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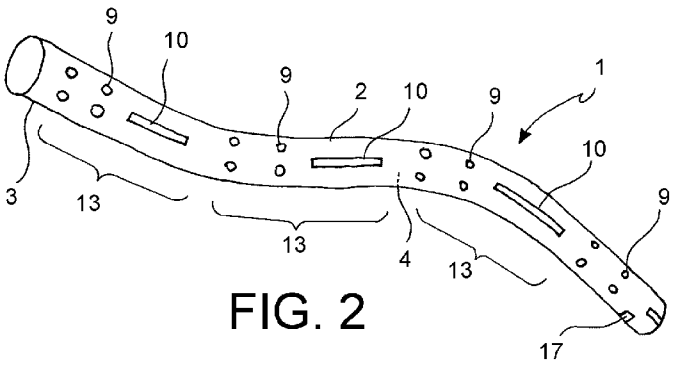

FIG. 2

(57) Abstract: An endoluminal sleeve device (1) for internally lining a section of the GI tract, comprises a sleeve (2) configured for deployment inside a duodenum, the sleeve (2) having walls of a flexible material defining a sleeve lumen (3), a proximal end (4) defining a proximal lumen opening (5), a distal end (6) defining a distal lumen opening **(7),** and a marking attached to the wall (3), the marking comprising a plurality of different markers (9, 10, 11) which are sequentially arranged in a longitudinal direction of the sleeve (2).

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"DEVICES AND METHODS FOR VERIFYING THE DEPLOYMENT STATE OF AN ENDOLUMINAL SLEEVE"

DESCRIPTION

FIELD OF THE INVENTION

[0001] The present invention relates generally to medical apparatuses and methods and more particularly to devices and methods for positioning a lining to a hollow body organ, such as a stomach, intestine or gastrointestinal tract.

BACKGROUND OF THE INVENTION

[0002] In cases of severe obesity, patients may currently undergo several types of surgery either to tie off or staple portions of the large or small intestine or stomach, and/or to bypass portions of the same to reduce the amount of food desired by the patient, and the amount absorbed by the gastrointestinal tract. The procedures currently available include laparoscopic banding, where a device is used to "tie off" or constrict a portion of the stomach, vertical banded gastroplasty (VBG), or a more invasive surgical procedure known as a Roux-En-Y gastric bypass to effect permanent surgical reduction of the stomach's volume and subsequent bypass of the intestine.

[0003] Although the outcome of these stomach reduction surgeries leads to patient weight loss because patients are physically forced to eat less due to the reduced size of their stomach, several limitations exist due to the invasiveness of the procedures, including time, general anesthesia, healing of the incisions and other complications attendant to major surgery. In addition, these procedures are only available to severely obese patients (morbid obesity, Body Mass Index >=40) due to their complications, including the risk of death, leaving patients who are considered obese or moderately obese with few, if any, interventional options.

[0004] In addition to the above described gastrointestinal reduction surgery, endoluminal sleeves are known for partially or totally lining certain portions of the stomach and of the intestine with the aim to separate or bypass at least part of the food flow from the lined portions of the gastrointestinal tract. It has been observed that by creating a physical barrier between the ingested food and certain regions of the gastrointestinal wall by means of endoluminal sleeves, similar benefits for weight loss and improvement or resolution of type 2 diabetes may be achieved as with gastric bypass surgery. Physicians observed that by creating a physical barrier between the ingested food and selected regions of the gastrointestinal wall, it is possible to purposefully influence the mechanism of hormonal signal activation originating from the intestine. It was observed that

endoluminal sleeves in certain regions of the stomach and the duodenum contributed to improve glycemic control and to reduce or eliminate other co-morbidities of obesity. Moreover the lining of parts of the GI-tract by means of endosleeves provide an alternative or an additional therapy to traditional therapies of type II diabetes and obesity. Endosleeves may be placed in a brief and less invasive procedure and address the patient's fear of surgery. Contrary to traditional gastric bypass surgery, the result of endoluminal sleeve surgery is reversible and the sleeve can be removed after achievement of the clinical result, but also in case of the occurrence of undesired side effects or clinical complications.

[0005] A typical duodenal sleeve device is described in U.S. Pat. No. 7,267,694 where the proximal end of a flexible, floppy sleeve of impermeable material defining a sleeve lumen is endoscopically deployed and anchored in the pylorus or in the superior section of the duodenum. Chyme from the stomach enters the proximal lumen opening of the sleeve and passes through the sleeve lumen to the distal lumen opening. Digestive enzymes secreted in the duodenum pass through the duodenum on the outside of the sleeve. The enzymes and the chyme do not mix until the chyme exits from the distal lumen opening of the liner tube. In such a way, the efficiency of the process of digestion of the chyme is diminished, reducing the ability of the gastrointestinal tract to absorb calories from the food.

[0006] Known endosleeves are often difficult to deploy longitudinally without tangling and twisting and tend to move inside the GI tract and migrate away from their originally planned position.

[0007] US 2008/0208357 A1 describes an endoluminal sleeve with a marking on an exterior surface of the sleeve to detect the position and orientation of the sleeve on fluoroscopic image and whether the sleeve is twisted. For this purpose a stripe of tantalum impregnated ink can be painted or tantalum bands can be bonded to the exterior surface of the sleeve device.

[0008] US 2008/0255594 A1 describes a sleeve having a longitudinal strip of radio-opaque material incorporated into at least a portion of the length of the sleeve to determine the appropriate deployment of the sleeve or alternatively to allow tailoring the sleeve to a desired length.

[0009] The known devices allow to a certain extent a confirmation of the deployed position of an endoluminal sleeve after it has been deployed. However, there is a need for improved devices and procedures for monitoring the sleeve position and extension both

during and after deployment.

SUMMARY OF THE INVENTION

[0010] The present invention provides for an endoluminal, particularly duodenal, sleeve device and method for the monitoring of the sleeve shape and extension within a hollow organ of the body, particularly within a gastrointestinal tract, including, but not limited to, the pylorus, the esophagus, stomach, duodenum as well as other portions of or the entire length of the intestinal tract, etc., unless specified otherwise. In the case of the present invention, the surgeon or endoscopist may insert sleeve devices as described below through the patient's mouth, down the esophagus and into the stomach or intestine as appropriate. Alternatively, the surgeon may insert the sleeve devices as described below laparoscopically into the stomach or intestine as appropriate. Monitoring and confirmation of the deployed sleeve position, shape and extension can be made both through extracorporeal devices or endoluminally.

[001 1] According to an aspect of the invention, there is provided a duodenal sleeve device, comprising:

- a sleeve configured for deployment inside a duodenum of a human subject, the sleeve having a wall of a flexible material defining a sleeve lumen, a proximal end defining a proximal lumen opening, and a distal end defining a distal lumen opening;
- a marking attached to the wall of the sleeve, said marking comprising a plurality of different markers which are sequentially arranged in a longitudinal direction of the sleeve.

[0012] The sequential arrangement of the markers in a predetermined pattern helps identify the state of longitudinal deployment of the sleeve, its extension within the hollow organ and the distance of certain sleeve portions from each other and from physiological structures of the patient. The identification, e.g. using fluoroscopy or ultrasound or x-ray, of the individual markers whose sequence along the sleeve is known to the doctor, aids in the determination and confirmation of the placement of the sleeve inside the lumen of the hollow organ and in the identification of ineffective positioning of the sleeve, as well as of potentially harmful situations of incomplete deployment or entanglement of the sleeve.

[0013] In accordance with an aspect of the invention, the marking comprises a longitudinally repeating pattern of identical subgroups of at least two, preferably from two to six individual markers which are all different from each other and which are arranged in a longitudinal sleeve direction in a predetermined sub-sequence, e.g. of the type ...-[M1-M2-M3]-[M1-M2-M3]-[M1-M2-M3]-... .

[0014] This configuration of the marking allows to easily identify possible local folds or

twists in the sleeve, as the subgroups of individual markers provide a characteristic image (e.g. ultrasound image or fluoroscopy image) and a change or mismatch within such a characteristic image due to a twist or fold in the sleeve wall can be easily and intuitively recognized by the human eye or identified by computer aided image analysis algorithms.

[0015] In accordance with a further aspect of the invention, the marking comprises a sequence of markers which represent or codify a consecutive sequence of numbers or values, e.g. length or distance values, and which are arranged along a prevalent portion of the length of the sleeve, e.g. of the type $[M_1\text{-}M_2\text{-}M3\text{-}...\text{-}M_{(n-1)}\text{-}M_n]$.

[0016] This configuration of the marking allows to more easily determine and confirm the deployed longitudinal extension of the sleeve within a GI-tract, as well as to verify whether the entire sleeve has been actually visualized and, if parts of the sleeve are missing in the visualization (e.g. on the ultrasound image), to determine the length and position of the invisible sleeve parts.

[0017] In accordance with a yet further aspect of the invention, the markers comprises optically visible markers, e.g. multi-chromatic markers or markers which are chromatically distinguished from the internal sleeve surface color. The optically visible markers are provided at an internal surface of the sleeve wall and adapted to be visualized by means of an endoscope from inside the sleeve. This allows endoscopic verification of sleeve deployment progress during placement of the sleeve or during endoscopic inspection after deployment.

[0018] In accordance with a yet further aspect of the invention, the sleeve device comprises an identification tag, preferably a passive radio frequency identification tag (passive RFID-tag), permanently connected to the sleeve and configured to be read at a distance, i.e. extracorporeally, by a handheld or stationary identification reader, preferably a radio frequency ID reader (RFID reader).

[0019] The identification tag may contain RF readable data related to the marking configuration and marking sequence and, possibly, to the type of visualization technology. Additionally or alternatively, the identification tag may contain RF readable target position data related to the planned position and longitudinal extension of the deployed sleeve within the hollow organ, particularly a GI tract, thereby providing immediately available reference data for a verification of the sleeve position by comparison of the RF read target position data with the visualized actual sleeve position and shape.

[0020] In accordance with a yet further aspect of the invention, there is provided a duodenal sleeve device, comprising:

- a sleeve configured for deployment inside a duodenum of a human subject, the sleeve having a wall of a flexible material defining a sleeve lumen, a proximal end defining a proximal lumen opening, and a distal end defining a distal lumen opening;
- a marking string constrained by the sleeve wall in a manner that the sleeve wall extends and can slide longitudinally along the marking string, said marking string having a stationary string end fixedly attached (i.e. in a non-dislocatable manner) to the sleeve wall near the distal sleeve end and a proximal string portion extending beyond the proximal sleeve end, thereby passing through a string outlet passage provided at the sleeve wall near the proximal sleeve end,

[0021] in which, upon deployment of the sleeve from a longitudinally compacted shape to a longitudinally expanded shape, the sleeve wall can slide and longitudinally unfold along the marking string and a length of the proximal string portion corresponding to the actual longitudinal sleeve extension is thereby pulled distally into the string outlet passage,

[0022] said marking string comprising a plurality of different marking sections which are sequentially arranged in a longitudinal direction of the marking string such that the visible marking sections which extend proximally outside the string outlet passage indicate the actual longitudinal extension of the sleeve.

[0023] Full or sufficient longitudinal deployment of the sleeve can therefore be directly confirmed by checking the color or any other characteristic indication feature of the marking sections of the marking string extending proximally out of the string outlet passage of the sleeve.

[0024] In accordance with a further aspect of the invention, there is provided a duodenal sleeve device, comprising:

- a sleeve configured for deployment inside a duodenum of a human subject, the sleeve having a wall of a flexible material defining a sleeve lumen, a proximal end defining a proximal lumen opening, and a distal end defining a distal lumen opening;
- a continuous channel formed by the sleeve wall and extending longitudinally along the sleeve from a channel opening near the proximal sleeve end to a closed channel end near the distal sleeve end;
- an elastically flexible, non compressible push rod adapted to be insertable through the channel opening into the channel up to the closed channel end, said push rod having a plurality of different marking sections which are sequentially arranged in a longitudinal direction of the push rod such that the visible marking sections which extend proximally

outside the channel opening indicate the actual longitudinal extension of the sleeve.

[0025] Full or sufficient longitudinal deployment of the sleeve can therefore be directly confirmed by checking the color or any other characteristic indication feature of the marking sections of the push rod extending proximally out of the channel opening of the sleeve.

[0026] In accordance with a further aspect of the invention, there is provided a method for verifying the deployment state of a duodenal sleeve device,

[0027] wherein the duodenal sleeve device comprises:

- a sleeve configured for deployment inside a duodenum of a human subject, the sleeve having a wall of a flexible material defining a sleeve lumen, a proximal end defining a proximal lumen opening, and a distal end defining a distal lumen opening,
- a continuous inflation channel formed by the sleeve wall and extending longitudinally along the sleeve from a proximal inflation channel opening near the proximal sleeve end to a distal channel opening near the distal sleeve end,

[0028] wherein the method comprises the steps:

- rolling up the sleeve starting from the distal sleeve end such that an internal lumen of the inflation channel is progressively closed from the distal channel opening towards the proximal channel opening;
- deploying the sleeve from the rolled up shape to a longitudinally extended shape by applying a fluid pressure to the proximal channel opening, thereby inflating the inflation channel progressively from the proximal channel opening towards the distal channel opening and unrolling the sleeve starting from the proximal sleeve end;
- monitoring the fluid pressure applied to the proximal channel opening during inflation of the inflation channel and confirming the complete deployment of the sleeve when a sudden drop in said fluid pressure corresponding to the aperture of the distal channel opening is observed or registered.

[0029] 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.

BRIEF DESCRIPTION OF THE DRAWINGS

- Figure 1 illustrates a GI tract of a human subject and a duodenal sleeve device in accordance with an embodiment;

- Figure 2 illustrates a section of a duodenal sleeve device in accordance with a further embodiment;
- Figure 3 illustrates a partially broken away section of a duodenal sleeve device in accordance with a further embodiment;
- Figure 4 illustrates a duodenal sleeve device in accordance with an embodiment of the invention, the sleeve device being in a longitudinally compacted configuration;
- Figure 5 illustrates the sleeve device of figure 4 after deployment in a longitudinally extended shape;
- Figure 6 illustrates a duodenal sleeve device in accordance with an embodiment of the invention, the sleeve device being in a longitudinally compacted configuration;
- Figure 7 illustrates the sleeve device of figure 6 after deployment in a longitudinally extended shape;
- Figure 8 illustrates devices and method steps for the longitudinal deployment of a duodenal sleeve and for the verification of an achieved state of deployment in accordance with an embodiment of the invention;
- Figure 9 illustrates devices and method steps for the longitudinal deployment of a duodenal sleeve and for the verification of an achieved state of deployment in accordance with a further embodiment of the invention;

DETAILED DESCRIPTION OF EMBODIMENTS

[0030] Referring to the drawings where like numerals denote like anatomical structures and components throughout the several views, an endoluminal sleeve device 1 for internally lining a section of the GI tract, particularly a section of duodenum distally from the pylorus, comprises a sleeve 2 configured for deployment inside a duodenum of a human subject, the sleeve 2 having a wall 3 of a flexible material defining a sleeve lumen 4, a proximal end 5 defining a proximal lumen opening 6, and a distal end 7 defining a distal lumen opening 8. The device 1 comprises further a marking attached to the wall 3 of the sleeve 2, said marking comprising a plurality of different markers 9, 10, 11 which are sequentially arranged in a longitudinal direction of the sleeve 2.

[0031] The sequential arrangement of the markers 9, 10, 11 in a predetermined pattern helps identify the state of longitudinal deployment of the sleeve 2, its extension within the hollow organ, particularly a GI tract 12, and the distance of certain sleeve portions from each other and from physiological structures of the patient. The identification, e.g. using fluoroscopy or ultrasound or x-ray from outside the body of the patient, of the individual markers 9, 10, 11 whose sequence along the sleeve 2 is known to the doctor, aids in the

determination and confirmation of the placement of the sleeve 2 and also in the identification of a possible ineffective positioning of the sleeve, as well as of potentially harmful situations of incomplete deployment or entanglement of the sleeve 2.

[0032] In accordance with embodiments, the markers 9, 10, 11 may comprise radio-opaque material embedded within the wall 3 of the sleeve 2 or attached to one of its external and internal surfaces. The radio-opaque markers may be made of metal or of a barium containing polymer.

[0033] In accordance with further embodiments, the markers may comprise echogenic material, i.e. material which forms or contains structures that reflect high-frequency sound waves and thus can be imaged by ultrasound techniques. The echogenic material may comprise a polymeric support medium which is impregnated with or which encapsulates or contains high-frequency sound reflecting particles. The high-frequency sound reflecting particles have a relative density of at least 5 (i.e. a density of more than 5 times the density of water) and may have an average particle size of less than 500 nanometers, preferably less than 100 nanometers. The sound reflecting particles may constitute from 5%(volume) to 40%(volume) of the echogenic material forming the markers 9, 10, 11.

[0034] In accordance with further embodiments, the markers 9, 10, 11 may encapsulate a fluid which contains microbubbles formed by an elastically deformable shell (e.g. of albumin, galactose, lipid, or polymers) and a gas core (e.g. air or heavy gases such as perfluorocarbon, or nitrogen) held within the shell and adapted to compress, oscillate, and reflect a characteristic echo when entering an ultrasound field, thereby generating a sonogram in contrast-enhanced ultrasound.

[0035] Possible shape and attachment examples of the markers 9, 10, 11 include multiple rings, bands, spheres, disks, wires forming lines, spirals, coils, etc. attached externally (from outside the sleeve 2 or from inside the sleeve 2) to the sleeve wall 3 or, alternatively, encapsulated within the thickness of the sleeve wall 3 or between at least two layers of a multi-layer sleeve wall.

[0036] In accordance with an embodiment (Figure 2), the marking comprises a longitudinally (with respect to the longitudinal extension of the sleeve 2) repeating pattern of identical subgroups 13 of at least two, preferably from two to six individual markers 9, 10 which are all different from each other and which are arranged in the longitudinal sleeve direction in a predetermined sub-sequence, e.g. of the type ...-[M1-M2-M3]-[M1-M2-M3]-[M1-M2-M3]-... .

[0037] This configuration of the marking allows to easily identify possible local folds or

twists in the sleeve 2, as the subgroups 13 of individual markers 9, 10 provide a characteristic image (e.g. ultrasound image or fluoroscopy image) and a change or mismatch within such a characteristic image due to a twist or fold in the sleeve wall 3 can be easily and intuitively recognized by the human eye or identified by computer aided image analysis algorithms.

[0038] In accordance with a further embodiment, the marking comprises a sequence 14 of markers 9, 10, 11 which represent or codify a consecutive sequence of numbers or values and which are arranged along a prevalent portion of the length of the sleeve 2, e.g. of the type $[MrM_2\text{-}M_3\text{-}\ldots\text{-}M_{(n}\text{-}i)\text{-}M_n]$.

[0039] This configuration of the marking allows to more easily determine and confirm the deployed longitudinal extension of the sleeve 2 within a GI-tract, as well as to verify whether the entire sleeve 2 has been actually visualized and, if parts of the sleeve 2 are missing in the visualization (e.g. on the ultrasound image), to determine the length and position of the invisible sleeve parts.

[0040] In accordance with an embodiment, the markers 9, 10, 11 comprise optically visible markers, e.g. multi-chromatic markers or markers which are chromatically distinguished from the internal sleeve surface color. The optically visible markers 9, 10, 11 are provided at an internal surface 15 of the sleeve wall 3 and adapted to be visualized by means of an endoscope (not shown in the figures) from inside the sleeve 2. This allows endoscopic verification of sleeve deployment progress during placement of the sleeve or during endoscopic inspection of the internal sleeve lumen 4 after deployment.

[0041] The optically visible markers 9, 10, 11 at the internal sleeve surface 15 may be configured and arranged sequentially as previously described. Alternatively or additionally, an optically visible (preferably rectilinear) continuous marking line 16 or stripe may be provided at the internal sleeve surface 15 and extend along substantially the entire length of the sleeve 2. The continuous marking line 15 or stripe may be multi-chromatic or chromatically distinguished from the adjacent internal sleeve surface color.

[0042] During endoscopic inspection of the sleeve lumen 4, the chromatically distinguished continuous marking line 16 provides a better visual orientation reference than the otherwise monochromatic sleeve lumen, so that discontinuities and mismatches of the marking line 16 or stripe evidences folds, twists and bulged up portions of the sleeve 2.

[0043] The optically visible markers 9, 10, 11 and/or the optically visible continuous marking line 16 or stripe may be provided in combination with or in addition to the above

described indirect imaging markers, e.g. ultrasound reflecting or radio-opaque markers.

[0044] In accordance with a further embodiment, the sleeve device 1 may comprise an identification tag 17, preferably a passive radio frequency identification tag (passive RFID-tag), permanently connected to the sleeve 2 and configured to be read at a distance, i.e. extracorporeal^, by a handheld or stationary identification reader, preferably a radio frequency ID reader (RFID reader).

[0045] The identification tag 17 may contain RF readable data related to the marking configuration and marking sequence and, possibly, to the type of visualization technology. Additionally or alternatively, the identification tag may contain RF readable target position data related to the planned position and longitudinal extension of the deployed sleeve 2 within the hollow organ, particularly a GI tract 12, thereby providing immediately available reference data for a verification of the sleeve position by comparison of the RF read target position data with the visualized actual sleeve position and shape.

[0046] In accordance with further embodiments, the identification tag 17 may contain RF readable data concerning the sleeve type (e.g. sleeve material batch code) and/or sleeve manufacturing information and/or the patient information and/or implantation date information and/or implantation procedure information.

[0047] The RFID-Tag may be positioned in predetermined locations (e.g. distal sleeve end 7) along the sleeve length and extracorporeal ly read from different positions, thereby determining the position of the said predetermined locations and, hence, the position and extension of the sleeve 2 within the patient. Additionally to the increased amount of stored information compared to e.g. fluoroscopy, a deployment verification and confirmation based on RFID technology reduces also the exposure of the patient to radiation.

[0048] In accordance with a further aspect of the present invention (Figures 4 and 5), there is provided a duodenal sleeve device 101 , comprising a sleeve 102 configured for deployment inside a duodenum of a human subject, the sleeve 102 having a wall 103 of a flexible material defining a sleeve lumen 104, a proximal end 105 defining a proximal lumen opening 106, and a distal end 107 defining a distal lumen opening 108.

[0049] The sleeve device 101 includes further a marking string 18 constrained by the sleeve wall 103 in a manner that the sleeve wall 103 extends and can slide longitudinally along the marking string 18. A stationary string end 19 of the marking string 18 is fixedly attached (i.e. attached in a non-dislocatable manner) to the sleeve wall 103 near the distal sleeve end 107 and a proximal string portion 20 runs through a string outlet passage 2 1 provided at the sleeve wall 103 near the proximal sleeve end 105 and extends beyond

said proximal sleeve end 105. During deployment of the sleeve 102 from a longitudinally compacted shape (Figure 4) to a longitudinally expanded shape (Figure 5), the sleeve wall 103 can slide and longitudinally unfold along the marking string 18 and a length of the proximal string portion 20 corresponding to the actual longitudinal sleeve 102 extension is thereby pulled distally into the string outlet passage 21. The marking string 18, particularly the its proximal string portion 20, comprises a plurality of different marking sections 109, 110 which are sequentially arranged in a longitudinal direction of the marking string 18 such that the (visible) marking sections 109, 110 which extend proximally outside the string outlet passage 21 indicate the actual longitudinal extension (and, hence, deployment state) of the sleeve 102.

[0050] Full or sufficient longitudinal deployment of the sleeve 102 can therefore be directly confirmed by checking the color or any other characteristic indication feature of the marking sections 109, 110 of the marking string 18 extending proximally out of the string outlet passage 21 of the sleeve 102.

[0051] In accordance with an embodiment (Figures 4 and 5), the marking string 18 may be made of a flexible substantially non-extensible thread or wire material, e.g. suture strand, whose non dislocatable stationary string end 19 may be attached by bonding, such as e.g. over-molding or adhesive bonding, or by knotting, to the distal sleeve end 107. The proximally extending marking string 18 may run inside the sleeve lumen 104 or, alternatively, inside a longitudinal channel 22 formed by and within the thickness of the sleeve wall 103, wherein the channel 22 may comprise a plurality of discrete channel sections arranged at a certain distance from one another, or one single continuous channel section which, however, must have a size that allows the sleeve wall 103 to slide and fold or corrugate during longitudinal compacting of the sleeve 102 along the substantially straightened marking string 18. If the marking string 18 would be forced to fold or corrugate together with the sleeve wall 103, the marking string 18 could not be automatically pulled distally into the sleeve wall 103 during longitudinal deployment.

[0052] Figure 4 shows the sleeve 102 in a non-deployed, longitudinally compacted and shortened configuration, in which a considerable length of the marking string 18 with the sequence of different marking sections 109, 110 extends proximally outside the string outlet passage 21. The marking sections 109, 110 may be distinguished from one another by different color, string thickness and/or by attachment of auxiliary marking features, such as marking tags or flags 23 (broken line in figures 4 and 5).

[0053] Figure 5 illustrates the sleeve device 101 after longitudinal deployment of the

sleeve 102. The increased distance between the stationary end 19 of the marking string 18 at the distal sleeve end 107 and the string outlet passage 21 near the proximal sleeve end 105 results in a corresponding length of the marking string 18 being pulled distally through the string outlet passage 21 into the channel 22 of the sleeve wall 103. Full or incomplete longitudinal deployment of the sleeve 102 can be now verified by visually checking the color or marking feature of the marking section 109, 110 emerging from the string outlet passage 21.

[0054] In accordance with a yet further aspect of the invention (Figures 6, 7), there is provided a duodenal sleeve device 201 comprising a sleeve 202 configured for deployment inside a duodenum of a human subject, the sleeve 202 having a wall 203 of a flexible material defining a sleeve lumen 204, a proximal end 205 defining a proximal lumen opening 206, and a distal end 207 defining a distal lumen opening 208. A continuous channel 24 (which is separate from the sleeve lumen 204) is formed by or connected to the sleeve wall 203 and extends longitudinally along the sleeve 202 from a proximal channel opening 25 near the proximal sleeve end 205 to a closed distal channel end 26 near the distal sleeve end 207.

[0055] The sleeve device 201 comprises further an elastically flexible, non compressible push rod 27 adapted to be inserted through the proximal channel opening 25 into the channel 24 up to the closed distal channel end 26. The push rod 27 has a plurality of different visible marking sections 209, 210 which are sequentially arranged in a longitudinal direction of the push rod 27 such that the visible marking sections 209, 210 which extend outside the proximal channel opening 25 indicate the actual longitudinal extension of the sleeve 202.

[0056] Full or sufficient longitudinal deployment of the sleeve 202 can therefore be directly confirmed by checking the color or any other characteristic indication feature of the marking sections 209, 210 of the push rod 27 which extend proximally out of the channel opening 25 of the sleeve 202.

[0057] In accordance with an embodiment (Figures 6 and 7), the channel 24 and the push rod 27 may be configured in a manner that by pushing the push rod 27 distally into the channel 24, the push rod 27 distally pushes the sleeve wall 203 from a longitudinally compacted (e.g. folded or corrugated) shape (shown in figure 6) to a longitudinally extended deployed shape (shown in figure 7), whilst the marking sections 209, 210 of the push rod 27 provide immediate confirmation of the state of deployment.

[0058] The marking sections 209, 210 of the push rod 27 may be distinguished from one

another by different color, rod thickness or shape and/or by attachment of auxiliary marking features, such as marking tags or flags 23 (broken line in figure 7).

[0059] Figures 8 and 9 illustrates method steps and devices for verifying the deployment state of a duodenal sleeve device 301 which is deployable by means of inflation. The sleeve device 301 comprises a sleeve 302 configured for deployment inside a duodenum of a human subject, the sleeve 302 having a wall 303 of a flexible material defining a sleeve lumen 304, a proximal end 305 defining a proximal lumen opening 306, and a distal end 307 defining a distal lumen opening 308. The sleeve wall 303 forms a continuous inflation channel 28 which extends longitudinally along the sleeve 302 from a proximal channel opening 29 near the proximal sleeve end 305 to a distal channel opening 30 near the distal sleeve end 307, the inflation channel 28 being adapted to be pressurized by a pressure fluid (e.g. saline solution, air or $C0_2$), thereby unfolding the sleeve 302 in a longitudinal sleeve direction.

[0060] The contemplated method for verifying the state of deployment and confirming complete deployment of the sleeve 302 comprises folding or rolling up the sleeve 302 starting from the distal sleeve end 307 such that an internal lumen of the inflation channel 28 is progressively closed from the distal channel opening 30 towards the proximal channel opening 29, subsequently inserting the folded or rolled up sleeve 302, e.g. endoluminally, to a target section of a GI tract of a patient and, then, deploying the sleeve 302 from the folded or rolled up shape (continuous lines in figures 8, 9) to a longitudinally extended shape (broken line in figures 8, 9) by applying a fluid pressure to the proximal channel opening 29, thereby filling and pressurizing the inflation channel progressively from the proximal channel opening 29 towards the distal channel opening 30 and unrolling or unfolding the sleeve 302 starting from the proximal sleeve end 305.

[0061] During inflation of the inflation channel 28, the fluid pressure applied to the proximal channel opening 29 is monitored and complete deployment of the sleeve 302 is confirmed when a sudden drop in the monitored fluid pressure (indicating the aperture of the distal channel opening 30 and escape of the pressure fluid) is observed or registered.

[0062] In accordance with an embodiment (Figure 9) the inflation channel 28 for the deployment of the sleeve 302 is formed directly by the sleeve lumen 304 and, after or prior to positioning the sleeve in the GI tract of a patient, the proximal sleeve opening 306 which forms the proximal inflation channel opening 29 is sealed to an endoscopic inflation device 31 which in turn is connected, via a pressure fluid line 32, to a remote, extracorporeal inflation pump 33.

[0063] By applying the fluid pressure to the proximal sleeve opening 306, the sleeve wall 303 tends to expand radially outward thereby unrolling the sleeve 302 progressively towards the distal sleeve end 307. In dependency of the inherent elastic retaining force of the initially coiled sleeve 302 and the more or less winding deployment path inside the GI tract 12, the pressure of the pumped fluid (e.g. saline solution, air or CO_2) generated by the inflation pump 33 will vary within certain limits and will generally tend to gradually increase during inflation due to the energy losses along the partially unfolded sleeve 302. However, when the sleeve 302 is eventually completely unrolled or unfolded, the distal sleeve end 307 will open and the escape of the pressurized fluid through the distal channel opening 30 will cause a sudden drop of pressure which can be observed by monitoring the inflation pressure directly by the pump 33 or by means of a dedicated pressure sensor. The comparison of the observed or registered total value and/or gradient of pressure drop with known reference values allows a correct interpretation of the pressure drop as a "full deployment achieved" state. Consequently, in response to such a confirmation of the deployment of the sleeve 302, the inflation pump 33 can be switched off and the deployment step can be terminated.

[0064] Figure 8 illustrates an alternative embodiment, in which the inflation channel 28 for the deployment of the sleeve may be isolated from the sleeve lumen 304 of the sleeve 302 and connected to the sleeve wall 303 or formed within the thickness of the sleeve wall 303.

[0065] The inflation pump 33 can be connected via a pressure fluid line 32 to the proximal channel opening 29 and the inflation channel 28 can be filled and pressurized with the pressure fluid such that the sleeve 302 unrolls or unfolds progressively towards the distal sleeve end 307. In dependency of the inherent elastic retaining force of the initially coiled or folded sleeve 302 and the more or less winding deployment path inside the GI tract 12, the pressure of the pumped fluid (e.g. saline solution, air or CO_2) generated by the inflation pump 33 will vary within certain limits and will generally tend to gradually increase during inflation due to the energy losses along the partially unfolded inflation channel 28. However, when the sleeve 302 is eventually completely unrolled, the distal channel opening 30 will open and the escape of the pressurized fluid through the distal channel opening 30 will cause a sudden drop of pressure which can be observed by monitoring the inflation pressure directly by means of the inflation pump 33 or by means of a dedicated pressure sensor (not illustrated). The comparison of the observed or registered total value and/or gradient of pressure drop with known reference values allows

a correct interpretation of the pressure drop as a "full deployment achieved" state. Consequently, in response to such a confirmation of the deployment of the sleeve 302, the inflation pump 33 can be switched off and the deployment step can be terminated.

[0066] Even though at least some of the described device and method features have been individually illustrated in the figures, a combination of the described features can be implemented in a single sleeve device and a combination of the described method features can be performed during deployment of an endosleeve within a GI tract of a patient and during verification of the state of deployment of the sleeve during and after placement.

[0067] The sleeve itself is sufficiently flexible to follow the curvature of the duodenum. Further, in some embodiments the walls of the sleeve are sufficiently flexible and/or collapsible to allow duodenal peristalsis to drive chyme through the lumen of the sleeve. Sufficient collapsibility of the walls of the sleeve prevents continuous intimate contact of the outer surface of the sleeve with the duodenal mucosa, avoiding damage to the duodenal mucosa and allowing digestive secretions not collected into the sleeve lumen to pass through the duodenal lumen outside the sleeve lumen.

[0068] In some embodiments, at least a portion of the wall of a sleeve may be porous or semipermeable to allow entry of digestive secretions into the sleeve lumen and/or to allow the flow of fluids and digested matter out of the sleeve lumen.

[0069] In some embodiments, at least a portion of the wall of a sleeve may be impermeable, analogous to the Endobarrier(R) by GI Dynamics Inc, Watertown, Mass., USA and as described in U.S. Pat. No. 7,267,694 which is included by reference as if fully set forth herein.

[0070] The diameter of the sleeve lumen may be substantially constant along the entire length of the liner tube. Although any suitable luminal diameter may be used, in some embodiments, the luminal diameter may be not more than about 30 mm, not more than about 25 mm and even not more than about 20 mm.

[0071] In some embodiments, the proximal end of the sleeve may be flared and may define a funnel-like structure.

[0072] The length of the sleeve may be any suitable length and may be selected in accordance with clinical decisions made by the treating physician. A typical sleeve is between about 25 cm and about 160 cm long. Generally, the sleeve is selected so that when the duodenal sleeve device is deployed, the distal lumen opening of the sleeve is located distal to the duodenal-jejunal flexure and empties out into the jejunum. In some

embodiments, the sleeve may be even longer.

[0073] Suitable materials from which the sleeve for implementing the invention are fashioned include silicone, polyurethane, polyethylene (e.g., low density polyethylene films) and fluoropolymers (e.g., expanded polytetrafluoroethylene). In some embodiments, the sleeve is fashioned from fluoropolymer or polyethylene film impregnated with polyurethane or silicone to reduce permeability, as taught in U.S. Pat. No. 7,267,694.

[0074] The sleeve may include components that inhibit twisting or kinking of the sleeve itself. In one embodiment, these components include one or more stiffening elements, such as rings, coupled to either the inside or the outside of the sleeve at spaced locations along its length. These rings can, for example, be made of a slightly thicker silicone material that would resist twisting or kinking of the sleeve around the ring. In other embodiments, the stiffening elements may be in spiral shape or extending lengthwise along at least a portion of the sleeve.

[0075] In an implantation method, the sleeve may be initially folded or rolled up and packed into the interior of an applier. The distal end of sleeve may be initially closed, e.g. with a small polymeric or silicone seal and forms a programmed tearing line, e.g. a perforation, along which the distal end can tear open by the internal pressure of the chyme flow.

[0076] In this way bypass conduits can be created in the GI tract of a patient to achieve a malabsorptive effect in cases where such an effect may enhance weight loss, as well as the initially described effects on hormonal signaling in general.

[0077] Particularly, the described devices and procedures allow confirmation of the state of deployment of the sleeve and determination or visualization of the actual sleeve shape and position within the GI tract.

[0078] 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. Endoluminal sleeve device (1) for internally lining a section of the GI tract, comprising:

- a sleeve (2) configured for deployment inside a duodenum, the sleeve (2) having a wall (3) of a flexible material defining a sleeve lumen (4), a proximal end (5) defining a proximal lumen opening (6), and a distal end (7) defining a distal lumen opening (8),

- a marking attached to the wall (3), said marking comprising a plurality of different markers (9, 10, 11) which are sequentially arranged in a longitudinal direction of the sleeve (2).

2. Endoluminal sleeve device (1) according to claim 1, wherein said markers (9, 10, 11) are selected in the group consisting of:

- radio-opaque material,

- echogenic material,

- an encapsulated fluid which contains microbubbles formed by an elastically deformable shell and a gas core held within the shell and adapted to compress, oscillate, and reflect a characteristic echo when entering an ultrasound field,

- optically visible markers.

3. Endoluminal sleeve device (1) according to claim 1, wherein said marking comprises a longitudinally repeating pattern of identical subgroups (13) of at least two individual markers (9, 10) which are all different from each other and which are arranged in the longitudinal sleeve direction in a predetermined sub-sequence.

4. Endoluminal sleeve device (1) according to claim 1, wherein said marking comprises a sequence (14) of markers (9, 10, 11) which codify a consecutive sequence of values and which are arranged along a prevalent portion of the length of the sleeve (2).

5. Endoluminal sleeve device (1) according to any one of the preceding claims, wherein said markers (9, 10, 11) comprise optically visible markers provided on an internal surface (15) of the sleeve wall (3), said optically visible markers being chromatically distinguished from the color of the internal surface (15) and adapted to be visualized by means of an endoscope from inside the sleeve lumen (4).

6. Endoluminal sleeve device (1) according to any one of the preceding claims, wherein said marking comprises an optically visible continuous marking line (16) on an internal surface (15) of the sleeve (2) and extended along substantially the entire length of the sleeve (2), said continuous marking line (15) being chromatically distinguished from an adjacent internal surface (15) color of the sleeve (2).

7. Endoluminal sleeve device (1) according to any one of the preceding claims,

comprising a passive radio frequency identification tag (17) permanently connected to the sleeve (2) and configured to be read at a distance by a radio frequency ID reader, said identification tag (17) containing radio frequency readable data related to said marking.

8. Endoluminal sleeve device (1) according to claim 7, wherein said identification tag (17) contains RF readable data related to the type of visualization technology adapted to visualize said markers (9, 10, 11).

9. Endoluminal sleeve device (1) according to claim 7 or 8, wherein said identification tag (17) contains RF readable data related to a planned position and longitudinal extension of the deployed sleeve (2) within a GI tract (12).

10. Endoluminal sleeve device (1) according to any one of claims 7 to 9, wherein said identification tag (17) contains RF readable data related to:

- sleeve manufacturing information,
- patient information,
- sleeve (2) implantation procedure information.

11. Endoluminal sleeve device (101) according to claim 1, comprising a marking string (18) constrained by the sleeve wall (103) in a manner that the sleeve wall (103) extends and can slide longitudinally along the marking string (18),

wherein a stationary string end (19) of the marking string (18) is fixedly attached to the wall (103) near the distal sleeve end (107) and a proximal string portion (20) runs through a string outlet passage (21) provided at the sleeve wall (103) near the proximal sleeve end (105) and extends beyond said proximal sleeve end (105),

wherein, during deployment of the sleeve (102) from a longitudinally compacted shape to a longitudinally expanded shape, the sleeve wall (103) can slide and longitudinally unfold along the marking string (18) and a length of the proximal string portion (20) corresponding to the actual longitudinal extension of the sleeve (102) is thereby pulled distally into the string outlet passage (21),

wherein the marking string (18) comprises a plurality of visibly different marking sections (109, 110) sequentially arranged in a longitudinal direction of the marking string (18) such that a part of said marking sections (109, 110) extending proximally outside the string outlet passage (21) indicates the actual longitudinal extension of the sleeve (102).

12. Endoluminal sleeve device (101) according to claim 11, in which the marking string (18) runs inside the sleeve lumen (104).

13. Endoluminal sleeve device (101) according to claim 11, in which the marking string (18) runs inside a longitudinal channel (22) system formed by the sleeve wall (103)

separate from the sleeve lumen (104) and configured to allow the sleeve wall (103) to slide and corrugate during longitudinal compacting of the sleeve (102) along the substantially straightened marking string (18).

14. Endoluminal sleeve device (101) according to claim 13, in which said channel system (22) comprises a plurality of discrete channel sections arranged at a certain distance from one another.

15. Endoluminal sleeve device (101) according to any one of claims 11 to 14, wherein said marking sections (109, 110) are distinguished from one another by visible features selected in the group consisting of:

- different colors,
- different string thickness,
- attachment of marking flags (23).

16. Endoluminal sleeve device (201) according to claim 1, comprising:

- a channel (24) formed by the sleeve wall (203) and separate from the sleeve lumen (204), said channel (24) being extended longitudinally along the sleeve (202) from a proximal channel opening (25) near the proximal sleeve end (205) to a closed distal channel end (26) near the distal sleeve end (207),
- a flexible, non compressible push rod (27) adapted to be inserted through the proximal channel opening (25) into the channel (24) up to the closed distal channel end (26), said push rod (27) having a plurality of different visible marking sections (209, 210) sequentially arranged in a longitudinal direction of the push rod (27) such that the visible marking sections (209, 210) which extend outside the proximal channel opening (25) indicate the actual longitudinal extension of the sleeve (202).

17. Endoluminal sleeve device (201) according to claim 16, in which the channel (24) and the push rod (27) may be configured in a manner that by pushing the push rod (27) distally into the channel (24), the push rod (27) distally pushes the sleeve wall (203) from a longitudinally compacted shape to a longitudinally extended deployed shape.

18. Endoluminal sleeve device (201) according to claim 16 or 17, in which the marking sections (209, 210) of the push rod (27) are distinguished from one another by visible features selected in the group consisting of:

- different colors,
- different rod thickness,
- attachment of marking flags (23).

19. Method for deploying an endoluminal sleeve device (301) in a GI tract of a patient,

the sleeve device (301) comprising:

- a sleeve (302) configured for deployment inside a duodenum of a human subject, the sleeve (302) having a wall (303) of a flexible material defining a sleeve lumen (304), a proximal end (305) defining a proximal lumen opening (306), and a distal end (307) defining a distal lumen opening (308),

the sleeve wall (303) forming an inflation channel (28) which extends longitudinally along the sleeve (302) from a proximal channel opening (29) near the proximal sleeve end (305) to a distal channel opening (30) near the distal sleeve end (307), said sleeve (302) being adapted to unfold from a longitudinally compacted shape to a longitudinally extended shape in response to a pressurization of the inflation channel (28),

the method comprising:

- compacting the sleeve (302) to said longitudinally compacted shape,

- inserting the compacted sleeve (302) endoluminally to a target section of the GI tract,

- deploying the sleeve (302) from the longitudinally compacted shape to the longitudinally extended shape by applying a fluid pressure to the proximal channel opening (29), thereby inflating the inflation channel (28),

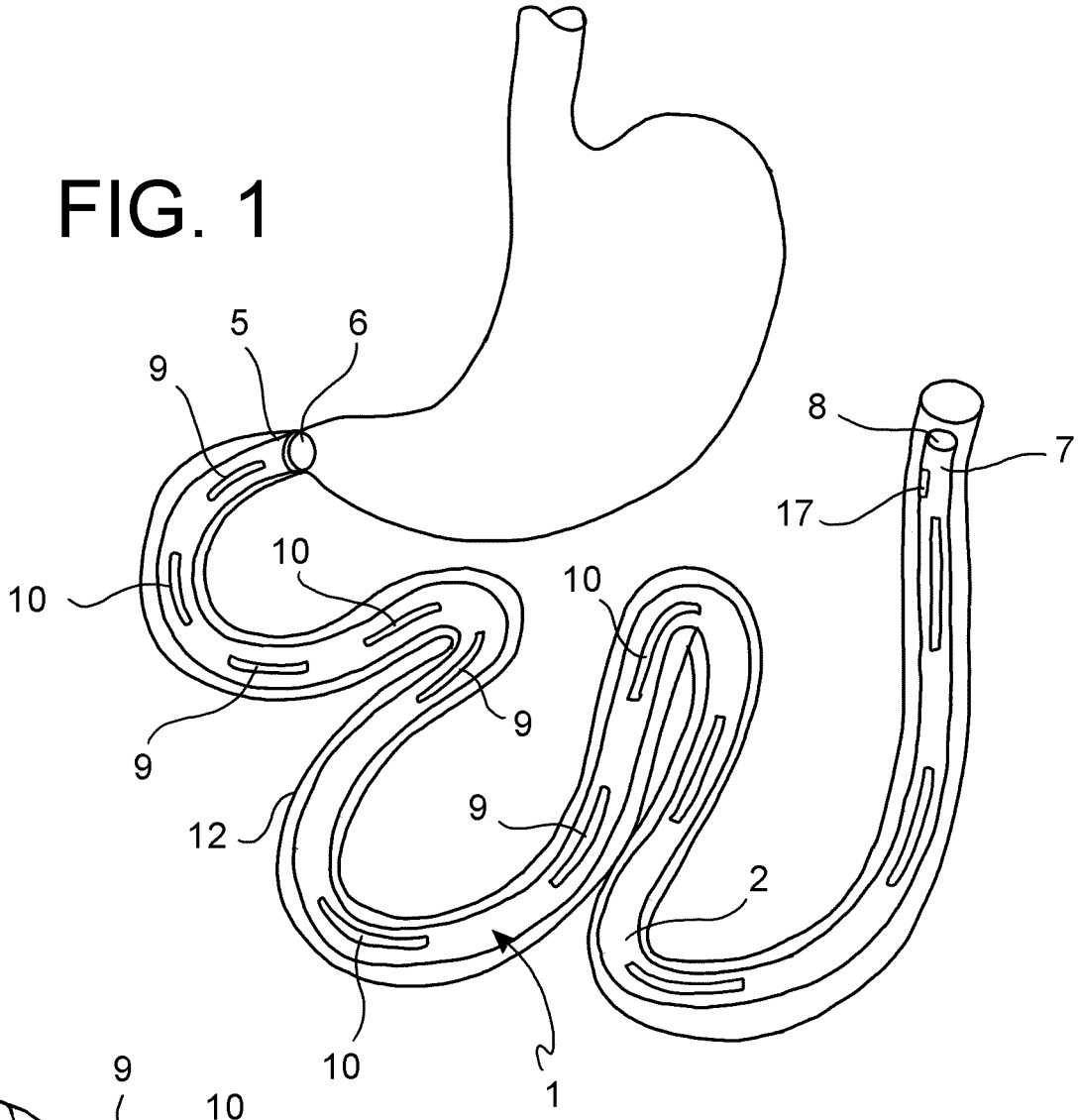
- during inflation of the inflation channel (28), monitoring the fluid pressure applied to the proximal channel opening (29) to detect a sudden drop in the fluid pressure, said sudden drop in the fluid pressure indicating a complete deployment of the sleeve (302) and an aperture of the distal channel opening (30).

20. Method according to claim 19, in which the step of compacting the sleeve (302) comprises rolling up the sleeve (302) starting from the distal sleeve end (307) such that an internal lumen of the inflation channel (28) is progressively closed from the distal channel opening (30) towards the proximal channel opening (29).

21. Method according to claim 19 or 20, comprising:

- sealing the proximal sleeve opening (306) to an endoscopic inflation device (31) and using the sleeve lumen (304) as said inflation channel (28).

FIG. 1



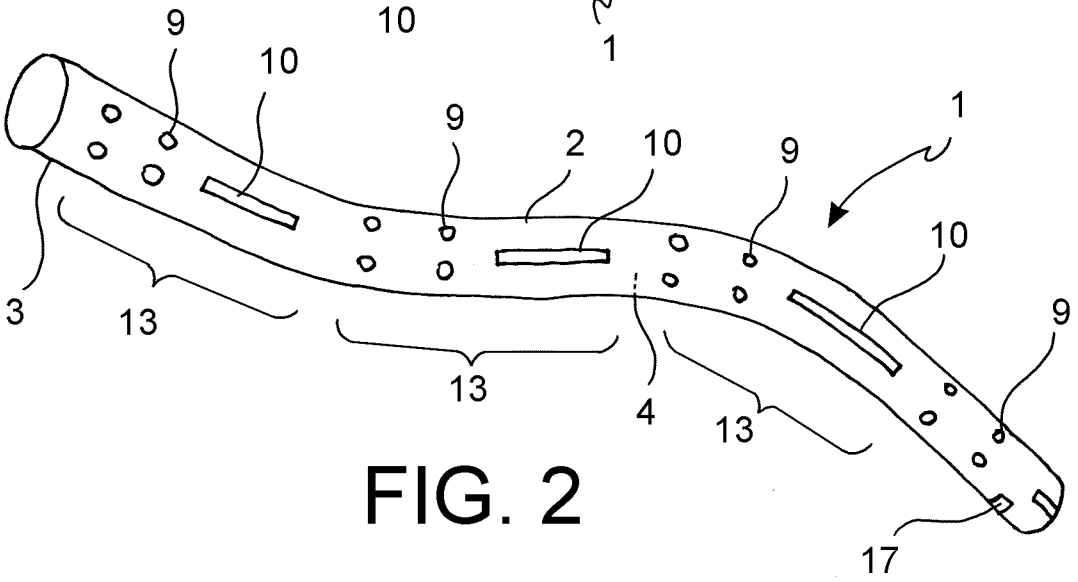


FIG. 2

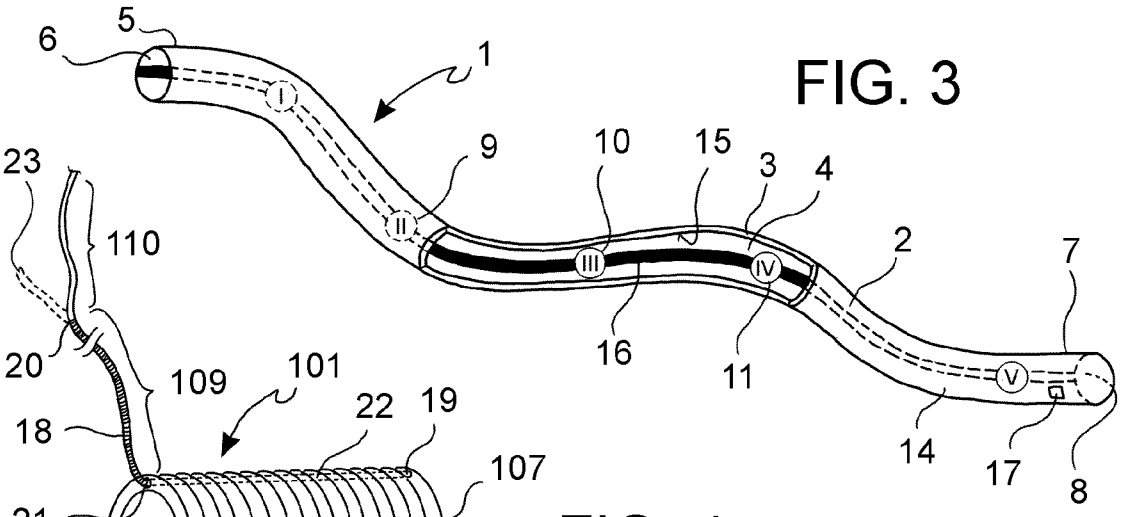


FIG. 3

FIG. 4

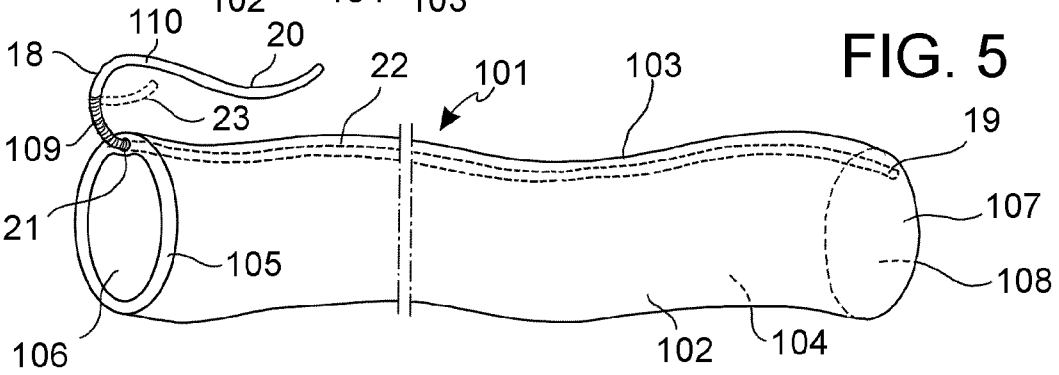


FIG. 5

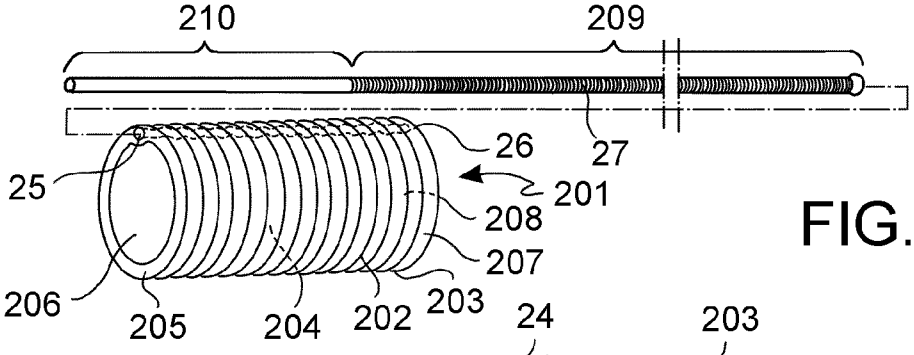


FIG. 6

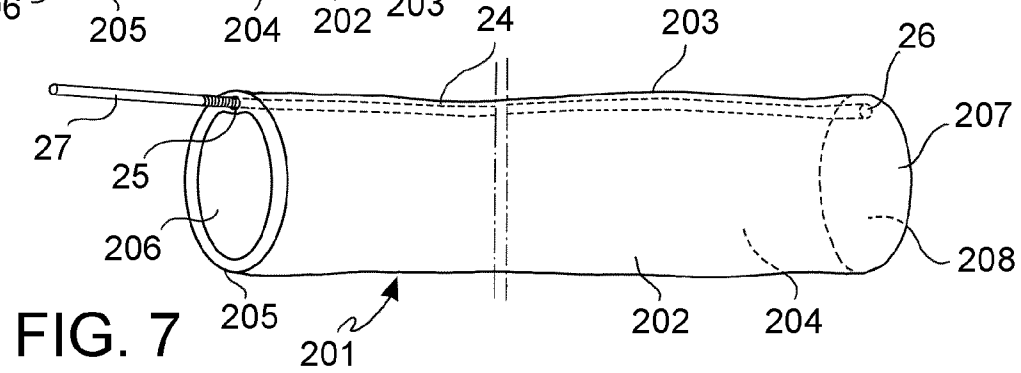


FIG. 7

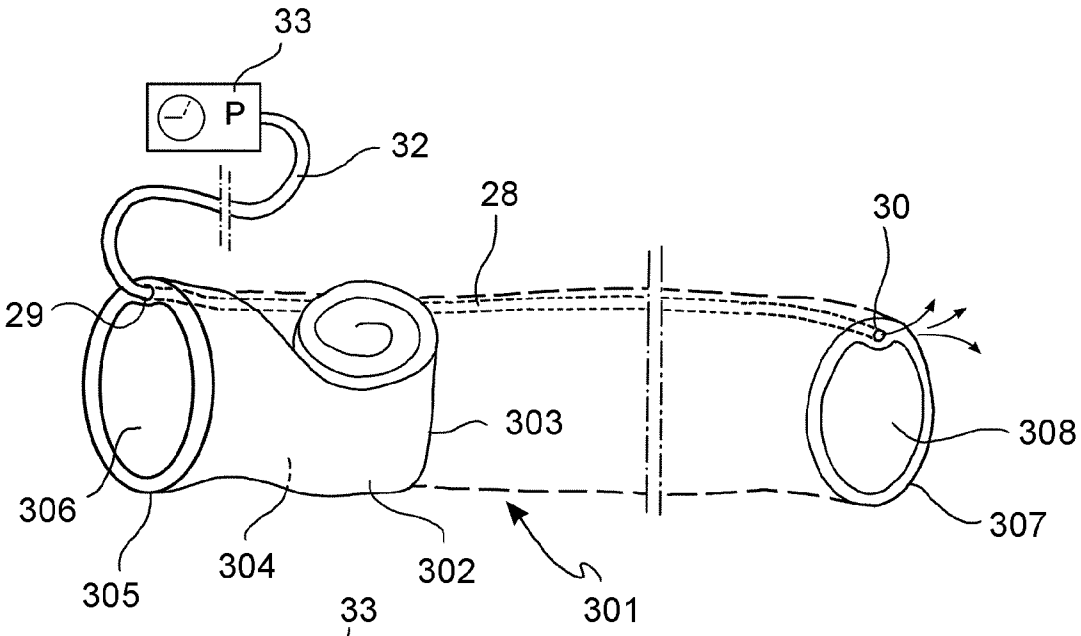

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FIG. 8

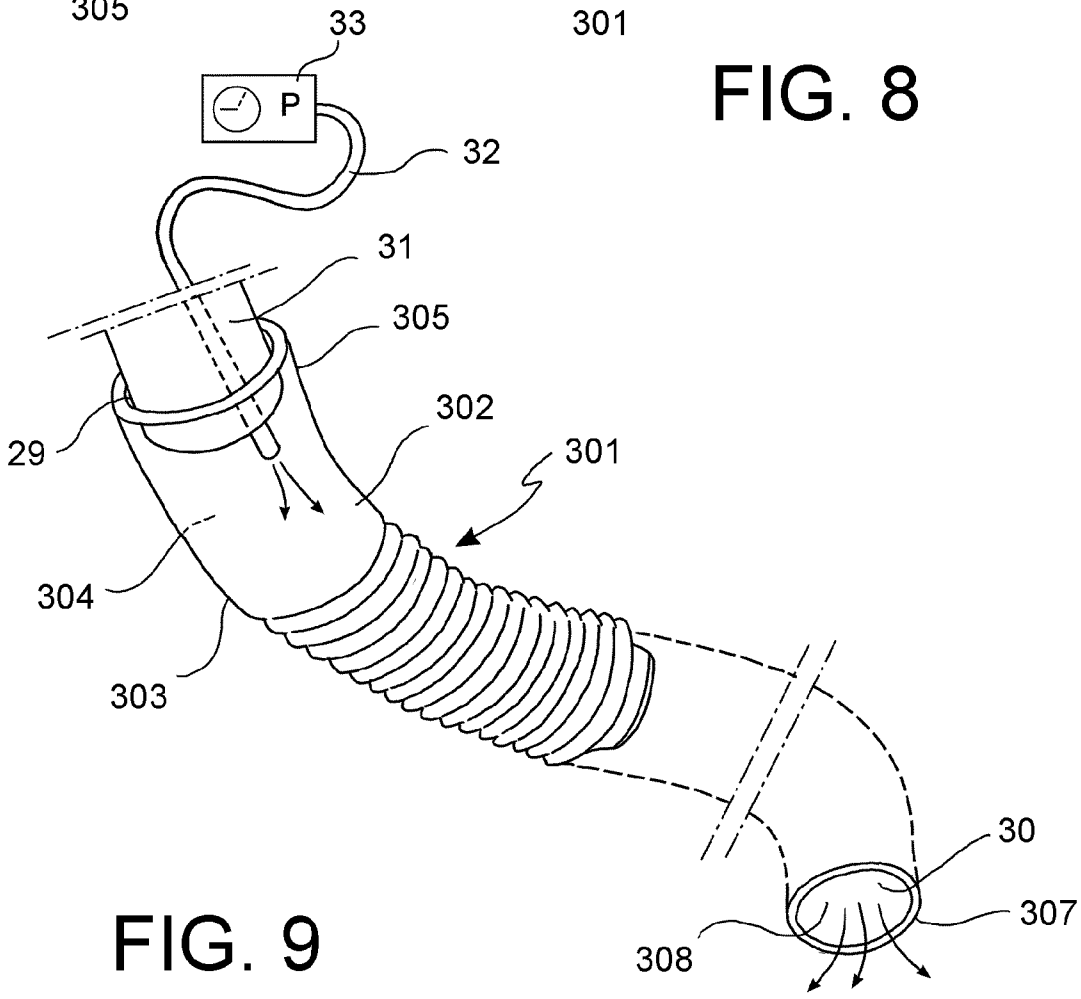
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FIG. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/072562

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/04
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where 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.
X	US 2009/187206 A1 (BINMOELLER KENNETH F [US] ET AL) 23 July 2009 (2009-07-23)	1,2
Y	paragraph [0100] figure 5	7

X	US 2010/256775 A1 (BELHE KEDAR R [US] ET AL) 7 October 2010 (2010-10-07) paragraph [0002] paragraph [0138] figure 46A	1,2

Y	WO 2006/044640 A1 (BFKW LLC [US] ; BAKER RANDAL S [US] ; KEMMETER PAUL R [US] ; F00TE JAMES) 27 April 2006 (2006-04-27) page 11, line 21 - line 30 figure 5	7

	-/- .	

[X] Further documents are listed in the continuation of Box C.

[X] 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" documentwhich may throw doubts on priority claim(s) orwhich 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
10 July 2012	18/07/2012

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	Storer, John

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/072562

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/107004 A1 (LEVINE ANDY H [US] ET AL) 3 June 2004 (2004-06-03) abstract paragraph [0064] -----	1

1

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/072562

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.: 19-21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by 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/EP2011/072562

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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