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(54) PERCUTANEOUS CATHETER SYSTEM COMPRISING A RETENTION DEVICE

PERKUTANES KATHETERSYSTEM MIT RÜCKHALTEVORRICHTUNG

SYSTÈME DE CATHÉTER PERCUTANÉ COMPRENANT UN DISPOSITIF DE RETENUE

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Description

[0001] The invention relates to a percutaneous catheter system for percutaneously accessing body cavities of a patient according to the preamble of claim 1 and to a method for manufacturing a percutaneous catheter system.

[0002] A percutaneous catheter system of this kind comprises a tube having a first, proximal end and a second, distal end, a port arranged at the first, proximal end of the tube for feeding a medical solution into the tube, and a retention device arranged for example at the second, distal end of the tube. The retention device comprises an inflatable chamber which is configured to, in a first, deflated state, allow a passing of the tube percutaneously towards a body cavity to be accessed by the percutaneous catheter system and, in a second, inflated state, retain the tube in a body cavity accessed by the percutaneous catheter system.

[0003] A percutaneous catheter system of this kind provides an access e.g. for the long-term enteral feeding of a patient. For placement of the percutaneous catheter system on a patient, the tube of the percutaneous catheter system is inserted through a small incision in the abdomen of the patient into the stomach or the intestinal tract (e.g., the jejunum) of the patient such that the port of the percutaneous catheter system is placed outside of the patient and the tube extends into the stomach or the intestinal tract of the patient. An external tubing can be attached to the port of the head to feed a medical solution, such as for example a nutritional feeding solution, a medication or biotics, into the stomach or small intestine of the patient via the percutaneous catheter system.

[0004] When placing a percutaneous catheter system of this kind in a patient it is to be ensured that the percutaneous catheter system, with the distal end of the tube, remains in the accessed body cavity such that the medical solution securely is delivered into the body cavity of interest and the catheter may not slip out of the accessed body cavity. For this the retention device is arranged on the second, distal end of the tube, the retention device having an inflatable chamber which may be inflated to, in the second, inflated state, have a volume preventing a withdrawing of the second, distal end of the tube from the accessed body cavity. For guiding the percutaneous catheter system through for example the patient's stomach wall towards the body cavity to be accessed, the retention device with its inflatable chamber is brought into the first, deflated state having a reduced volume (with respect to the second, inflated state) such that the tube with its second, distal end may easily pass through a small-sized incision in the stomach wall. Conventional catheter systems use, as retention devices, inflatable balloons made of a silicon rubber having medium/high elasticity. Such balloons for example are inflated using an isotonic solution, causing potentially a substantial filling volume and weight within the accessed body cavity in the inflated state.

[0005] US 4,943,275 discloses a balloon assembly having an intrinsic curvature adapted to a passage in a blood vessel.

[0006] US 5,308,326 discloses a balloon tamponade device for treating bleeding sites within the upper digestive tract of a patient comprising a tube having proximal and distal open ends and at least one inflatable balloon mounted over the tube.

[0007] US 6,213,975 discloses an intra-aortic balloon catheter having an ultrathin stretch blow molded balloon membrane.

[0008] EP0920882 discloses a balloon catheter with a guide wire.

[0009] It is an object of the instant invention to provide a percutaneous catheter system and a method for manufacturing a percutaneous catheter system which allow providing a retention device having improved characteristics with respect to the retaining of the tube within an accessed body cavity.

[0010] This object is achieved by means of a percutaneous catheter system comprising the features of claim 1.

[0011] Accordingly, the inflatable chamber is defined by a membrane envelope made of a material having a Shore-hardness A equal to or greater than 60.

[0012] The Shore-hardness is a characteristic value for material properties of elastomers and plastics. It is specified in the DIN 53505 and DIN EN ISO 868 standards. The Shore-hardness-tester (or "Durometer") consists of a spring-loaded indenter, which elastic indentation is inversely related to the Shore-hardness of the material. The scale is from 0 to 100. A high figure means a high hardness.

[0013] Generally, different Shore-hardness scales exist. Shore A hardness applies to soft elastomers, whereas Shore D applies to materials having increased hardness. If not specified otherwise, it in the following is referred to Shore A.

[0014] The retention device with its inflatable chamber may in particular be arranged in the proximity of the distal end of the tube by which a desired body cavity is accessed. Once the body cavity is accessed the inflatable chamber may be inflated to assume the second, inflated state such that the transnasal tube device is retained within the accessed body cavity and/or, for example, blocking of a channel such as a stoma channel is achieved to prevent a leakage of liquid.

[0015] By forming the inflatable chamber by means of a membrane envelope made of a material having a substantial hardness, the inflatable chamber preferably is substantially not expandable beyond the second, inflated state. In contrast to an expandable balloon made of for example silicon rubber, the inflatable chamber may be inflated to assume the second, inflated state having a defined volume, but may substantially be not expanded beyond this second, inflated state. The inflatable chamber, in the second, inflated state, hence assumes a pre-

defined shape within the accessed body cavity, which may be adapted to anatomic needs of the patient and the body cavity to be accessed.

[0016] The membrane envelope may for example be made from material comprising polyurethane having a Shore-hardness greater than 60, preferably greater than 64, even more preferably greater than 70. Polyurethane is a polymer composed of organic units joined by carbamate (urethane) links. For example thermoplastic polyurethane may be used. By using a polyurethane material the retention device may exhibit a high strength and increased durability and may have a beneficial dimensional stability.

[0017] Forming the membrane envelope defining the inflatable chamber from a polyurethane material may provide for a retention device having improved characteristics with respect to durability and longevity, polyurethane being substantially inelastic such that an expansion of the planar extension of the membrane envelope is substantially prevented.

[0018] The membrane envelope may for example be formed as a foil integrally with the tube, wherein the material of the tube may however differ from the material of the membrane envelope.

[0019] The membrane envelope is formed using a (thermal) molding technique such as a stretch blow molding technique. Within such a stretch blow molding technique, the material may be first molded into a preform using an injection molding process. Such a preform may then later be fed into a reheat stretch blow molding machine to blow the preform using high pressure air into a suitable blow mold.

[0020] In the second, inflated state the inflatable chamber hence assumes a defined shape formed and defined by the molding technique. The shape of the retention device in the second, inflated state of the membrane envelope hence is known and reproducible, allowing to define the membrane envelope according to anatomic needs and a specific application of the percutaneous catheter system.

[0021] In the second, inflated state the inflatable chamber may be fully or only partially filled. In a fully filled state the inflatable chamber can substantially not be compressed, wherein even in the fully filled state a rather low gas pressure may be applied for filling the inflatable chamber. In a partially filled state the inflatable chamber does not comprise its full volume defined by the shape of the membrane envelope, but encompasses only a partial volume.

[0022] Because the inflatable chamber may be filled with a rather low pressure, a long-term use of the transnasal tube device for example within a patient is possible, for example over multiple days or even weeks - in contrast to for example cardiac applications in which generally only a short-term use over a rather short period of time is required. The inflatable chamber may be dimensionally stable even over the extended period of time of use.

[0023] The inflatable chamber comprises different portions, i.e. a first spherical portion adjoined by a second, cylindrical portion. Such portions serve different purposes, the first portion for example functioning as a retention device, the second portion in contrast providing for a channel blocking. The anatomic adaption of the inflatable chamber may furthermore be achieved or supported in that the inflatable chamber may provide for a sufficient retention even if it is only partially filled.

[0024] In the second, inflated state the inflatable chamber is filled for example with air, wherein a rather low pressure may be sufficient for filling the inflatable chamber. In the first, deflated state the volume of the inflatable chamber is reduced with respect to the volume of the inflatable chamber in the second, inflated state, hence allowing to pass the tube of the percutaneous catheter system percutaneously e.g. through the stomach wall of a patient during placement of the percutaneous catheter system in the patient's body for accessing a body cavity of interest.

[0025] The tube of the percutaneous catheter system may in particular be a multi-lumen tube.

[0026] For example, in one embodiment, the tube may comprise a first lumen for administering a medical solution, such as a nutritional feeding solution, a medication or biotics, into a body cavity accessed by the percutaneous catheter system. For this, feeding equipment may for example be connected to the port of the tube at the first, proximal end of the tube, allowing to feed or apply a medical solution to be delivered to the patient into the tube. A second lumen, in contrast, may be in fluid connection with the inflatable chamber of the retention device, such that via the second lumen the inflatable chamber may be transferred from its first, deflated state to its second, inflated state and vice versa.

[0027] In particular, through the second lumen air may be guided to inflate the inflatable chamber to assume the second, inflated state. Because the inflatable chamber preferably comprises a predefined shape formed by a suitable molding technique of a material having an increased hardness, a filling of the inflatable chamber at rather low pressure using air may be sufficient.

[0028] In one embodiment, a suction device may be connected to the second lumen of the tube at the first, proximal end of the tube, the suction device for example being constituted as a syringe which may be used to suck a predefined amount of air from the inflatable chamber such that the retention device assumes the first, deflated state. For transferring the inflatable chamber, after passing the tube percutaneously towards the body cavity to be accessed, to the second, inflated state the amount of air previously sucked from the inflatable chamber using the suction device may be refilled into the inflatable chamber, having the advantage that the filling state of the inflatable chamber in the second, inflated state is exactly known. Such suction device, for example formed by a syringe, is cost-effective and may easily and intuitively be operated manually by a user.

[0029] The retention device, with its inflatable chamber, shall in particular provide for a retaining of the second, distal end of the tube within the body cavity accessed by the percutaneous catheter system. For this the inflatable chamber is brought into the second, inflated state such that due to the increased volume of the inflatable chamber the tube may not be withdrawn from the body cavity. In addition, the inflatable chamber is shaped in a defined way to provide for a blocking of a stoma channel formed in the patient's stomach wall for guiding the tube into the stomach or intestinal tract of then patient such that the stoma channel is tightly closed to prevent a fluid flow through the stoma channel and to also prevent infections at the site of the stoma channel.

[0030] Because the retention device can be changed between its first, deflated state and the second, inflated state from the outside by using a suitable suction device such as a syringe, an easy percutaneous placement from the outside as well as a non-endoscopic removal of the catheter system is possible. The catheter system may be suitable for a first time placement as well as for providing a replacement of a previously placed catheter system.

[0031] The inflatable chamber may be placed at or close to the distal end of the tube or may be placed at a different location on the tube, for example close to the proximal end of the tube or in between the distal end and the proximal end.

[0032] The object is also achieved by a method for manufacturing a percutaneous catheter system for percutaneously accessing a body cavity of a patient, according to claim 8. The advantages and advantageous embodiments described above for the percutaneous catheter system equally apply also to the method, such that it shall be referred to the above.

[0033] The idea underlying the invention shall subsequently be described in more detail with reference to the embodiments shown in the figures. Herein,

Fig. 1 shows a schematic drawing (not forming part of the invention) of a percutaneous catheter system for providing access to a body cavity of a patient;

Fig. 2 shows a schematic drawing of an embodiment (not forming part of the invention) of a percutaneous catheter system inserted into a patient;

Fig. 3 shows a schematic view of an embodiment (not forming part of the invention) of a retention device of a percutaneous catheter system;

Fig. 4 shows a schematic view of another embodiment (not forming part of the invention) of a retention device of a percutaneous catheter system;

Fig. 5 shows a schematic drawing of an embodiment (not forming part of the invention) of a percutaneous catheter system for accessing a patient's stomach, for an initial placement;

Fig. 6 shows a schematic drawing of an embodiment (not forming part of the invention) of a percutaneous catheter system to be inserted into the patient's stomach via an existing stoma channel;

Fig. 7 shows a schematic drawing of a percutaneous catheter system, according to the invention, to be inserted into the patient's stomach via an existing stoma channel, the percutaneous catheter system comprising a tube having an inflatable chamber comprising multiple portions;

Fig. 8 shows a schematic drawing (not forming part of the invention) of a percutaneous catheter system for accessing a patient's intestinal tract; and

Fig. 9 shows a schematic drawing (not forming part of the invention) of a percutaneous catheter system for accessing a patient's intestinal tract via a so-called PEG probe.

[0034] With reference to the illustrative drawing of Fig. 1, a percutaneous catheter system 1 comprises a tube 10 to be guided percutaneously through a patient's stomach wall 22 towards a body cavity such as the patient's stomach 20 or the patient intestinal tract 21, in particular the patient's jejunum.

[0035] Via the percutaneous catheter system 1 a medical solution such as a nutritional feeding solution for the enteral feeding of the patient 2, a medication or biotics may be fed directly into the body cavity 20, 21 accessed by the percutaneous catheter system 1, a suitable feeding device for this being connectable to a port 11 at a first, proximal end 100 of the tube 10 for feeding the medical solution into the tube 10 towards a second, distal end 101 of the tube 10 placed within the body cavity 20, 21 to be accessed.

[0036] For placing the percutaneous catheter system 1 within the patient 2, the tube 10 is guided through an incision in the patient's stomach wall 22 (during a first-time, initial placement of a catheter system 1) or through an existing stoma channel 220 formed in the stomach wall 22 (see Fig. 2) towards the body cavity 20, 21 to be accessed. Once the second, distal end 101 of the tube 10 has entered the body cavity 20, 21 to be accessed, the position of the second, distal end 101 of the tube 10 is to be secured within the body cavity 20, 21 to be accessed by means of a retention device 15, which may be altered in its shape between a first, deflated state (which allows a passing of the tube 10 through the incision in the stomach wall 22) and a second, inflated state in which the volume of the retention device 15 is increased with

respect to the first, deflated state such that a withdrawal of the tube 10 with its second, distal end 101 from the accessed body cavity 21, 22 is prevented.

[0037] A percutaneous catheter system 1 may be designed for a first-time placement on a patient 2. A percutaneous catheter system 1 may however also be designed as a replacement system, in particular for patients requiring e.g. a long-term enteral feeding.

[0038] Fig. 2 shows a schematic view of an embodiment of a percutaneous catheter system 1 inserted into a patient 2, the percutaneous catheter system 1 in this embodiment being designed as a so-called button for replacement of another catheter system for a long-term use. The percutaneous catheter system 1, as known per se, comprises a port 11, which is placed outside the patient 2, and a tube 10 extending from the port 11 through the stomach wall 22 towards the stomach 20 of the patient 2. The tube 10 adjoins, with a first, proximal end 100, the port 11 and with a second, distal end 101 is placed within the stomach 2 of the patient 2. At the second, distal end 101 the tube 10 carries a retention device 15 which prevents the percutaneous catheter system 1 from slipping out of the stoma channel 220 in the stomach wall 22 through which the tube 10 extends.

[0039] The tube 10 together with the port 11 of the percutaneous catheter system 1 defines a first lumen 13 having an end 130 associated with the port 11 to which an external tubing may be attached to feed a fluid, in particular a nutritional liquid, through the lumen 13 towards an end 131 of the lumen 13 and into the stomach 20 of the patient 2. The lumen 13 comprises, in one embodiment, a valve which allows for a feeding of a fluid into the stomach 2, but prevents liquids to pass from the stomach 2 towards the outside.

[0040] The port 11, in the embodiment of Fig. 2, comprises a head body 110 having a first end 111 and a second end 112. At the second end 112, in the embodiment of Fig. 2, a strap 12 is integrally connected to the head body 110 with a strap end 120. The strap 12 extends elastically from the head body 110 such that, by means of a pin arranged on the strap 12, the lumen 13 may be closed towards the outside so that dirt or other undesired matter may not enter into the lumen 13 from the outside when no external tubing is connected to the lumen 13 at its end 130.

[0041] Another, second lumen 14 opens with an end 140 at the first end 111 of the head body 100, the second lumen 14 extending through the tube 10 and providing a fluid connection to the retention device 15. For this, the lumen 14, with an opening 141, is in a fluid connection with the retention device 15 such that a fluid, for example air, may be fed into the retention device 15 for inflating the retention device 15 within the stomach 2 of the patient 2.

[0042] The retention device 15 defines, as shown in the embodiment of Fig. 3, an inflatable chamber 150 enclosed by a membrane envelope 151. The inflatable chamber 150 is in fluid connection with the second lumen 14 such that fluid may be removed from or fed into the inflatable chamber 150 via the second lumen14.

[0043] The membrane envelope 151 is made of a material having a Shore-hardness equal to or greater than 60, preferably greater than 64, even more preferably greater than 70. The material may for example be a polyurethane material, the membrane envelope 151 being formed for example by a stretch blow molding technique to assume a predefined shape in its second, inflated state.

[0044] As illustrated in Fig. 3, the inflatable chamber 150 defined by the membrane envelope 151 in its first, deflated state (dashed lines in Fig. 3) has a reduced volume with respect to the second, inflated state (solid lines in Fig. 3), the membrane envelope 151 in the first, deflated state being situated approximate the tube 10 at the second, distal end 101 such that the radial diameter of the tube 10 is substantially not increased by the retention device 15 on the second, distal end 101 of the tube 10, hence allowing to pass the tube 10 through a small-sized incision in the patient's stomach wall 22 or a stoma channel 220 formed in the stomach wall 22 (see Fig. 2) for accessing the desired body cavity 20, 21.

[0045] In the second, inflated state (solid lines in Fig. 3) the inflatable chamber 150 in contrast is inflated for example with air, the shape of the membrane envelope 151 being defined by the forming of the membrane envelope 151 during manufacturing, for example using a stretch blow molding technique. Due to the substantial hardness of the material of the membrane envelope 151 the inflatable chamber 150 may substantially not expand beyond the second, inflated state such that the retention device 15 in the second, inflated state assumes a known, defined shape within the body cavity 20, 21 accessed by the tube 10.

[0046] The membrane envelope 151 of the retention device 15 may, in the second, inflated state, assume for example a substantially spherical shape as in the embodiment of Fig. 3 or a substantially cylindrical shape as in the embodiment of Fig. 4, the shape of the membrane envelope 151 being defined by the molding technique used to manufacture the retention device 15 on the tube 10. The shape of the membrane envelope 151 may for example be adapted to anatomic needs and a specific application of the percutaneous catheter system 1.

[0047] The membrane envelope 151 may suitably be molded integrally with the tube 10 on the second, distal end 101 of the tube 10. The tube 10 and the membrane envelope 151 herein may be formed using different materials.

[0048] For transferring the retention device 15 from the first, deflated state of the membrane envelope 151 to the second, inflated state and vice versa a suction device 16 for example in the shape of a syringe may be connected via a line 17 (see Fig. 2) to the port 11 and to the second lumen 14 of the tube 10. The suction device 16 may be used to suck air from the inflatable chamber 150 for transferring the retention device 15 to the first, deflated state,

the suction device 16 for example being applicable to suck a predefined amount of air from the inflatable chamber 150 such that the first, deflated state is obtained. To then transfer the retention device 15 to the second, inflated state, after placement of the tube 10 within the patient 2, the amount of air previously withdrawn from the inflatable chamber 150 is refilled into the inflatable chamber 150 by delivering the air from the suction device 16 into the inflatable chamber 150 (for example by pressing on a piston of the syringe forming a suction device 16), such that the chamber 150 is filled by a known amount of air at a known pressure.

[0049] The first lumen 13, at a first end 130, is in fluid connection with the port 11, such that a delivery device may be connected to the port 11 for feeding a medical solution into the first lumen 13 at the first end 130, a second end 131 of the first lumen 13 forming an opening at the second, distal end 101 of the tube 10 for passing the medical solution into the body cavity 20, 21 accessed by the tube 10.

[0050] The shape of the retention device 15 with its membrane envelope 151 may be adapted to anatomic needs of the patient 2 and to a specific application, for example for placement of the tube 10 within the stomach 20 or the intestinal tract 21 of the patient 2. In addition, the membrane envelope 151 may be shaped to prevent a fluid flow from the stomach 20 or the intestinal tract 21 through a stoma channel 220 (see Fig. 2) towards the outside. For this, the retention device 15 in the second, inflated state may be formed to tightly close the stoma channel 220 such that fluid may not enter from the stomach 20 or the intestinal tract 21 into the stoma channel 220.

[0051] The embodiments of Fig. 3 and Fig. 4 are functionally identical, besides the different shape of the retention device 15, the membrane envelope 151 in the second, inflated state having a spherical shape in the embodiment of Fig. 3 and a cylindrical shape in the embodiment of Fig. 4.

[0052] Figs. 5 to 9 show different embodiments of percutaneous catheter systems 1 for accessing a patient's stomach 20 or a patient's intestinal tract 21, in particular the patient's jejunum.

[0053] In the embodiment of Fig. 5 a percutaneous catheter system 1 is introduced into a patient's stomach 20. The percutaneous catheter system 1 may be placed on the patient 2 by inserting it for example through a small incision in the patient's stomach wall 22, for example in combination with a so-called gastroplexie 23 by means of which the stomach 20 is fixed to the stomach wall 22 for maintaining the stomach 20 in position with respect to the stomach wall 22.

[0054] The percutaneous catheter system 1 comprises a tube 10, on the distal end 101 of which an inflatable chamber 150 is placed, the inflatable chamber 150 for example having a substantially spherical shape for retaining the percutaneous catheter system 1 within the patient's stomach 20. The inflatable chamber 150 assumes a first, deflated state for introducing the tube 10 through the stomach wall 22 into the patient's stomach 20 and is inflated once the tube 10 is placed with its distal end 101 within the stomach 20 such that the tube 10 is retained within the stomach 20.

[0055] Whereas the embodiment of Fig. 5 may relate to an initial placement of a catheter system 1 on a patient 2, in the embodiment of Fig. 6 a catheter system 1 is introduced into the patient's stomach 20 using an existing stoma channel 220 reaching through the stomach wall 22, allowing for a replacement in particular in the context of a long-term use, for example for the enteral feeding of a patient 2. Again, on the distal end 101 of a tube 10 an inflatable chamber 150 is formed which is inflated within the patient's stomach 20 to retain the tube 10 within the patient's stomach 20.

[0056] Fig. 7 shows an embodiment of a catheter system 1, according to the invention, having a tube 10 and an inflatable chamber 150 formed on the tube 10, the inflatable chamber 150 comprising multiple chamber portions 152, 153 having different shapes and providing for different functions.

[0057] In particular, a first chamber portion 152 of the inflatable chamber 150 has a substantially spherical shape and may provide for a retention function for retaining the tube 10 within the patient's stomach 20 upon introduction through for example an existing stoma channel 220 reaching through the stomach wall 22. A second portion 153 adjoining the first portion 152 may have a substantially cylindrical shape and may be formed to substantially block the stoma channel 220 in the inflated state of the chamber 150 such that no liquid may flow out of the patient's stomach 20 through the stoma channel 220, hence preventing a leakage of liquid through the stoma channel 220. The portions 152, 153 are in fluid connection, such that by filling the inflatable chamber 150 the portions 152, 153 are inflated together.

[0058] By providing an inflatable chamber 150 having different portions 152, 153 a reliable closing of a stoma channel 220 as well as a reliable retention of the tube 10 within the patient's stomach 20 or any other cavity accessed by the catheter system 1 may be provided.

[0059] In the embodiment of Fig. 8 a catheter system 1 comprising a tube 10 is used to access a patient's intestinal tract 21, in particular the patient's jejunum. The tube 10, for this, is introduced for example via an incision in the stomach wall 22 using e.g. a trocar into the intestinal tract 21 and is retained in the intestinal tract 21 by means of an inflatable chamber 150, which for introducing the tube 10 through the trocar into the intestinal tract 21 is deflated, but is inflated once the tube 10 with its distal end 101 is placed in the intestinal tract 21 as desired such that the tube 10 is retained with its distal end 101 in the intestinal tract 21.

[0060] In the embodiment of Fig. 9 a catheter system 1 having a tube 10 is introduced into the patient 2 using a probe 24, such as a so-called PEG (percutaneous endoscopic gastrostomy) probe placed on the stomach wall

22. Through the probe 24 the tube 10 of the catheter system 1 is introduced into the stomach 20 and is guided into the intestinal tract 21 of the patient 2, where it is fixed by means of an inflatable chamber 150 which in its inflated state provides for a retention of the distal end 101 of the tube 10 in the intestinal tract 21.

[0061] In different embodiments, one or multiple inflatable chambers 150 can be formed at different locations on the tube 10 of a catheter system 1, in particular close to the distal end 101, close to the proximal end 100 or in between the distal end 101 and the proximal end 100. Herein, multiple chambers 150 of equal or different shape and of equal or different function may be provided on the tube 10 on different axial locations.

[0062] A percutaneous catheter system of the type described herein may be used for different applications, for example for feeding a nutritional solution for the enteral feeding of a patient, for feeding a medication or for feeding biotics.

[0063] The tube of the catheter system may be a single lumen tube or a multi-lumen tube.

List of reference numerals

[0064]

1	Percutaneous catheter system
10	Tube
100	Proximal end
101	Distal end
11	Port
110	Head body
111, 112	End
12	Strap
120, 121	End
122	Pin
13, 14	Lumen
130, 140	End
131,141	End
15	Retention device
150	Chamber
151	Membrane (polyurethane foil)
152, 153	Portion
16	Suction device (syringe)
17	Line
2	Patient
20	Stomach
21	Intestinal tract
22	Stomach wall
220	Stoma channel
23	Gastroplexie
24	Probe (PEG probe)

Claims

1. Percutaneous catheter system (1) for percutaneously accessing a body cavity (20, 21) of a patient (2) for enteral feeding, comprising:

- a tube (10) having a first, proximal end (100) and a second, distal end (101),
- a port (11) arranged at the first, proximal end (100) of the tube (10) for feeding a medical solution into the tube (10), and
- a retention device (15) arranged on the tube (10), the retention device (15) comprising an inflatable chamber (150) which is configured to, in a first, deflated state, allow a passing of the tube (10) percutaneously towards a body cavity (20, 21) to be accessed by the percutaneous catheter system (1) and, in a second, inflated state, retain the tube (10) in a body cavity (20, 21) accessed by the percutaneous catheter system (1),

wherein the inflatable chamber (150) is defined by a membrane envelope (151) made of a material having a Shore-hardness A equal to or greater than 60, **characterized in that** the membrane envelope (151) assumes, in the second, inflated state, a predefined shape formed by a molding technique, wherein a first portion (152) of the inflatable chamber (150) has a substantially spherical shape and a second portion (153) adjoining the first portion has a substantially cylindrical shape to block a stoma channel through which the tube (10) is guided.

2. Percutaneous catheter system (1) according to claim 1, **characterized in that** the membrane envelope (151) is substantially not expandable beyond the second, inflated state of the inflatable chamber (150).

3. Percutaneous catheter system (1) according to claim 1 or 2, **characterized in that** the membrane envelope (151) is made from a material comprising polyurethane.

4. Percutaneous catheter system (1) according to one of claims 1 to 3, **characterized in that** the membrane envelope (151) is made from a material having a Shore-hardness A greater than 64, preferably greater than 70.

5. Percutaneous catheter system (1) according to one of the preceding claims, **characterized in that** the tube (10) comprises a first lumen (13) for administering a medical solution into a body cavity (20, 21) accessed by the Percutaneous catheter system (1) and a second lumen (14) which is in fluid connection with the inflatable chamber (150) of the retention device (15).

6. Percutaneous catheter system (1) according to claim 7, **characterized in that** the inflatable chamber

(150) of the retention device (15) is inflatable by filling the inflatable chamber (150) with air through the second lumen (14).

7. Percutaneous catheter system (1) according to claim 7 or 8, **characterized by** a suction device (16) connectable to the second lumen (14) at the first, proximal end (100) of the tube (10) for transferring the inflatable chamber (150) between the first, deflated state and the second, inflated state.

8. Method for manufacturing a percutaneous catheter system (1) for percutaneously accessing a body cavity (20, 21) of a patient (2) for enteral feeding, comprising:

- providing a tube (10) having a first, proximal end (100) and a second, distal end (101),
- arranging a port (11) at the first, proximal end (100) of the tube (10) for feeding a medical solution into the tube (10), and
- arranging a retention device (15) on the tube (10), the retention device (15) comprising an inflatable chamber (150) which is configured to, in a first, deflated state, allow a passing of the tube (10) percutaneously towards a body cavity (20, 21) to be accessed by the percutaneous catheter system (1) and, in a second, inflated state, retain the tube (10) in a body cavity (20, 21) accessed by the percutaneous catheter system (1),
- -forming the inflatable chamber (150) by a membrane envelope (151) made of a material having a Shore-hardness A equal to or greater than 60, **characterized in that** the membrane envelope (151) assumes, in the second, inflated state, a predefined shape formed by a molding technique, wherein a first portion (152) of the inflatable chamber (150) has a substantially spherical shape and a second portion (153) adjoining the first portion has a substantially cylindrical shape to block a stoma channel through which the tube (10) is guided.

Patentansprüche

1. Perkutanes Kathetersystem (1) zum perkutanen Zugriff zu einer Körperhöhle (20, 21) eines Patienten (2) zur enteralen Ernährung, Folgendes umfassend:

- ein Rohr (10), das ein erstes, proximales Ende (100) und ein zweites, distales Ende (101) aufweist,
- einen am ersten, proximalen Ende (100) des Rohrs (10) angeordneten Port (11) zum Zuführen einer medizinischen Lösung in das Rohr (10) und
- eine am Rohr (10) angeordnete Rückhaltevorrichtung (15), wobei die Rückhaltevorrichtung (15) eine aufblasbare Kammer (150) umfasst, die ausgebildet ist, um in einem ersten, entleerten Zustand ein perkutanes Passieren des Rohres (10) in Richtung einer Körperhöhle (20, 21) zu ermöglichen, auf die das perkutane Kathetersystem (1) zugreifen soll, und in einem zweiten, aufgeblasenen Zustand das Rohr (10) in einer Körperhöhle (20, 21) zurückzuhalten, auf die das perkutane Kathetersystem (1) zugreift,

wobei die aufblasbare Kammer (150) durch eine Membranhülle (151) aus einem Material definiert ist, das eine Shore-Härte A gleich oder größer als 60 aufweist, **dadurch gekennzeichnet, dass** die Membranhülle (151) im zweiten, aufgeblasenen Zustand eine vordefinierte Form annimmt, die durch eine Formtechnik gebildet wird, wobei ein erster Abschnitt (152) der aufblasbaren Kammer (150) eine im Wesentlichen kugelförmige Form aufweist und ein zweiter Abschnitt (153), der an den ersten Abschnitt angrenzt, eine im Wesentlichen zylindrische Form aufweist, um einen Stomakanal zu blockieren, durch den das Rohr (10) geführt wird.

2. Perkutanes Kathetersystem (1) nach Anspruch 1, **dadurch gekennzeichnet, dass** die Membranhülle (151) im Wesentlichen nicht über den zweiten, aufgeblasenen Zustand der aufblasbaren Kammer (150) hinaus expandierbar ist.

3. Perkutanes Kathetersystem (1) nach Anspruch 1 oder 2, **dadurch gekennzeichnet, dass** die Membranhülle (151) aus einem Material besteht, das Polyurethan umfasst.

4. Perkutanes Kathetersystem (1) nach einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet, dass** die Membranhülle (151) aus einem Material besteht, das eine Shore-Härte A größer als 64, vorzugsweise größer als 70 aufweist.

5. Perkutanes Kathetersystem (1) nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** das Rohr (10) ein erstes Lumen (13) zum Verabreichen einer medizinischen Lösung in eine Körperhöhle (20, 21), auf die das perkutane Kathetersystem (1) zugreift, und ein zweites Lumen (14) umfasst, das mit der aufblasbaren Kammer (150) der Rückhaltevorrichtung (15) in Fluidverbindung steht.

6. Perkutanes Kathetersystem (1) nach Anspruch 7, **dadurch gekennzeichnet, dass** die aufblasbare Kammer (150) der Rückhaltevorrichtung (15) aufblasbar ist, indem die aufblasbare Kammer (150) durch das zweite Lumen (14) mit Luft gefüllt wird.

7. Perkutanes Kathetersystem (1) nach Anspruch 7 oder 8, **gekennzeichnet durch** eine Saugvorrichtung (16), die mit dem zweiten Lumen (14) am ersten, proximalen Ende (100) des Rohres (10) verbindbar ist, um die aufblasbare Kammer (150) zwischen dem ersten, entleerten Zustand und dem zweiten, aufgeblasenen Zustand zu überführen.

8. Verfahren zur Herstellung eines perkutanen Kathetersystems (1) zum perkutanen Zugriff zu einer Körperhöhle (20, 21) eines Patienten (2) zur enteralen Ernährung, Folgendes umfassend:

- Bereitstellen eines Rohres (10), das ein erstes, proximales Ende (100) und ein zweites, distales Ende (101) aufweist,
- Anordnen eines Ports (11) am ersten, proximalen Ende (100) des Rohrs (10) zum Zuführen einer medizinischen Lösung in das Rohr (10) und
- Anordnen einer Rückhaltevorrichtung (15) am Rohr (10), wobei die Rückhaltevorrichtung (15) eine aufblasbare Kammer (150) umfasst, die ausgebildet ist, um in einem ersten, entleerten Zustand ein perkutanes Passieren des Rohres (10) in Richtung einer Körperhöhle (20, 21) zu ermöglichen, auf die das perkutane Kathetersystem (1) zugreifen soll, und in einem zweiten, aufgeblasenen Zustand das Rohr (10) in einer Körperhöhle (20, 21) zurückzuhalten, auf die das perkutane Kathetersystem (1) zugreift,
- Bilden der aufblasbaren Kammer (150) durch eine Membranhülle (151) aus einem Material, das eine Shore-Härte A gleich oder größer als 60 aufweist, **dadurch gekennzeichnet, dass** die Membranhülle (151) im zweiten, aufgeblasenen Zustand eine vordefinierte Form annimmt, die durch eine Formtechnik gebildet wird, wobei ein erster Abschnitt (152) der aufblasbaren Kammer (150) eine im Wesentlichen kugelförmige Form aufweist und ein zweiter Abschnitt (153), der an den ersten Abschnitt angrenzt, eine im Wesentlichen zylindrische Form aufweist, um einen Stomakanal zu blockieren, durch den das Rohr (10) geführt wird.

Revendications

1. Système de cathéter percutané (1) pour accéder par voie percutanée à une cavité corporelle (20, 21) d'un patient (2) pour une alimentation entérale, comprenant :

- un tube (10) ayant une première, extrémité proximale (100) et une seconde, extrémité distale (101),
- un orifice (11) agencé au niveau de la première, extrémité proximale (100) du tube (10) pour alimenter une solution médicale dans le tube (10), et
- un dispositif de rétention (15) agencé sur le tube (10), le dispositif de rétention (15) comprenant une chambre gonflable (150) qui est conçue pour, dans un premier, état dégonflé, permettre un passage du tube (10) de manière percutanée vers une cavité corporelle (20, 21) à laquelle doit accéder le système de cathéter percutané (1) et, dans un second, état gonflé, retenir le tube (10) dans une cavité corporelle (20, 21) à laquelle le système de cathéter percutané (1) accède,
dans lequel la chambre gonflable (150) est définie par une enveloppe membranaire (151) réalisée dans un matériau ayant une dureté Shore A égale ou supérieure à 60,
caractérisé en ce que l'enveloppe membranaire (151) assume, dans le second, état gonflé, une forme prédéfinie formée par une technique de moulage, dans lequel une première partie (152) de la chambre gonflable (150) a une forme sensiblement sphérique et une seconde partie (153) adjacente à la première partie a une forme sensiblement cylindrique pour bloquer un canal de stomie à travers lequel le tube (10) est guidé.

2. Système de cathéter percutané (1) selon la revendication 1, **caractérisé en ce que** l'enveloppe membranaire (151) n'est sensiblement pas extensible au-delà du second, état gonflé de la chambre gonflable (150).

3. Système de cathéter percutané (1) selon la revendication 1 ou 2, **caractérisé en ce que** l'enveloppe membranaire (151) est réalisée à partir d'un matériau comprenant du polyuréthane.

4. Système de cathéter percutané (1) selon l'une des revendications 1 à 3, **caractérisé en ce que** l'enveloppe membranaire (151) est réalisée à partir d'un matériau présentant une dureté Shore A supérieure à 64, de préférence supérieure à 70.

5. Système de cathéter percutané (1) selon l'une des revendications précédentes, **caractérisé en ce que** le tube (10) comprend une première lumière (13) pour administrer une solution médicale dans une cavité corporelle (20, 21) à laquelle le système de cathéter percutané (1) accède et une seconde lumière (14) qui est en liaison fluidique avec la chambre gonflable (150) du dispositif de rétention (15).

6. Système de cathéter percutané (1) selon la revendication 7, **caractérisé en ce que** la chambre gonflable (150) du dispositif de rétention (15) est gonflable en remplissant la chambre gonflable (150)

avec de l'air à travers la seconde lumière (14).

7. Système de cathéter percutané (1) selon la revendication 7 ou 8, **caractérisé par** un dispositif d'aspiration (16) pouvant être relié à la seconde lumière (14) au niveau de la première, extrémité proximale (100) du tube (10) pour le transfert de la chambre gonflable (150) entre le premier, état dégonflé et le second, état gonflé.

8. Procédé de fabrication d'un système de cathéter percutané (1) pour accéder par voie percutanée à une cavité corporelle (20, 21) d'un patient (2) pour une alimentation entérale, comprenant :

- la fourniture d'un tube (10) ayant une première, extrémité proximale (100) et une seconde, extrémité distale (101),
- l'agencement d'un orifice (11) au niveau de la première, extrémité proximale (100) du tube (10) pour alimenter une solution médicale dans le tube (10), et
- l'agencement d'un dispositif de rétention (15) sur le tube (10), le dispositif de rétention (15) comprenant une chambre gonflable (150) qui est conçue pour, dans un premier, état dégonflé, permettre un passage du tube (10) de manière percutanée vers une cavité corporelle (20, 21) à laquelle doit accéder le système de cathéter percutané (1) et, dans un second, état gonflé, retenir le tube (10) dans une cavité corporelle (20, 21) à laquelle le système de cathéter percutané (1) accède,
- la formation de la chambre gonflable (150) par une enveloppe membranaire (151) réalisée dans un matériau présentant une dureté Shore A égale ou supérieure à 60, **caractérisé en ce que** dans **lequel** l'enveloppe membranaire (151) assume, dans le second, état gonflé, une forme prédéfinie formée par une technique de moulage, dans lequel une première partie (152) de la chambre gonflable (150) a une forme sensiblement sphérique et une seconde partie (153) adjacente à la première partie a une forme sensiblement cylindrique pour bloquer un canal de stomie à travers lequel le tube (10) est guidé.

FIG 1

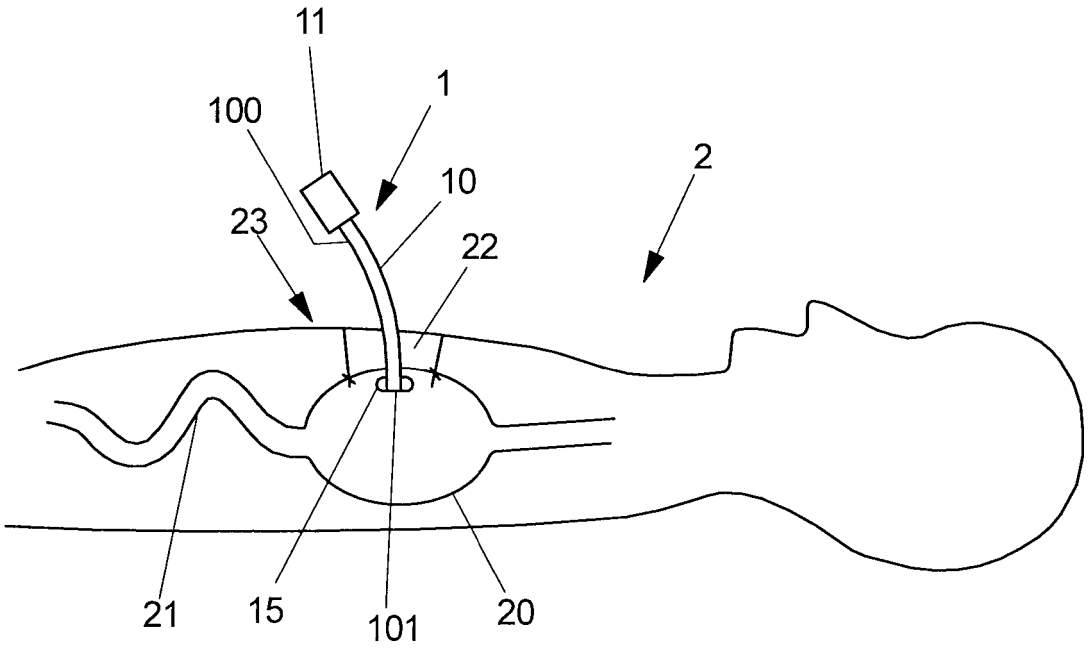

FIG 2

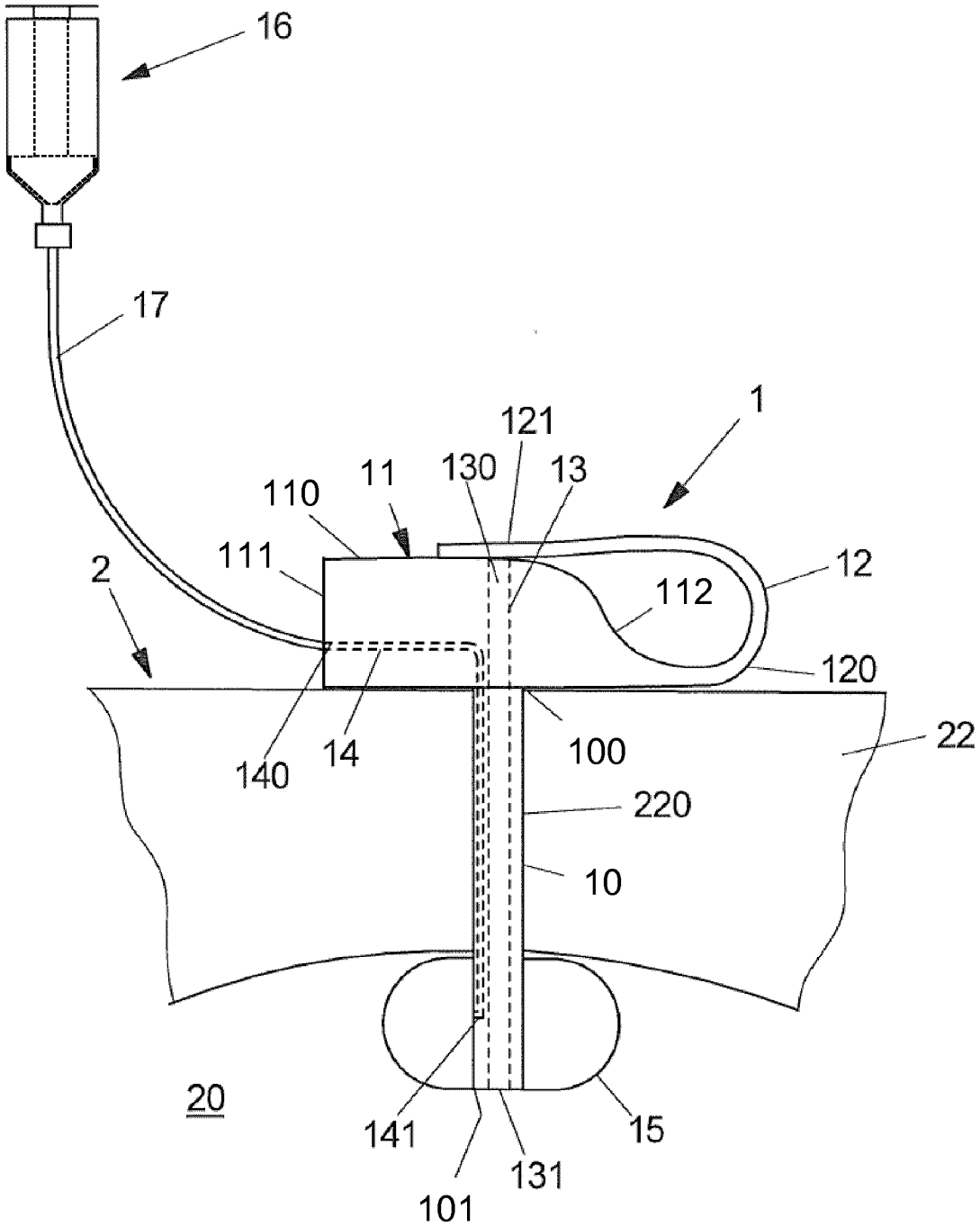
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FIG 3

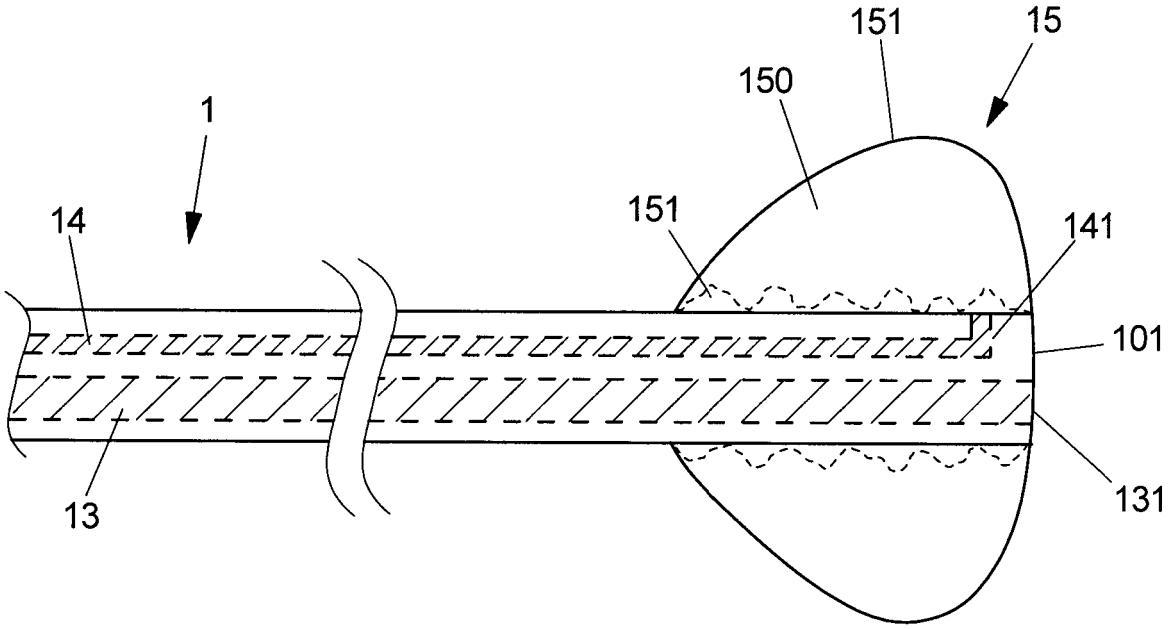
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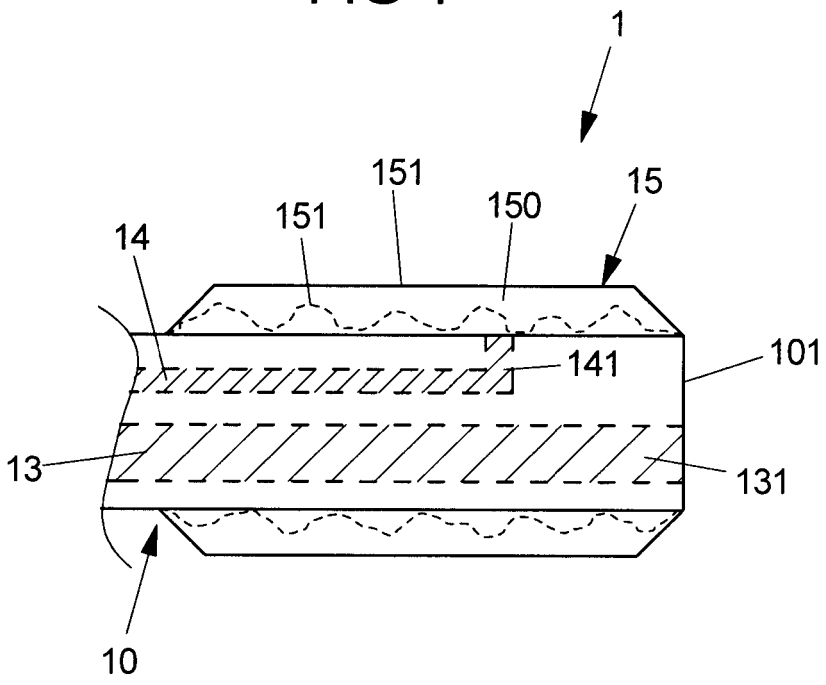
FIG 4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10

FIG 5

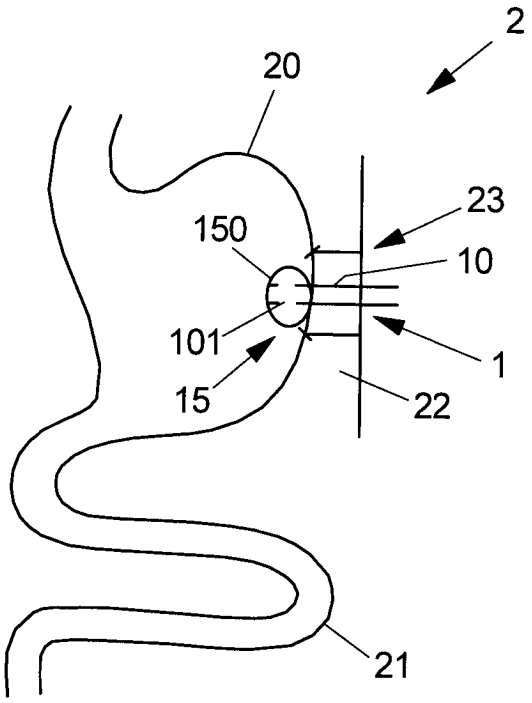
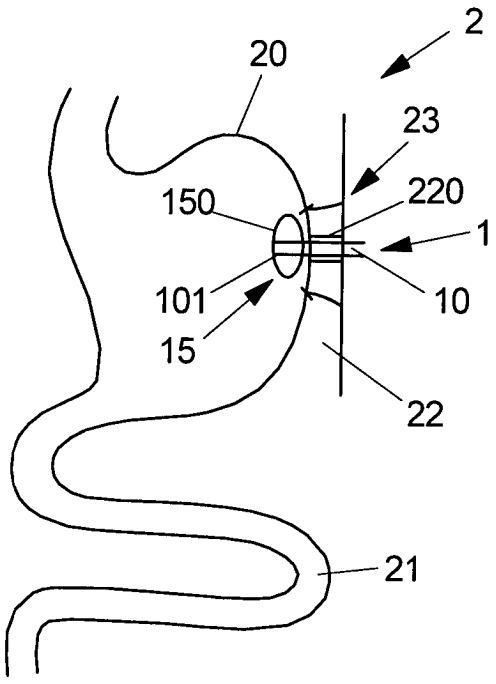


FIG 6



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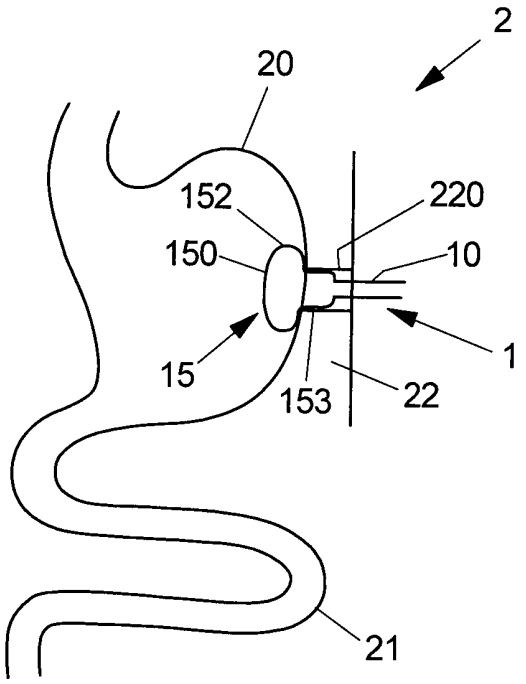


FIG 8

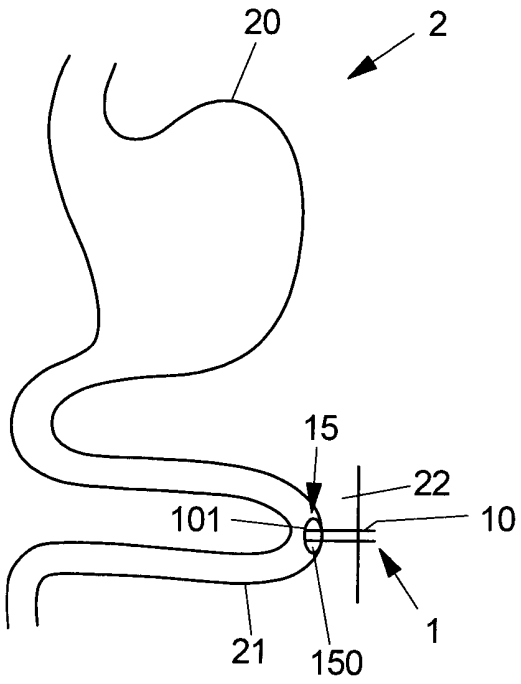
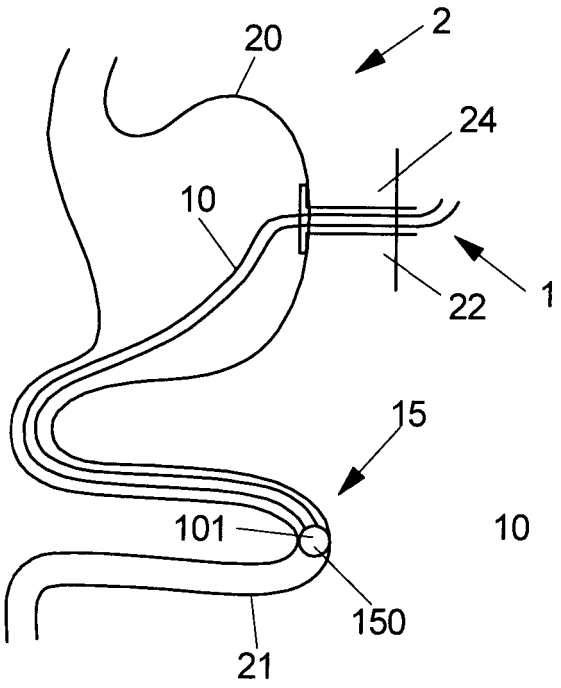


FIG 9



REFERENCES CITED IN THE DESCRIPTION

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