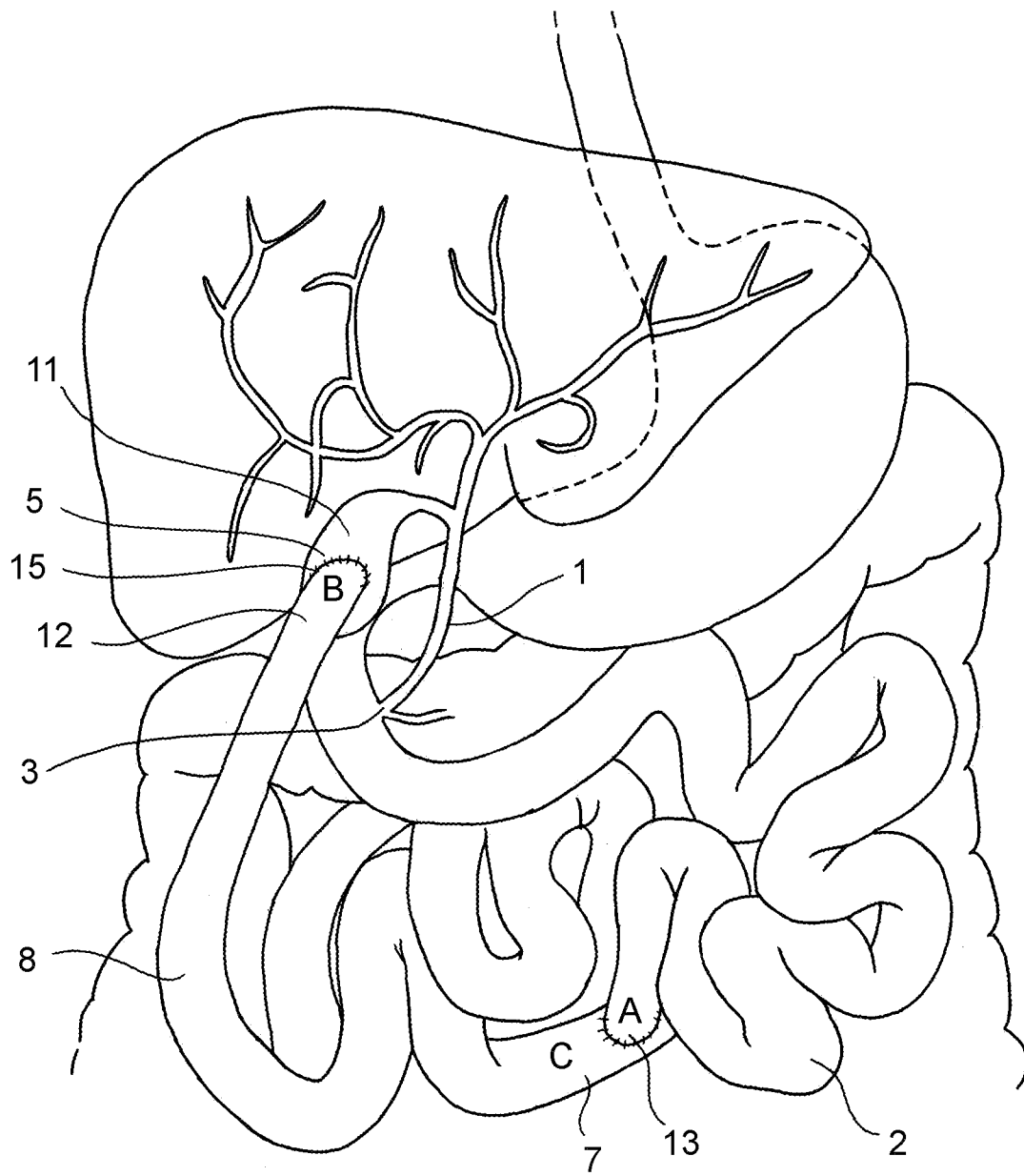


FIG. 11

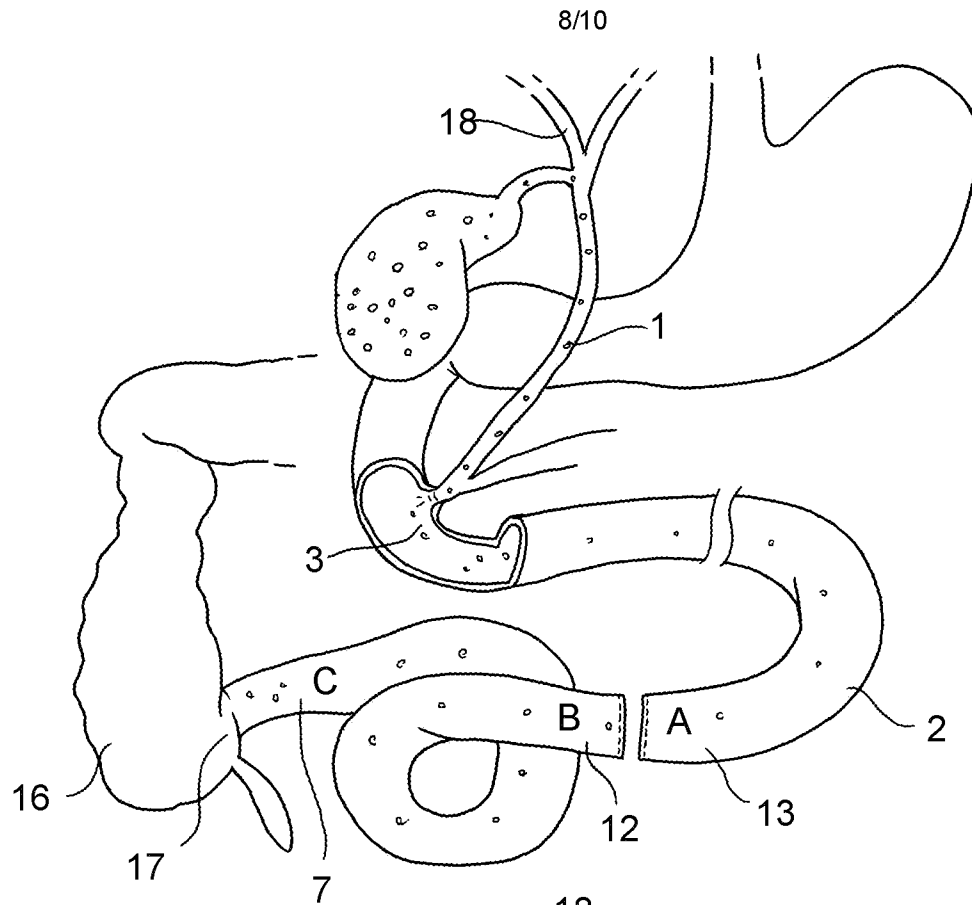


FIG. 12

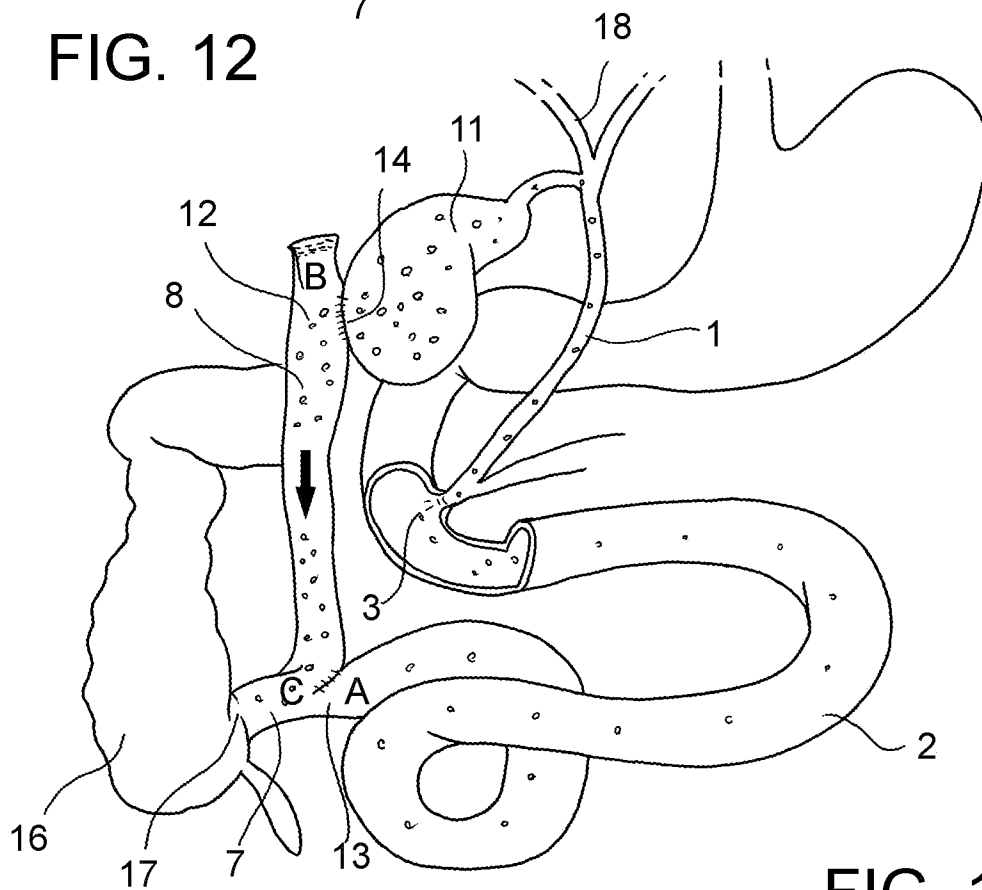


FIG. 13

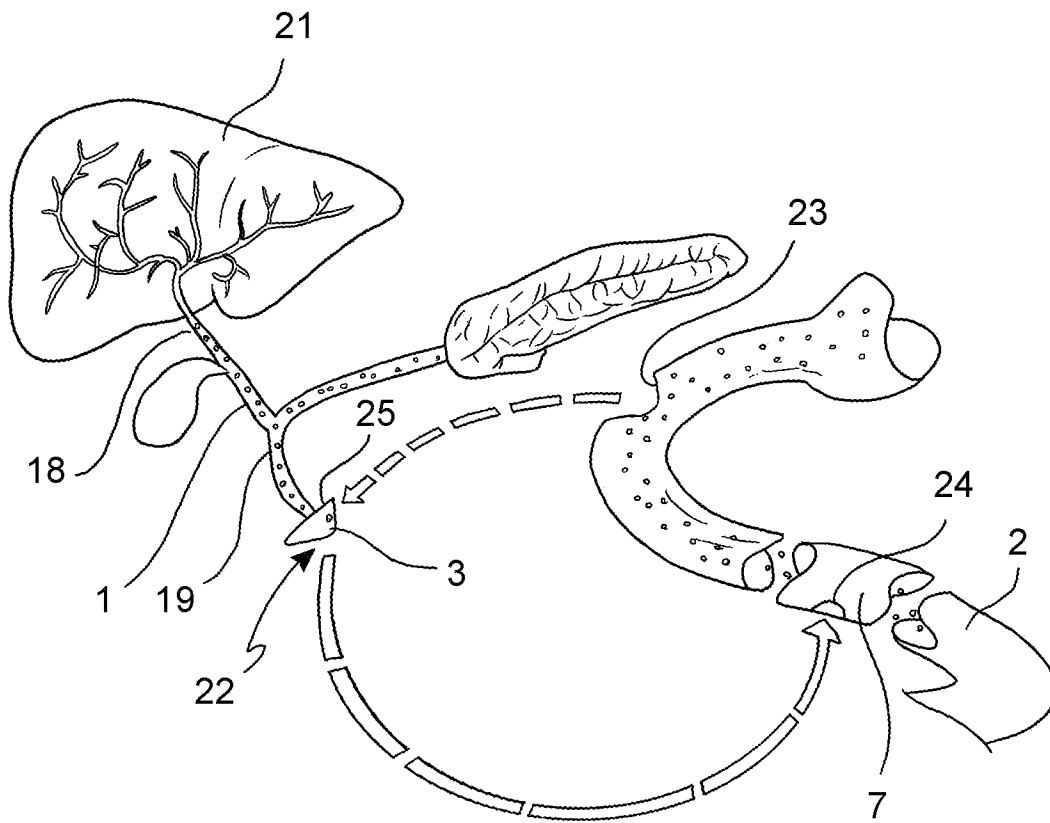


FIG. 14

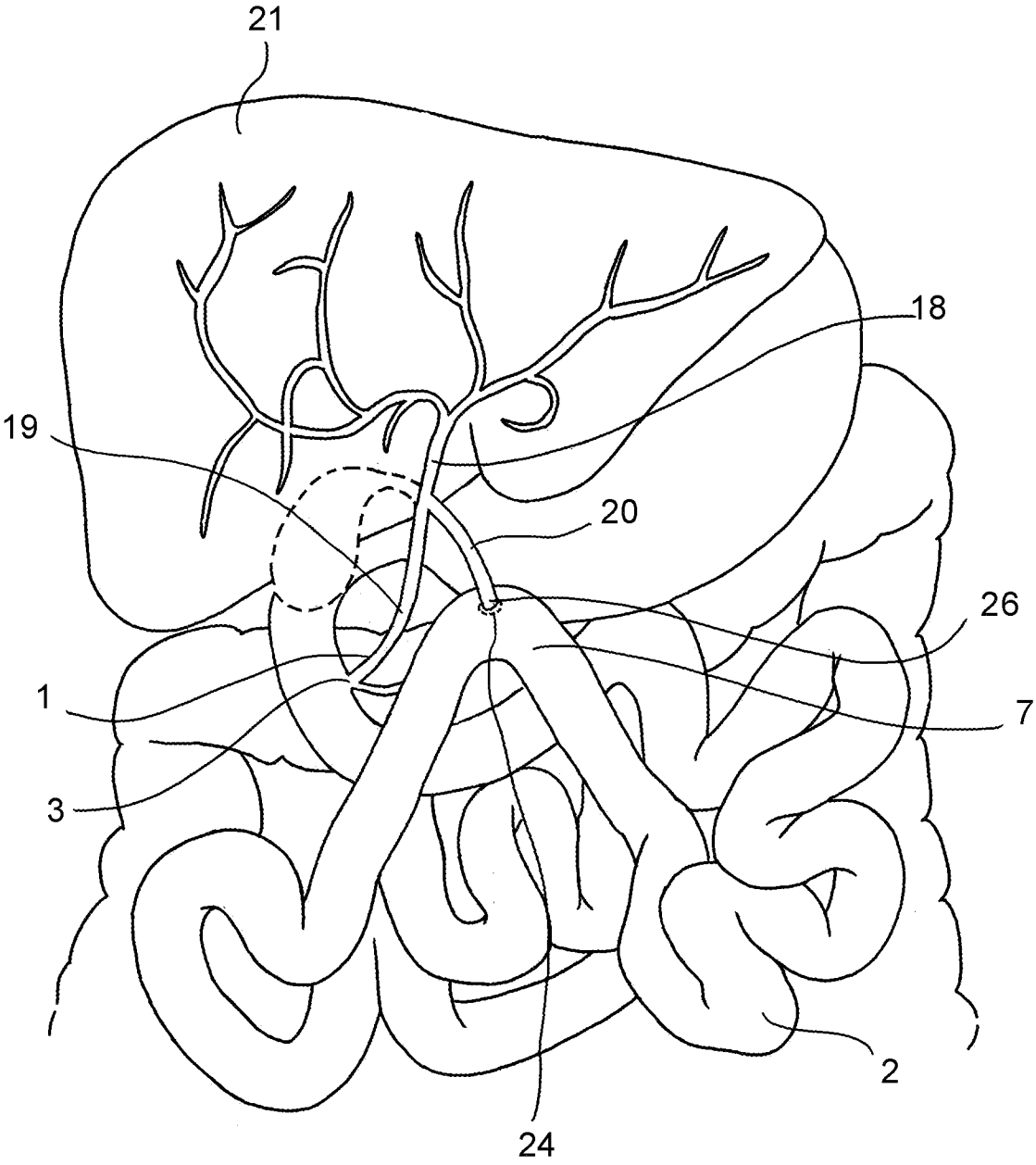


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/061105

A. CLASSIFICATION OF SUBJECT MATTER		
ADD. A61B17/11	A61F5/00	A61B17/00 A61B17/064 A61F2/06
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 A61B		
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 practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007/225642 A1 (HOUSER RUSSELL A [US] ET AL) 27 September 2007 (2007-09-27) abstract; figures 49-57 -----	1
A	WO 98/52474 A1 (KENSEY NASH CORP [US]) 26 November 1998 (1998-11-26) abstract; figures 13-14,18 page 6, paragraph 7 - page 7, paragraph 2 page 23, paragraph 3 -----	1
A	US 2005/080439 A1 (CARSON DEAN F [US] ET AL) 14 April 2005 (2005-04-14) abstract; figures 9-10B,65b,66b -----	1
A	US 2010/069933 A1 (D ARCANGELO MICHELE [IT] ET AL) 18 March 2010 (2010-03-18) abstract; figures 22-27,30-34 ----- -/-	1
☒ 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 application or patent 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 8 May 2012		Date of mailing of the international search report 16/05/2012
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 Macaire, Stéphane

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2011/061105

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1 908 420 A1 (ETHICON ENDO SURGERY INC [US]) 9 April 2008 (2008-04-09) abstract; figures 1-6,13 -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/061105

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.: 10-21
because they relate to subject matter not required to be searched by this Authority, namely:
Pursuant to Article 17(2)(a)(i) and Rule 39.1 (iv) PCT, the subject-matter of claims 10-21 has not been searched, since it is directed to a method for treatment of the human body by surgery (step of accessing the intestine).
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/EP2011/061105

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		CN 101522110 A	02-09-2009
		EP 1908420 A1	09-04-2008
		WO 2008040582 A1	10-04-2008
