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(54) **Title**: CATHETER FOR DIRECTING BILIOPANCREATIC SECRETIONS

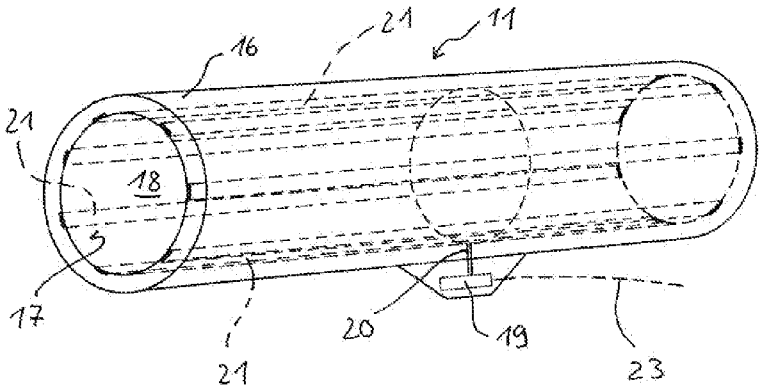

FIG. 3

(57) **Abstract**: A catheter (11) for directing biliopancreatic secretions comprises an elongate tubular wall (16) extending between a proximal end portion (12) and a distal end portion (13) and having an internal surface (17) which defines a fluid passage channel (18), and a vibration generator (19) connected to the tubular wall (16) and adapted to generate vibrations and transmit the generated vibrations to the internal surface (17).

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DESCRIPTION

CATHETER FOR DIRECTING BILIOPANCREATIC SECRETIONS

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

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

Surgical methods of treating morbid obesity, such as open, laparoscopic and endoluminal gastric bypass surgery aiming to permanent malabsorption of the food, have been increasingly used with greater success. However, current methods for performing a gastric bypass involve time-consuming and highly dexterity dependent surgical techniques as well as significant and generally highly invasive modifications of the patients gastrointestinal anatomy. These procedures are reserved only for the severely obese patients because they have a number of significant complications, including the risk of death. In order to avoid the drawbacks of gastric bypass surgery and to influence the digestion of a

patient in a more specific and aimed way, the present invention focuses on methods and devices for primarily influencing and modifying the entero-hepatic bile cycling rather than the digestive tract itself. To this end, the following possible approaches and mechanisms of action on the entero-hepatic bile cycling are contemplated:

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

A known minimally invasive bypass system and method for modifying the location at which bile and pancreatic secretions interact with nutrients in a gastrointestinal tract has been e.g. 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.

One of the major problems with plastic catheters is their tendency to clog over time. Bile catheter obstructions and the subsequent failure of drainage of the biliopancreatic juices would lead to complications, such as jaundice and cholangitis, and must therefore be obviated by exchanging the entire catheter. Clinical catheter occlusion has been observed to occur in 28% - 58% of patients after a time interval of 131 days to 324 days. Even though the mechanism of catheter occlusion is not yet completely understood, it has been postulated that shortly after the implantation of a plastic stent or catheter, proteins contained in the biliary fluid, such as fibronectin, collagen, fibrin and immunoglobulin A, coat the internal catheter surface and promote harboring of bacteria. Subsequent glycocalix formation by the adhered bacteria forms a gel-like biofilm that protects the bacteria from antibiotics, from the action of the immune system and also from the mechanical shearing effect of the bile flow through the catheter. In addition, commonly found microorganisms in the sludge, such as Escherichia coli, can produce β-glucoronidase, which can deconjugate bilirubin glucoronide and precipitate calcium bilirubinate which adds to the depositions inside the catheter.

Research over the past two decades has concentrated on improving the patency of implanted catheters and stents focusing on appropriate materials, catheter- and stent position, catheter shape and dimensions, as well as on the administration of antibiotics and drugs affecting the constituents of the biliary fluid and the depositions and sediments inside the catheter. However, to date, catheter diameter dimensioning is the only factor that has proven to effectively influence catheter patency and clogging time.

An aim of the present invention is therefore to provide a catheter for directing biliopancreatic secretions, wherein the catheter obviates premature obstruction and assures a sufficient patency for the planned catheter life time.

This aim is achieved by a catheter for directing biliopancreatic secretions, the catheter comprising an elongate tubular wall extending between a first end portion and a second end portion and having an internal surface defining a fluid passage channel, and a vibration generator connected to the tubular wall and adapted to generate vibrations and transmit the generated vibrations to said internal surface.

Thanks to the vibrating internal surface of the catheter, the harboring of sludge becomes more difficult

and adhering deposits detach from the internal surface and are carried away by the flow of bodily fluid through the fluid passage channel. Moreover, the bodily fluid agitated by the vibrations exert a much stronger rinsing effect on the internal surface of the tubular wall than e.g. normally flowing bile or pancreatic juices. The resulting patency and duration of the catheter is significantly increased.

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 catheter for directing biliopancreatic juices implanted in the GI tract of a patient;
- Figure 2 illustrates a detail of a catheter for directing biliopancreatic juices in accordance with an embodiment of the invention;
- Figure 3 illustrates a further detail of a catheter for directing biliopancreatic juices in accordance with an embodiment of the invention;

- Figure 4 illustrates a schematic cross-section of a detail of the catheter for directing biliopancreatic juices implanted in the GI tract of a patient.

Referring to the drawings in which 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 gastrointestinal tract with the esophagus 1, stomach 2, duodenum 3, jejunum 4, ileum 5, colon 6, as well as the hepatic-biliary system with the liver, the biliary tree 7 with gall bladder 8, the pancreatic duct 9 and the mayor duodenal papilla of Vater 10 through which the bile and pancreatic fluid normally enter the duodenum 3. Figure 1 shows further a catheter 11 for modifying the location at which biliopancreatic secretions interact with nutrients and with the intestinal wall in a gastrointestinal tract.

The catheter 11 comprises a proximal end portion 12 adapted to be fluid connected to the common bile duct 7 to collect biliopancreatic secretions and a distal end portion 13 adapted to be placed in a location downstream in the gastrointestinal tract, that is to say in a location significantly distal to the papilla of Vater, such as in the distal section of the duodenum 3, in the jejunum 4 or ileum 5. The catheter proximal end portion

12 may have only one proximal open end 14 which can be arranged and anchored (e.g. by means of a stent) in the bile duct proximally (to collect only bile) or distally to the junction point with the pancreatic duct 9 (to collect both bile and pancreatic juices). Alternatively, the proximal end portion 12 may be bifurcated or Y-shaped and define a proximal open bile end 14 intended and adapted to be inserted in the bile duct 7 proximal to the junction point with the pancreatic duct 9, and a proximal open pancreatic end 14' intended and adapted to be inserted in the pancreatic duct 7. Such a Y-shaped proximal end portion 12 would allow to collect bile and pancreatic juices separately and to keep them isolated or mix them further distally in the catheter 11.

The catheter distal end portion 13 forms one or more bile outlet openings 15 through which the biliopancreatic juices are released into the intestine 3, 4, 5.

In accordance with an aspect of the invention, the catheter 11 comprises an elongate tubular wall 16 extending between the proximal end portion 12 and the distal end portion 13 and having an internal surface 17 which defines a fluid passage channel 18 of the catheter 11. A vibration generator 19 is connected to the tubular wall 16 and adapted to generate vibrations and transmit

the generated vibrations to the internal surface 17.

Thanks to the vibrating internal surface 17 of the catheter 11, the harboring of sludge becomes more difficult and adhering deposits detach from the internal surface and are carried away by the flow of bodily fluid through the fluid passage channel. Moreover, the bodily fluid agitated by the vibrations exert a much stronger rinsing effect on the internal surface of the tubular wall than e.g. normally flowing bile or pancreatic juices. The resulting patency and duration of the catheter is significantly increased.

In accordance with an embodiment, the vibration generator 19 comprises a piezoelectric sonic or ultrasonic vibration generator having one or more piezoelectric crystals which expand and contract or bend in response to an alternating voltage. The piezoelectric crystals can be e.g. connected on either side of a leaf spring which is then caused to shorten and lengthen alternately, thus producing longitudinal vibrations whose amplitude may be further enhanced by an amplitude enhancing member.

In accordance with a further embodiment, the vibration generator 19 comprises an electromagnetic vibration generator.

A vibration output member (or in other words: an

oscillating member) of the vibration generator 19 is connected to the tubular wall 16, particularly near the internal surface 17 thereof, by means of a vibration transmitter 20. The vibration transmitter 20 may comprise a comparatively stiff and preferably linear-elastic transmitting wire or shell, e.g. a spring steel wire or shell, or by an encapsulated transmitting fluid, e.g. distilled water. The vibration transmitter 20 may form a plurality of vibration diffusion paths 21 which can be interconnected and form a net-like vibrating mesh. Alternatively, the vibration diffusion paths 21 may be connected to a common vibration generator 19 but not networked in order to avoid direct vibration interference downstream the connection of the vibration diffusion paths 21 with the vibration generator 19. As already explained above, also the vibration diffusion paths 21 may be embodied by transmitting wire or shell or, alternatively by a transmitting fluid encapsulated within a conduit system.

In accordance with a further embodiment, the vibration generator 19 may be locally controlled by an onboard controller or remote controlled, e.g. by means of wireless RF signal communication between an extracorporeal control unit and a local controller associated with the vibration generator 19. The

vibration generator 19 may further comprise a battery having a charging level sufficient for the planned life time of the catheter 11 or a remotely rechargeable battery, e.g. by means of an inductive extracorporeal charger.

In accordance with an embodiment, the vibration generator 19 may be configured to automatically vibrate, following an intermittent actuation scheme which performs e.g. a short vibration period of e.g. 120 seconds - 240 seconds every 6 hours.

In accordance with an alternative embodiment, the vibration generator 19 may be configured to automatically vibrate continuously after an initial switch on.

The tubular wall 16 is preferably flexible to facilitate the implantation of the catheter 11 and to better follow the physiological structures to which the catheter 11 is applied. The tubular wall 16 may be grafted at least partially in silicone, polyethylene, polypropylene, butylated rubber, latex and the like, and may have an inner coating of PTFE or Dacron (Polyethylene terephthalate) to provide a low friction and inert biocompatible internal surface 17 for the biliary fluid to flow through.

In order to increase torque-, kink- and compression

resistance of the catheter 11, the tubular wall 16 may be additionally reinforced with a metal or plastic wire mesh, e.g. with a braided wire mesh, which can be coextruded together with or incorporated and encapsulated in the tubular wall 16 base material (e.g. polyethylene). The vibration generator 19 may be directly connected to the reinforcement mesh which has a greater stiffness than the base material and is therefore adapted to propagate the vibrations along the entire catheter 11 and to accomplish the function of the above said vibration transmitter and vibration diffusion paths.

The catheter 11 can be installed endoluminally, e.g. transorally, in the intestine and the proximal end portion 12 of the catheter 11 may be inserted in the papilla of Vater 10 using e.g. an ERCP (Endoscopic Retrograde Cholangio Pancreatography) like technique. The ERCP procedure involves passing a flexible endoscope through the mouth, esophagus 1, and stomach 2 into the duodenum 3 near the papilla of Vater 10. The doctor then passes the catheter 11 through a channel in the endoscope and out into view in the duodenum 3 and inserts it into the papilla of Vater 10.

The present invention further contemplates the possibility of placing the catheter 11 in the intestine

and introducing the catheter proximal end portion 12 in the papilla of Vater 10 by laparoscopically accessing the abdominal space, translumenally accessing the duodenum 3 near the papilla of Vater 10 and placing the catheter 11 through the duodenum 3 in the desired position within the intestine and, from inside the duodenum 3, laparoscopically introducing the catheter proximal end portion 12 into the papilla of Vater 10.

Alternatively or additionally, the vibration generator 19 or a battery thereof can be placed and anchored in the stomach (which provides more space than the small bowel), e.g. by means of a gastric coil 22 which can elastically deform from an extended configuration adapted for transoral or transnasal transportation thereof into the stomach 2, to a wound arched or circular configuration adapted to shape interfere with the stomach 2. The gastric coil can hold or house the vibration generator 19 and/or its battery which in turn can be connected by a connecting line 23 electrically and/or in a vibration transmitting manner to the catheter 11 tubular wall 16 (compare figure 1).

The catheter 11 and methods of the described invention assure an improved patency over time and reduce the risk of catheter clogging and related clinical complications. Moreover, the described catheter obviates the need of

frequent catheter replacements and, hence, the need of frequent surgical manipulation of the region of the biliary tree and pancreatic duct

In accordance with a further embodiment, the catheter may benefit from vibrations generated by the natural stomach motion and transmitted from the stomach to the catheter by a vibration transmitter, e.g. through a spring connected between a gastric coil and the catheter. The stomach motion causes an oscillating deformation of the gastric coil which is transmitted by the spring to the catheter wall or to a stirring wire inside the catheter, thereby preventing bile from clogging the lumen of the catheter. The gastric coil and the vibration transmitter can be configured to generate, in response to the stomach motion, a substantially pulsating or sinusoidal movement which is then transmitted to the catheter wall.

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 catheter (11) for directing biliopancreatic secretions, the catheter (11) comprising:

- an elongate tubular wall (16) extending between a proximal end portion (12) and a distal end portion (13) and having an internal surface (17) which defines a fluid passage channel (18),

- a vibration generator (19) connected to the tubular wall (16) and adapted to generate vibrations and transmit the generated vibrations to the internal surface (17).

2. A catheter (11) according to claim 1, in which a vibration output member of the vibration generator (19) is connected to the tubular wall (16) by means of a vibration transmitter (20) which forms a plurality of vibration diffusion paths (21) extending along the tubular wall.

3. A catheter (11) according to claim 2, in which the vibration diffusion paths (21) are interconnected to form a net-like vibrating mesh.

4. A catheter (11) according to claim 2, in which the vibration diffusion paths (21) are commonly connected to the vibration generator (19) but not networked in order to avoid direct vibration interference downstream the with the vibration generator (19).

5. A catheter (11) according to any one of claims 2 to 4, in which said vibration transmitter (20) comprises a linear-elastic transmitting wire or shell which has a greater stiffness than a base material of the tubular wall (16).

6. A catheter (11) according to any one of claims 2 to 4, in which said vibration transmitter (20) comprises an encapsulated transmitting fluid.

7. A catheter (11) according to claim 6, in which said vibration diffusion paths (21) comprise a transmitting fluid encapsulated within a conduit system.

8. A catheter (11) according to any one of the preceding claims, in which the vibration generator (19) comprises a piezoelectric vibration generator.

9. A catheter (11) according to any one of the preceding claims, in which the vibration generator (19) comprises an electromagnetic vibration generator.

10. A catheter (11) according to any one of the preceding claims, in which the vibration generator (19) is configured to automatically and intermittently vibrate.

11. A catheter (11) according to any one of the preceding claims, in which the vibration generator (19) is configured to automatically and continuously vibrate after an initial switch on.

12. A catheter (11) according to any one of the preceding claims, in which the tubular wall (16) has an inner coating of PTFE or Dacron (Polyethylene terephthalate) to provide a low friction and inert biocompatible internal surface (17).

13. A catheter (11) according to any one of the preceding claims, in which the tubular wall (16) is reinforced with a reinforcing wire mesh incorporated in the tubular wall (16) base material and having a greater stiffness than said base material, wherein the vibration generator (19) is directly connected to the reinforcement wire mesh.

14. A catheter (11) according to any one of the preceding claims, comprising a gastric coil (22) which can elastically deform from an extended configuration to a wound configuration adapted to shape interfere with the stomach (2), wherein the gastric coil supports the vibration generator (19) which in turn is connected by a connecting line (23) in a vibration transmitting manner to the tubular wall (16).

15. A catheter according to claim 1, comprising a gastric coil (22) elastically deformable from an extended configuration to a wound configuration and coupled to the tubular wall (16) by a vibration transmitter, the gastric coil being adapted to shape

interfere with the stomach (2) and the vibration transmitter being adapted to transmit a motion to the tubular wall (16) proportional to a deformation of the gastric coil.

16. A method for improving the patency of a catheter (11) for directing biliopancreatic secretions, the catheter (11) comprising an elongate tubular wall (16) extending between a proximal end portion (12) and a distal end portion (13), the tubular wall (16) having an internal surface (17) which defines a fluid passage channel (18), the method comprising:

- generating vibrations and transmitting the generated vibrations to the internal surface (17).

17. A method according to claim 16, comprising the step of generating and transmitting the vibrations automatically by means of a vibration generator which is permanently connected to the tubular wall.

18. A method according to claim 16 or 17, comprising the step of applying the vibration intermittently.

19. A method according to claim 16 or 17, comprising the step of applying the vibration continuously.

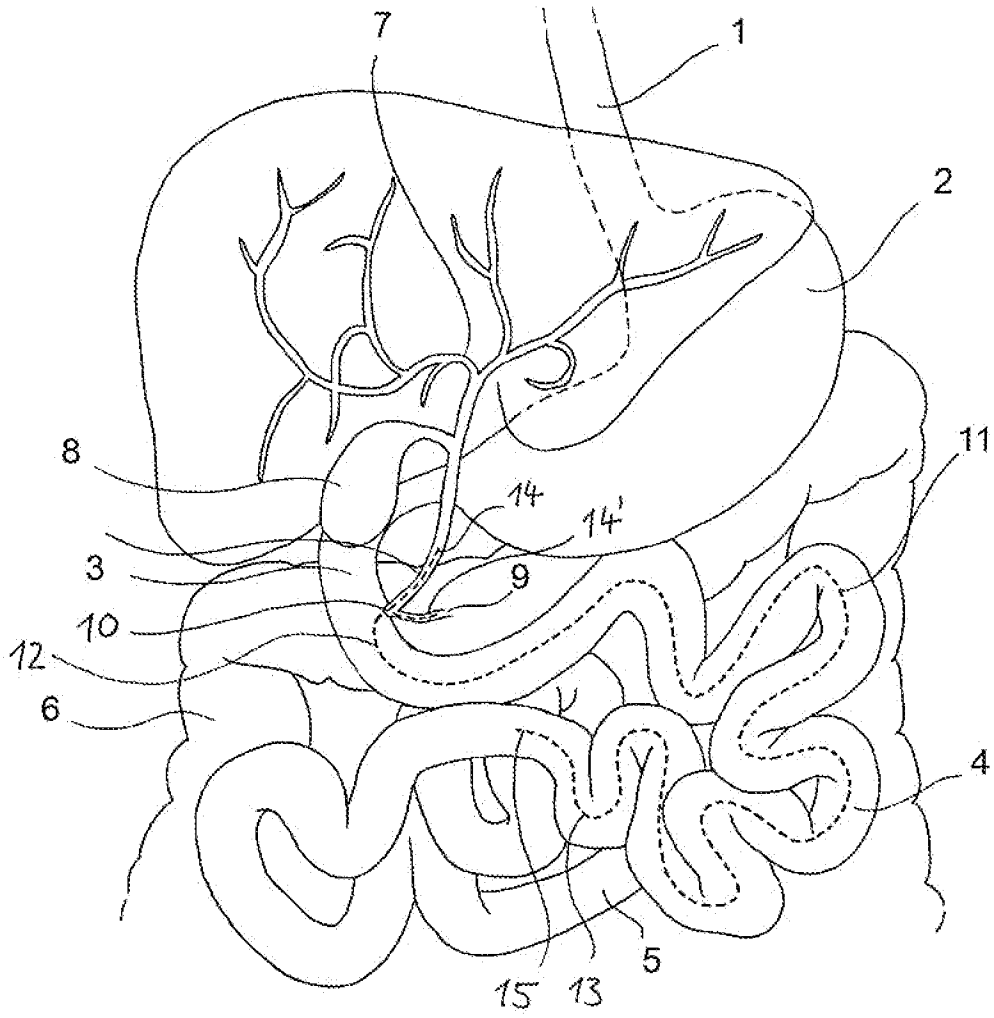

FIG. 1

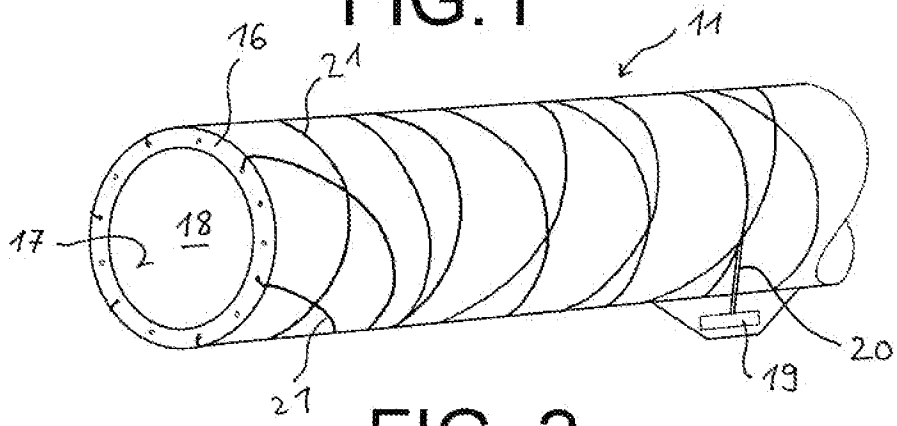

FIG. 2

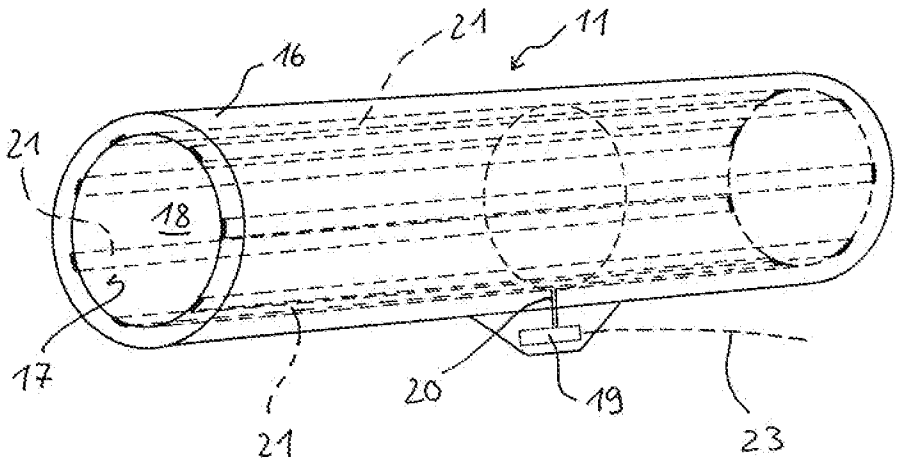

FIG. 3

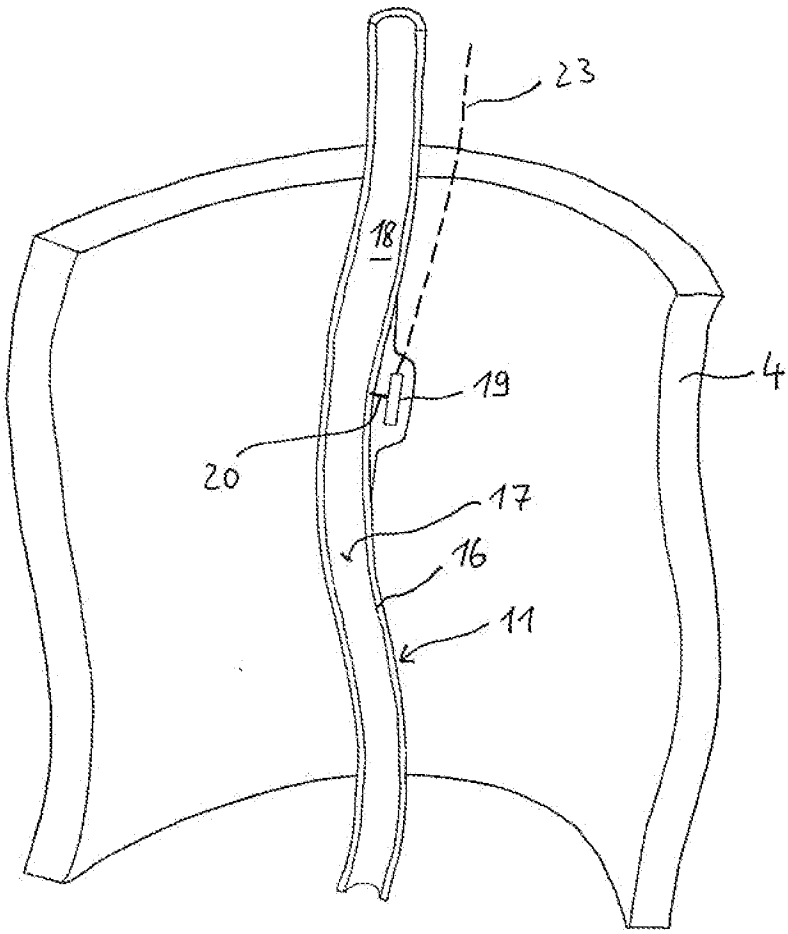

FIG. 4

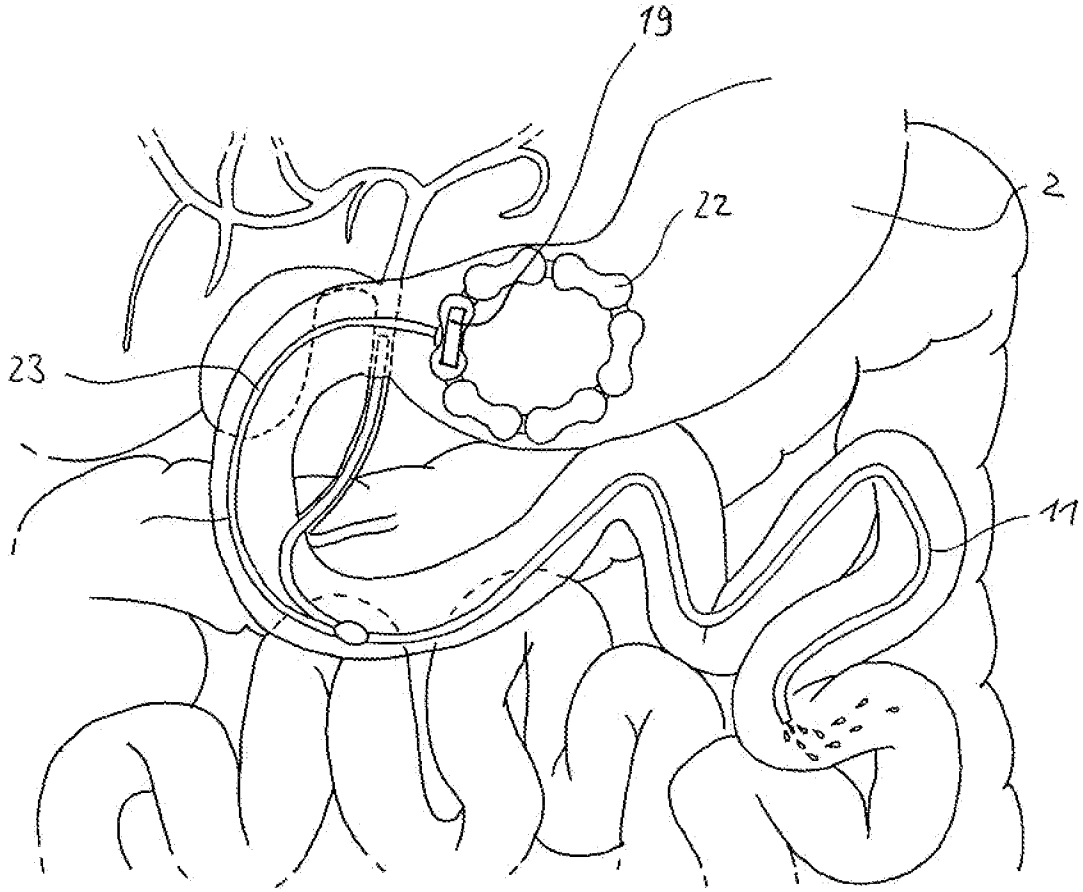

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/058980

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61L2/02 A61M25/00
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)
A61M A61L

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/038376 A1 (NANO VIBRONIX INC) 17 February 2005 (2005-02-17) paragraph [0069] - paragraph [0072]; figures 8A-D	1,9-12, 16-19
X	WO 2007/110870 A2 (NANO VIBRONIX INC) 4 October 2007 (2007-10-04)	1,2,8
Y	page 26, line 1 - page 27, line 11; figure 10	3-5,13
Y	US 2002/142119 A1 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) 3 October 2002 (2002-10-03) paragraph [0081]; figures 12, 16	3-5,13

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

☒ See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
17 February 2012	29/02/2012

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2011/058980

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005038376 A1	17-02-2005	NONE	
WO 2007110870 A2	04-10-2007	CN 101616707 A	30-12-2009
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