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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 December 2012 (06.12.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/163413 A1

(51) International Patent Classification:
A61M 25/00 (2006.01) *A61F 5/00* (2006.01)
A61F 2/04 (2006.01) *A61M 27/00* (2006.01)

(21) International Application Number:
PCT/EP2011/058981

(22) International Filing Date:
31 May 2011 (31.05.2011)

(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, Ohio 45242-2839 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **D'ARCANGELO, Michele** [IT/IT]; Via Benedetto Croce, 26, I-00142 Roma (IT). **ORTIZ, Mark Steven** [US/US]; 1145 Glen Echo Ln, Milford, Ohio 45150 (US). **PASTORELLI, Alessandro** [IT/IT]; Via Francesco Sivori, 5, I-00136 Roma (IT). **DALESSANDRO, David A.** [US/US]; 7 Fields lane, Scotch Plains, New Jersey 07076 (US). **CONTILIANO, Joseph Henry** [US/US]; 303 Aldin Road, Stewartsville, New Jersey 08886 (US). **DAVE, Vipul Bhupendra** [US/US]; 20 Francis drive, Hillsborough, NJ 08884 (US).

(74) Agents: **LEIHKAUF, 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, RS, 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))*

WO 2012/163413 A1

(54) Title: CATHETER FOR DIRECTING BILIOPANCREATIC SECRETIONS

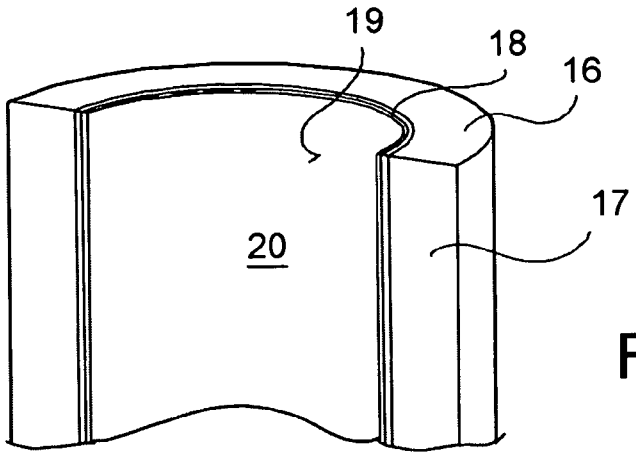

FIG. 3

(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), the tubular wall (16) having an outer layer (17) and at least one inner coating (18) forming an internal surface (19) which defines a fluid passage channel (20) of the catheter (11), wherein the inner coating (18) is degradable and adapted to detach from the tubular wall (16) together with possible depositions thereon.

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 and other aims are 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, the tubular wall having an outer layer and at least one inner coating, said inner coating forming an internal surface which defines a fluid passage channel of the catheter, in which the inner coating is degradable (or, in other words, erodible) and adapted to detach from the tubular wall together with possible depositions thereon.

Thanks to the detachment of the coating and the adhering deposits, the patency and duration of the catheter can be 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 is a perspective cross-sectional view of a portion of a catheter for directing biliopancreatic juices in accordance with an embodiment of the invention;
- Figure 4 is a cross-sectional view of a portion of the catheter for directing biliopancreatic juices in figure 3;
- Figure 5 is a perspective cross-sectional view of a

portion of the catheter in accordance with a further embodiment;

- Figure 6 is a perspective cross-sectional view of a catheter in accordance with a yet further embodiment.

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, the tubular wall 16 having an outer layer 17 and at least one inner coating 18. The inner coating 18 forms an internal surface 19 which

defines a fluid passage channel 20 of the catheter 11. The inner coating 18 is degradable (or, in other words, erodible or absorbable) and adapted to detach from the tubular wall 16 together with possible depositions thereon.

Thanks to the detachment of the inner coating 18 and the adhering deposits, the patency and duration of the catheter 11 can be significantly increased.

In accordance with an embodiment, the degradable coating 18 is adapted to exposure time-dependently degrade and detach from the tubular wall 16 by a decomposition process of a decomposition material contained in the coating 18, the decomposition material being responsive to an exposure to bodily fluids, such as biliopancreatic secretions.

In accordance with a further embodiment, the degradable coating 18 is adapted to time-dependently degrade and detach from the tubular wall 16 by a decomposition process of a decomposition material contained in the coating 18, wherein the decomposition material degrades in dependence of time, but substantially independently from the exposure to bodily fluids.

The coating 18 may comprise a water soluble decomposition material or an acid dissolvable decomposition material or a mixture of a water soluble

decomposition material and an acid dissolvable decomposition material.

In accordance with a further embodiment, the degradable coating 18 comprises a degradable multi-layer coating, in which each layer 21 of the multi-layer coating is adapted to detach individually from the tubular wall 16 together with possible depositions thereon.

In accordance with an embodiment, the degradable multi-layer coating is configured to erode gradually or stepwise starting from an innermost layer 21 to an outermost layer 22 thereof, such that each individual layer 21 detaches only after being exposed to the fluid passage channel 20 of the catheter 11.

In this way, after an innermost layer 21 of the multi-layer coating has been exposed for a given period of time to the transit of bodily fluid and covered by undesired depositions and bacteria, it detaches (by erosion, degradation, grumbling or dissolving) together with the undesired deposits and exposes the immediately underlying layer 21' to the transit of bodily fluid, which underlying layer 21' will now become the innermost layer and behave the same way. The mechanism will repeat until an outermost layer 22 of the multi-layer coating is exposed to the bodily fluid and decomposed.

The individual layers 21, 21', 22 of the multi-layer

coating may be of different materials or have different size in order to control the degradation rate.

In accordance with an embodiment, at least one of the individual layers 21, 21', 22 of the degradable multi-layer coating 18 may be adapted to degrade once activated by a magnetic field generated outside of the body or by an exogenous catalyst agent administered orally, intravenously or transcutaneosly.

In accordance with an embodiment, each individual layer 21, 21', 22 of the multi-layer coating is configured to detach from the tubular wall 16 after a period of exposure to bodily fluid from 15 days to 45 days, preferably from 25 days to 35 days, even more preferably after a period exposure of about 30 days.

Adjacent individual layers 21, 21', 22 of the multi-layer coating may be connected, e.g. bonded or glued by an adhesive, to each other substantially on the entire contact interface therebetween.

Alternatively, in order to improve the detachability of the individual layers 21, 21', 22 of the multi-layer coating from the underlying layer, adjacent layers may be connected, e.g. bonded or glued by an adhesive, to each other only in discrete connecting regions 23 which cover e.g. less than 50% of the contact interface therebetween.

As has already been explained in relation with a single layer degradable coating, one or more or all individual layers 21, 21', 22 of the degradable multi-layer coating 18 may be adapted to exposure time-dependently degrade and detach from the underlying layer and, hence, from the tubular wall 16 by a decomposition process of a decomposition material contained in the individual layer, said decomposition material being responsive to an exposure to bodily fluids, such as biliopancreatic secretions.

Analogously, one or more or all individual layers 21, 21', 22 of the degradable multi-layer coating 18 may be adapted to time-dependently degrade and detach from the underlying layer and, hence, from the tubular wall 16 by a decomposition process of a decomposition material contained in the individual layer, wherein the decomposition material degrades in dependency of time, but substantially independently from the exposure to bodily fluids.

The tubular wall 16 is preferably flexible to facilitate implantation of the catheter and to better follow the physiological structures to which the catheter 11 is applied. The outer layer 17 of the catheter tubular wall 16 may be grafted at least partially in silicone, polyethylene, polypropylene, butylated rubber, latex and

the like, and the inner coating 18 may comprise particles, fibers or film sections of PTFE or Dacron (Polyethylene terephthalate) to provide a low friction and inert biocompatible surface for the biliary fluid to flow through.

The degradable and/or absorbable inner coating 18 may comprise polyglycolated resins, polygalactic acid materials, and other similar materials, such as Keratin and collagens. Keratin is a family of more than 200 normally non-soluble proteins that play a fundamental role in nature. They are present in human tissues such as skin as well as in hair and nails. It is possible to extract keratin fractions in a soluble and digestible form, leaving the natural amino acid structure intact and therefore potent. Thus, keratin extracts become absorbable by the body.

Since thickness of the keratin material is a key factor in degradation rate, the rates of degradation of the inner coating may be programmed by controlling thickness of the keratin throughout the layer or at key points, such as desired detachment points.

In accordance with a yet further embodiment, also the outer layer 17 of the tubular wall 16 may be biodegradable and/or absorbable in such a manner that, after a given time or a given exposure time to bodily

fluids, the tubular wall 16 of the catheter 11 detaches from its implantation position within the body of the patient, e.g. inside the small bowel, and will be evacuated from the body or absorbed by the organism.

The outer layer 17 may be gradually erodible along its entire surface in response to the exposure to bodily fluids or in dependency of a decomposition time. Alternatively, the outer layer 17 may comprise one or more local erosion zones 24 (e.g. annular separation zones) which gradually dissolve or grumble in response to the exposure to bodily fluids, e.g. intestinal contents within the small bowel, or in dependency of a decomposition time, so that after a planned period of time, entire catheter sections detach from one another and can be evacuated from the body together with the stool.

In order to increase torque-, kink- and compression resistance of the catheter 11, the outer layer 17 of the tubular wall 16 may be additionally reinforced with a metal or plastic wire mesh 25, e.g. with a braided wire mesh, which can be coextruded together with or incorporated and encapsulated in the outer layer 17 base material (e.g. polyethylene).

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.

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

Further exemplary materials for the inner layer can be prepared from melt processable polymers or by solvent coated polymers that can degrade in 2-4 weeks time period. These materials can be low molecular weight poly(glycolic acid) or blends of water soluble polymers (PVP; PEO) with degradable materials; or blends of plasticized degradable polymers. The inner layer may also degrade in 1-3 months and prepared from poly(glycolic acid) or blends. The inner layer may degrade in 3-6 months with blends of poly(glycolic acid) with materials with longer absorption time such as poly(lactide-co-glycolide) with high glycolide content. The inner layer may absorb in 9 to 12 months prepared from poly(lactids-co-glycolide) with higher lactide content such as PLGA 85/15. These materials can be melt processed by co-extruding the tube with different layers prepared from the desired material composition.

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), the tubular wall (16) having an outer layer (17) and at least one inner coating (18) forming an internal surface (19) which defines a fluid passage channel (20) of the catheter (11), wherein the inner coating (18) is degradable and adapted to detach from the tubular wall (16) together with possible depositions thereon.

2. A catheter (11) according to claim 1, in which the degradable coating (18) is adapted to exposure time-dependently degrade and detach from the tubular wall (16) by a decomposition process of a decomposition material contained in the coating (18), the decomposition material being responsive to an exposure to bodily fluids.

3. A catheter (11) according to claim 1, in which the degradable coating (18) is adapted to time-dependently degrade and detach from the tubular wall (16) by a decomposition process of a decomposition material contained in the coating (18), wherein the decomposition material degrades in dependence of time, but substantially independently from the exposure to bodily

fluids.

4. A catheter (11) according to claim 1, in which the coating (18) may comprise a decomposition material selected in the group consisting of:

- water soluble materials,
- acid dissolvable materials,
- mixtures of a water soluble material and an acid dissolvable material,
- enzymatically dissolvable materials,
- magnetically degradable material.

5. A catheter (11) according to any one of the preceding claims, wherein the degradable coating (18) comprises a degradable multi-layer coating, in which each layer (21, 21', 22) of the multi-layer coating is adapted to detach individually from the tubular wall (16) together with possible depositions thereon.

6. A catheter (11) according to claim 5, wherein the degradable multi-layer coating is configured to erode stepwise starting from an innermost layer (21) to an outermost layer (22) thereof, such that each individual layer (21, 21', 22) detaches only after being exposed for a given period of time to the fluid passage channel (20) of the catheter (11).

7. A catheter (11) according to claim 5 or 6, wherein each individual layer (21, 21', 22) of the multi-layer

coating is configured to detach from the tubular wall (16) after a period of exposure to bodily fluid from 15 days to 45 days, preferably from 25 days to 35 days, even more preferably after a period exposure of about 30 days.

8. A catheter (11) according to claim 5, wherein adjacent individual layers (21, 21', 22) of the multi-layer coating are bonded to each other substantially on the entire contact interface therebetween.

9. A catheter (11) according to claim 5, wherein adjacent individual layers (21, 21', 22) of the multi-layer coating are bonded to each other only in discrete connecting regions (23) arranged between regions without bonding between the adjacent layers.

10. A catheter (11) according to claim 9, wherein said discrete connecting regions (23) cover less than 50% of the contact interface between the two adjacent layers.

11. A catheter (11) according to claim 5, wherein at least one of the individual layers (21, 21', 22) of the degradable multi-layer coating (18) is adapted to exposure time-dependently degrade and detach from the underlying layer by a decomposition process of a decomposition material contained in the individual layer, said decomposition material being responsive to an exposure to bodily fluids.

12. A catheter (11) according to claim 5, wherein at least one of the individual layers (21, 21', 22) of the degradable multi-layer coating (18) is adapted to time-dependently degrade and detach from the underlying layer by a decomposition process of a decomposition material contained in the individual layer, wherein the decomposition material degrades in dependency of time, but substantially independently from the exposure to bodily fluids.

13. A catheter (11) according any one of the preceding claims, wherein the inner coating (18) comprises particles, fibers or film sections of PTFE or polyethylene terephthalate.

14. A catheter (11) according any one of the preceding claims, wherein the outer layer (17) of the catheter tubular wall (16) is grafted of a material selected in the group consisting of silicone, polyethylene, polypropylene, butylated rubber, latex, and the degradable inner coating (18) comprise a decomposition material selected in the group consisting of polyglycolated resins, polygalactic acid materials, Keratin and collagen.

15. A catheter (11) according to claim 1, wherein also the outer layer (17) of the tubular wall (16) is at least partially biodegradable in such a manner that,

after a given exposure time to bodily fluids, the tubular wall (16) of the catheter (11) erodes and detaches from its implantation position within the body of the patient.

16. A catheter (11) according to claim 5, wherein the individual layers (21, 21', 22) of the multi-layer coating (18) are of different materials.

17. A catheter (11) according to claim 5, wherein the individual layers (21, 21', 22) of the multi-layer coating (18) have different thicknesses.

18. A catheter (11) according to claim 5, wherein at least one of the individual layers (21, 21', 22) of the multi-layer coating (18) is adapted to degrade in response to at least one of the

- administration of an exogenous catalyst agent,
- a magnetic field generated outside of the body.

19. 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 outer layer (17),

the method comprising the steps of:

- applying at least one inner coating (18) on the outer layer (17) such that the inner coating forms an internal

surface (19) which defines a fluid passage channel (20) of the catheter (11),

- during use of the catheter (11), degrading the inner coating (18) and detaching it from the tubular wall (16) together with possible depositions thereon.

20. A method according to claim 19, wherein said inner coating (18) comprises a multi-layer coating and, during use of the catheter (11),

- eroding the multi-layer coating stepwise starting from an innermost layer (21) to an outermost layer (22),

- detaching each individual layer (21, 21', 22) of the multi-layer coating only after exposure of said individual layer for a given period of time to the fluid passage channel (20) of the catheter (11).

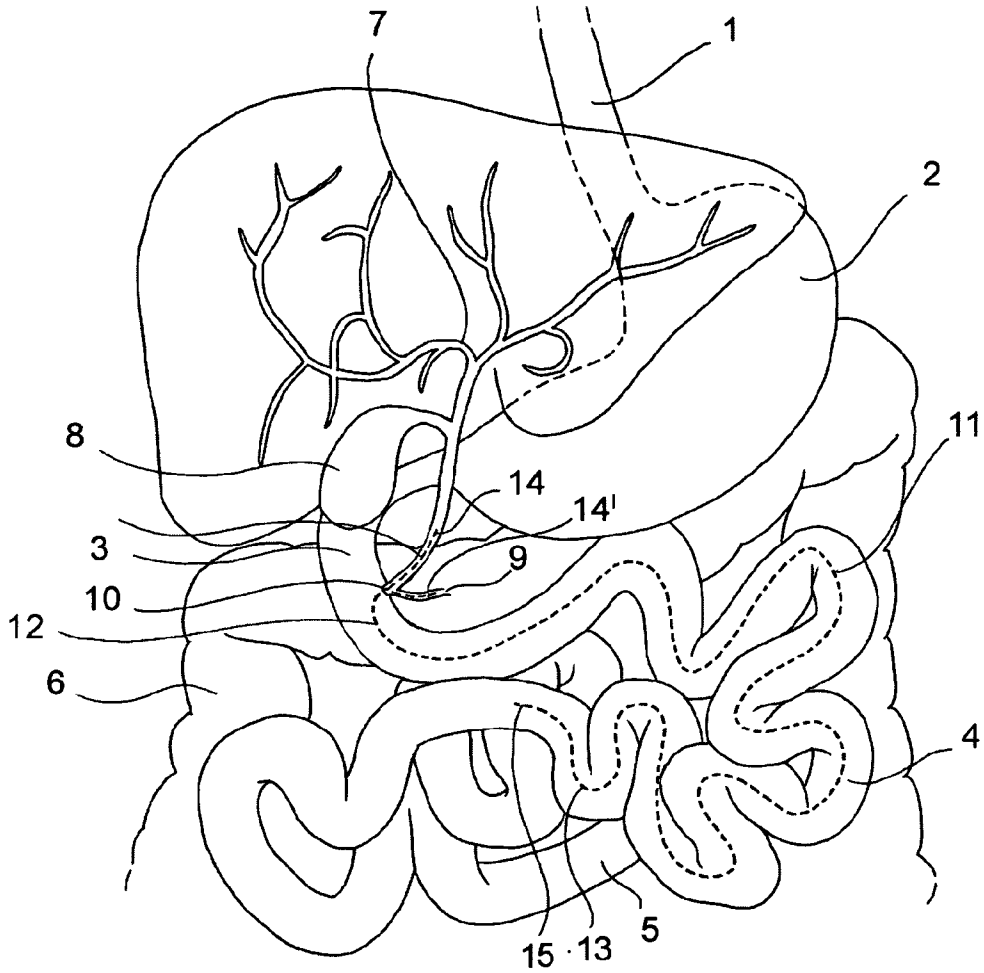

FIG. 1

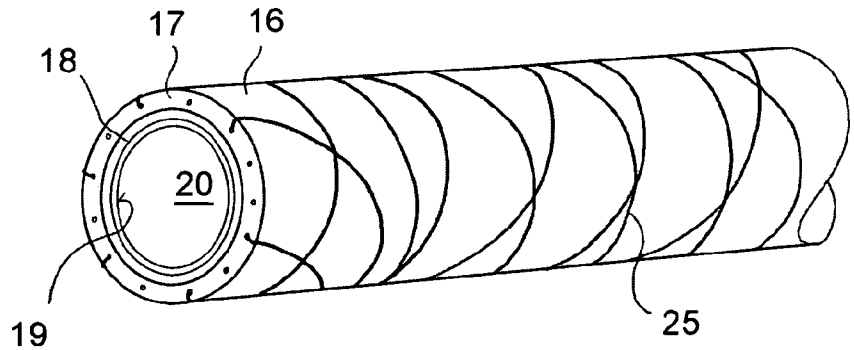

FIG.2

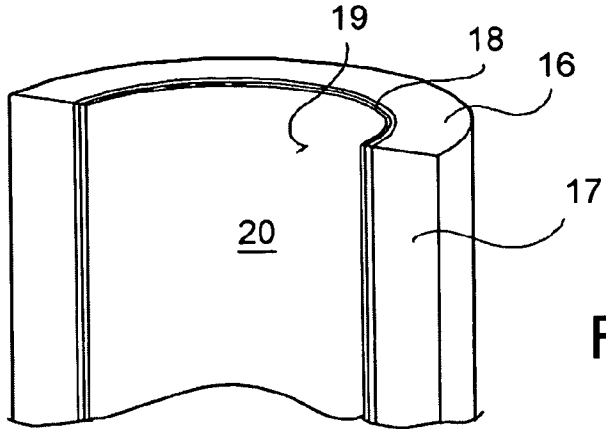

FIG. 3

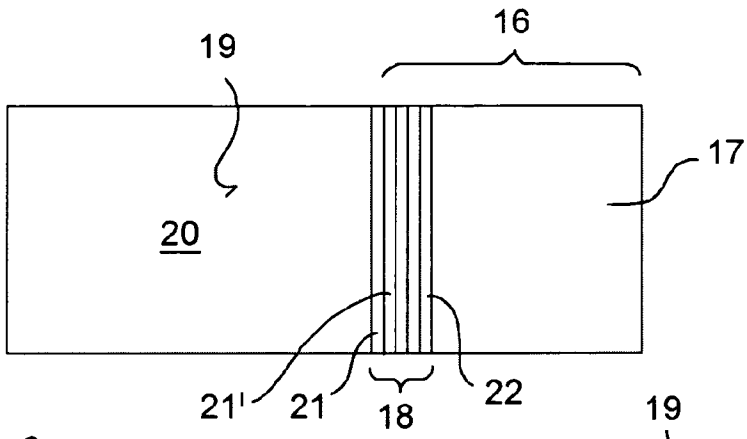

FIG. 4

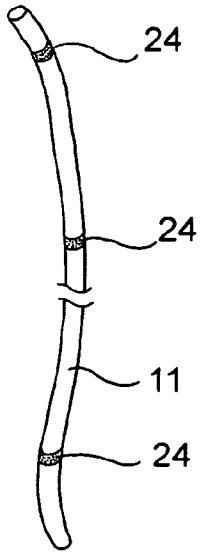

FIG. 6

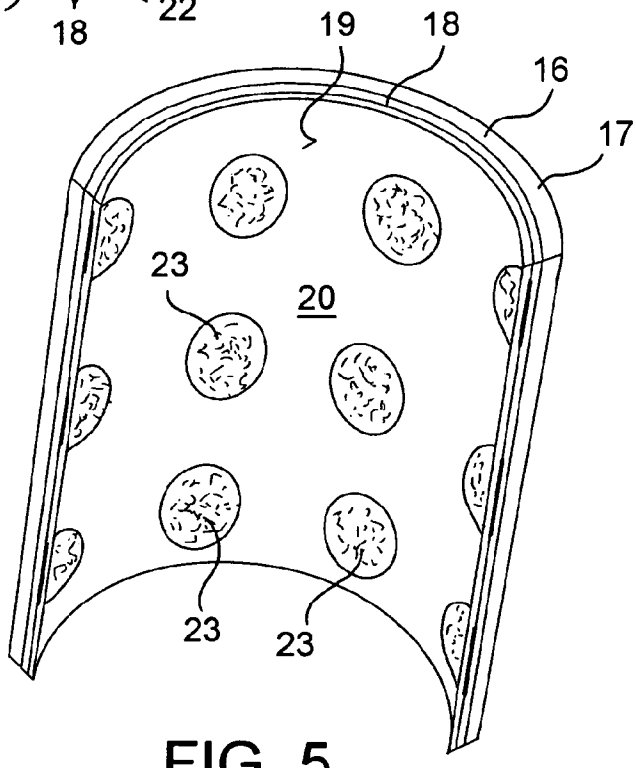

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/058981

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00 A61F2/04 A61F5/00 A61M27/00
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 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, 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	WO 2008/036711 A1 (BOSTON SCIENTIFIC SCIMED INC) 27 March 2008 (2008-03-27) paragraphs [0035] - [0038]; figures 5A-B	1,2
Y	US 2003/153983 A1 (SCIMED LIFE SYSTEMS INC) 14 August 2003 (2003-08-14) paragraphs [0063], [0069]; figure 2	3-18
Y	WO 2008/027720 A2 (WILSON COOK MEDICAL INC) 6 March 2008 (2008-03-06) paragraph [0041]; figure 4	3-18
A	WO 2007/050628 A2 (YOUNG ANDREW) 3 May 2007 (2007-05-03) paragraph [0029]; figure 1	1-18

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

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 February 2012	22/02/2012

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/058981

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

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

1. [X] Claims Nos.: 19, 20
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 19-20 relate to subject-matter concerning methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods, Rule 67.1(iv) PCT. The "use" of a biliopancreatic catheter involves at least therapy.

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/EP2011/058981

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2008036711 A1	27-03-2008	US 2008077250 A1	27-03-2008
		US 2010179666 A1	15-07-2010
		WO 2008036711 A1	27-03-2008
US 2003153983 A1	14-08-2003	AU 2003215079 A1	02-09-2003
		AU 2009200029 A1	05-02-2009
		CA 2478787 A1	14-08-2003
		EP 1476205 A1	17-11-2004
		JP 4846980 B2	28-12-2011
		JP 2005534350 A	17-11-2005
		US 2003153983 A1	14-08-2003
		US 2004249441 A1	09-12-2004
		US 2005161859 A1	28-07-2005
		WO 03066119 A1	14-08-2003
WO 2008027720 A2	06-03-2008	AT 458508 T	15-03-2010
		AU 2007290217 A1	06-03-2008
		CA 2661692 A1	06-03-2008
		EP 2063925 A2	03-06-2009
		JP 2010502298 A	28-01-2010
		WO 2008027720 A2	06-03-2008
WO 2007050628 A2	03-05-2007	EP 1948280 A2	30-07-2008
		US 2009264808 A1	22-10-2009
		WO 2007050628 A2	03-05-2007