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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 April 2009 (16.04.2009)

PCT

(10) International Publication Number
WO 2009/046997 A2

(51) International Patent Classification:
A61F 2/06 (2006.01) *A61F 5/445* (2006.01)
A61B 17/11 (2006.01) *A61F 2/02* (2006.01)
A61F 5/00 (2006.01) *A61B 5/07* (2006.01)
A61F 2/04 (2006.01)

(21) International Application Number:
PCT/EP2008/008589

(22) International Filing Date: 10 October 2008 (10.10.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/960,715	11 October 2007 (11.10.2007)	US
60/960,716	11 October 2007 (11.10.2007)	US
60/960,765	12 October 2007 (12.10.2007)	US

(71) Applicant *(for all designated States except US)*: **MILUX HOLDING SA** [LU/LU]; 12, rue Guillaume Schneider, L-2522 Luxembourg (LU).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **FORSELL, Peter** [SE/CH]; Aegeristrasse 66, CH-6300 Zug (CH).

(74) Agent: **KLUNKER.SCHMITT-NILSON.HIRSCH**; Destouchesstrasse 68, 80796 München (DE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *without international search report and to be republished upon receipt of that report*

WO 2009/046997 A2

(54) Title: ARTIFICIAL INTESTINE SECTION

(57) Abstract: An implantable artificial intestine section is provided for being connected to a surgically created lateral opening in a wall of a patient's intestine. The other end portion thereof may be connected to a surgically created stomy, the patient's rectum or anus, the patient's small intestine or the patient's large intestine. Alternatively, the artificial intestine section may be connected with both open ends to surgically created lateral openings in the wall of the patient's intestine, so as to form a by-pass. Further implantable elements, such as a flow control device, a pump, a motor, a control unit and the like may be combined with the artificial intestine section.

ARTIFICIAL INTESTINE SECTION

Background of the invention

[0001] The present invention relates to a system and method for treating a patient having a disorder related to the patient's intestine. Such disorder may be caused by injury, birth defect, cancer or other diseases, such as constipation or incontinence.

[0002] In an attempt to overcome such disorders, many different solutions have been proposed. These solutions often include surgery, in particular where a portion of the intestine has to be removed. The reason for such operation may be colorectal cancer, perforated diverticulitis or other kinds of diseases, such as ulceros colitis or Crohns disease. For instance, in the case of ileostomy, jejunostomy, colostomy and rectostomy operations the small intestine (jejunum or ileum) or the large intestine (colon or rectum) is cut and the open end of the healthy portion of the intestine is reattached either to a surgically created stoma in the patient's abdominal wall or, where possible, to the patient's rectum or anus or to tissue adjacent the patient's anus.

[0003] The problem then arises to control the intestinal contents flow and, more particularly, to prevent feces from exiting the patient's body uncontrolled. The patient is typically required to excrete into a colostomy bag. This is obviously inconvenient and, in addition, may cause skin irritation since such a bag arrangement requires an adhesive plate to be attached to the patient's skin in order to render the bag liquid tight.

[0004] US patent no. 4,222,377 suggests the use of an inflatable artificial sphincter comprising a cuff around the anal or urethral canal. A manually operated pump is implanted in the patient's scrotum for inflating and deflating the artificial sphincter.

[0005] Similarly, US patent no. 5,593,443 discloses an artificial hydraulic anal sphincter under voluntary control. More specifically, the patient may actuate a mechanical or electrical pump for inflating and deflating a cuff. The cuff consists of two parts positioned on opposite sides of the intestine and pressing the intestinal walls together when inflated.

[0006] US 6,752,754 B1 discloses an artificial rectum for replacing a portion of a patient's rectum. An inlet of the artificial rectum is operatively connected to the distal, cross-sectional end of the patient's large intestine and communicates fecal matter to a macerator-type pump that discharges the feces through an outlet of the artificial rectum connected to the patient's anus. The pump includes a helical screw-type impeller, which when rotated creates shearing effects on the feces, causing it to move down the thread of the screw impeller and discharge through the patient's anus.

Summary of the invention

[0007] It is an object of the present invention to provide an improved system and method for treating a patient having a disorder related to the patient's intestine.

LATERALLY CONNECTED ARTIFICIAL INTESTINE SECTION

[0008] The present invention provides an artificial intestine section adapted to be implanted inside the patient's body. The artificial intestine section of the present invention has a first open end portion and a second open end portion in flow communication with one another, wherein at least the first open end portion is adapted to being connected to a surgically created lateral opening in a wall of the patient's intestine. Thus, rather than connecting the artificial intestine section to the cross-sectional end of the patient's intestine, it will be connected to a lateral opening in the patient's intestinal wall, and for this purpose the respective end portion of the artificial intestine section is specifically adapted.

[0009] By connecting the artificial intestine section laterally to the intestine, forces caused by the peristaltic movement of the intestine and acting on the artificial intestine section of the intestine are largely avoided. More specifically, where the artificial intestine section is connected to the cross-sectional opening of the intestine, the peristaltic waves of the intestine tend to pull the intestine off of the connection between the intestine and the artificial intestine section. As compared to this, where the artificial intestine section is attached to an opening in the lateral wall of the intestine, the peristaltic waves pass the artificial intestine section substantially without any impact on the connection between the intestinal wall and the artificial intestine section.

[0010] The second open end portion of the artificial intestine section may be adapted to being connected to a surgically created stomy or to the patient's rectum or anus or to tissue adjacent the patient's anus. Alternatively, since direct contact of the artificial intestine section with the patient's skin may cause inflammation and

might not be acceptable on the long run for many reasons, it is likewise possible to adapt the second open end portion of the artificial intestine section so as to being connected to a portion of the large intestine or to a portion of the small intestine, as the case may be, and to connect that portion to the patient's rectum or anus or to tissue adjacent the patient's anus or to use that portion for creating a stomy.

BY-PASS ARRANGEMENT

[0011] Alternatively, both the first and second open end portions can be adapted to being connected to a surgically created lateral opening in a wall of the patient's intestine.

STRUCTURE OF ATTACHMENT

[0012] In order to securely attach the artificial intestine section to the lateral opening, at least the first open end portion may comprise a shoulder portion formed around the end portion for lateral connection to the patient's intestinal wall. Preferably, at least a part of the shoulder portion extends laterally from the artificial intestine section by 3 mm to 20 mm. Furthermore, the shoulder portion preferably has a curved cross section, so as to generally conform to the intestinal wall when laterally attached thereto. An open end portion adapted in this way can advantageously be attached to the intestinal wall from the outside thereof.

[0013] According to an improved embodiment, the shoulder portion may be split into an upper and a lower shoulder portion with a gap between the upper and lower shoulder portions for accommodating intestinal wall tissue therein. The lower shoulder portion, if suitably adapted, can then be placed inside the patient's intestine through the surgically created lateral wall opening, whereas the upper shoulder portion will be placed outside the intestinal wall.

[0014] In order to allow the lateral wall opening to be easily stretched over the lower shoulder portion when the lower shoulder portion is advanced there through and yet in order to have a large contact area between the intestinal wall and the shoulder portion, the upper shoulder portion may be made larger than the lower shoulder portion. Thus, the surface area of the upper shoulder portion contacting the intestinal wall is also larger than the surface area of the lower shoulder portion contacting the intestinal wall.

[0015] The open end portion for lateral connection to the patient's intestinal wall may be adapted to being connected to the patient's intestinal wall by gluing. For instance, it may have a particular rough surface structure for the glue to better

adhere. Also, the open end portion may be adapted to being connected to the patient's intestinal wall by sewing. For instance, a certain area of the shoulder portion may be perforated for stitching through the perforations or may be made from a material which is easy to penetrate with a needles. Similarly, the open end portion may specifically adapted to being connected to the patient's intestinal wall by stapling.

[0016] Preferably, at least the first open end portion is made from a biocompatible material. The biocompatible material of the open end portion may comprise at least one material of the following group of materials: titanium, stainless steel, ceramics, biocompatible polymer material. More specifically, the biocompatible polymer material may comprise at least one polymer of the following group of polymers: polytetrafluoroethylene, silicone, polyurethane, expanded polytetrafluoroethylene (ePTFE).

[0017] Also, at least the first open end portion preferably comprises a multilayer material. For instance, it is advantageous when the open end portion comprises a porous ingrowth layer that allows ingrowth of living tissue. The ingrowth layer may have a net-like structure and is most preferably made from Dacron®.

INTESTINAL CONTENT INTERACTING DEVICE WITHIN ARTIFICIAL INTESTINE SECTION

[0018] In a preferred embodiment, the artificial intestine section is adapted to directly or indirectly interact with intestinal contents contained in the artificial intestine section between the first and second open end portions thereof.

RESERVOIR

[0019] In its simplest form, the at least one element of the artificial intestine section comprises an artificial reservoir between the first and second open end portions for receiving and temporarily collecting therein intestinal contents supplied through the first open end portion.

FLOW CONTROL DEVICE

[0020] In a more advanced embodiment, the at least one element may comprise, possibly in addition to the reservoir, a flow control device adapted to control flow of intestinal contents from the artificial intestine section through the second open end portion. The flow control device is preferably adapted to prevent flow of intestinal contents from the artificial intestine section through the second open end portion.

EXIT VALVE AS FLOW CONTROL DEVICE

[0021] The flow control device preferably comprises at least one valve, including an exit valve preventing intestinal contents flow through the second open end portion in its closed position. Preferably, the exit valve is a normally closed valve so that no energy is needed to keep the valve closed during the system's inactive periods.

ENTRY VALVE AS AN ADDITITONAL PART OF THE FLOW CONTROL DEVICE

[0022] In addition, the flow control device may comprise an entry valve allowing intestinal contents to flow towards the reservoir in its open position. This can be advantageous particularly during the emptying of the reservoir, when the entry valve should be closed. Therefore, the entry valve is preferably a normally open valve. Accordingly, the exit valve and the entry valve are preferably adapted to cooperate such that when one of the two valves is closed, the respective other valve is open, and vice versa.

VALVE TYPES

[0023] As regards the various valve types that may be employed, the at least one valve may e.g. comprise a central opening which is normally closed by resilient means that can be urged apart mechanically by inserting a conduit through the central opening so as to open the central opening of the valve. In the simplest embodiment, the valve may be opened by mechanical force, such as by inserting a tube from outside the patient's body through the valve. The valve in this case can be a simple non-return valve.

[0024] According to a more complex embodiment, the at least one valve may comprise a compartment with a variable volume adapted to open and close the valve by changing the compartment's volume. Advantageously, the at least one valve comprises at least one passage for filling and emptying the compartment with hydraulic fluid. The compartment preferably has at least one flexible wall defining an opening for the intestine or a conduit of the reservoir to pass through, the opening being adapted to close upon increase of the compartment's volume.

[0025] According to a different embodiment, the at least one valve may be a flap valve permanently implanted inside the patient's intestine. The flap valve may for instance comprise a rotatable disc.

EXTRA VALVE SEPARATE FROM ARTIFICIAL INTESTINE PIECE

[0026] While the valve or valves preferably make an integral part of the artificial intestine section, the artificial intestine section may further comprise one or more extra valves adapted to control flow of intestinal contents in a natural section of the patient's intestine upstream and/or downstream the artificial intestine section. The

extra valve may be rigidly connected to the artificial section but may as well form a completely separate part, in which case the artificial intestine section and the extra valve together rather form a "system". The extra valve is adapted to being implanted inside the patient's body outside a section of the patient's natural intestine and comprises at least one element adapted to act on the natural intestine section from the outside thereof so as to prevent intestinal contents flow through the natural intestine section. This valve arrangement does not require any surgery on the respective part of the natural intestine when the valve is implanted.

[0027] The extra valve may comprise at least one electrical stimulation device adapted to electrically stimulate muscle or neural tissue of an intestine section so as to cause at least partial contraction of the natural intestine section. This is a very gender way of constricting the intestine. The stimulation device preferably comprises at least one electrode adapted to apply electric pulses to the natural intestine section.

[0028] It is particularly advantageous to make use of a stimulation device which is adapted to stimulate different portions of the intestine section over time. Thus, different portions of the intestine section can be constricted by stimulation at different times in any predetermined stimulation pattern, thereby giving the intestine portions currently not stimulated time to recover and, thus, improving the blood circulation in the respective intestine section.

[0029] Furthermore, the stimulation device can specifically be adapted to stimulate, over time, the different portions of the intestine section in a wave like manner in a direction opposite to natural intestinal contents flow. As a result, the valve counteracts the natural intestinal contents flow, thereby improving the valve's closing function.

[0030] Alternatively, or preferably in addition to the stimulation device, the at least one valve may comprise a constriction device implanted in the patient's body for at least partly constricting the natural intestine section mechanically from outside the natural intestine section. Where the stimulation device is combined with the constriction device, the stimulation device and the constriction device preferably act on the same intestine section. In that case, it is advantageous if the constriction device in its normal condition constricts the natural intestine section only partly, in order not to damage the intestine over time. Complete constriction and, thus, closing of the intestine may then be obtained by additionally stimulating the natural intestine section in a manner as described before.

[0031] In addition, when constriction of the intestine section caused by the constriction device is released, the stimulation device may, if accordingly adapted, be

used to pump intestinal contents along the natural intestine section by, over time, stimulating the different portions of the natural intestine section in a wave like manner in a direction of natural intestinal contents flow. In this situation, the valve may incorporate the additional function of a pump for actively supporting the discharge of feces from the human body.

PUMP AS PART OF THE IMPLANTABLE FLOW CONTROL DEVICE

[0032] The flow control device may comprise a pump for advancing intestinal contents through the second open end portion to outside the artificial intestine section. Where the artificial intestine section comprises a reservoir, the pump may be adapted for emptying the reservoir. A variety of different structures may be realized.

[0033] For instance, the reservoir may be formed by a bellow, said bellow having an end wall closing the bellow at one end thereof. The end wall may then make part of the pump such that a volume of the bellow is reduced upon advancement of said end wall. Preferably, bellow is made of a resilient material so as to urge the bellow into a normally expanded position.

[0034] In another embodiment, the pump may comprise a movable piston, with a front end of the piston extending into the reservoir such that a volume of the reservoir is reduced upon advancement of the piston. Preferably, the piston is spring loaded so as to urge the piston into a normally retracted position.

[0035] Alternatively, the pump may be adapted for being permanently arranged inside the reservoir.

[0036] In a further alternative, the reservoir may have a flexible wall and the pump is adapted for emptying the reservoir by squeezing the reservoir. In this case, the pump may e.g. include a constriction device adapted to alternately constrict and release sections of the reservoir so as to pump intestinal contents along the reservoir by, over time, constricting different sections of the reservoir in a wave like manner. More specifically, the reservoir may have a tube-like form and a roller pump may be used as the pump acting on the tube-like reservoir from the outside thereof.

MOTOR

[0037] Where the valves or pump or any other element of the flow control device is not or not only manually drivable, at least one motor can be provided for automatically driving at least one energy consuming part of the flow control device. The motor is preferably arranged to be driven by electric or electromagnetic energy.

[0038] A motor in the sense of the present invention is a device that transforms energy other than mechanical energy into mechanical energy. While a pump in the sense of the present invention is a device for advancing liquid or pasty material, a pump may at the same time be a motor in certain circumstances, such as where the transformation of energy into mechanical energy causes advancement of the liquid or pasty material without any intervening mechanical means such as a piston, bellow or the like.

[0039] For instance, the at least one motor can be arranged for driving at least one of the valve or valves, respectively, between its closed and open position. Also, the at least one motor can be arranged for driving the pump.

[0040] A manually operable switch may be provided for activating the at least one motor, the switch being preferably arranged for subcutaneous implantation so as to be operable from outside the patient's body.

ENERGY SOURCE

[0041] The artificial intestine section may be combined with further components to form a system. The further components may be integrated in the artificial intestine section to be implanted along therewith or may be separate from the artificial intestine section to be implanted separately or not to be implanted at all.

[0042] The system may for instance comprise an energy source for supplying energy directly or indirectly to at least one energy consuming part of the system. Preferably, the energy source includes a battery or an accumulator, such as one or more of a rechargeable battery and a capacitor, as an energy storage means. The energy storage means is advantageously adapted for being implanted inside the patient's body, more preferably as a part of the artificial intestine section.

WIRELESS ENERGY TRANSMISSION

[0043] Energy is preferably transmitted wirelessly. Thus, where the energy source is provided for supplying energy directly or indirectly to at least one energy consuming part of the system, the energy source may comprise a wireless energy transmitter adapted to wirelessly transmit energy from outside the patient's body to the at least one energy consuming part. Alternatively, where the energy source includes a battery or an accumulator, in particular one which is implanted in the patient's body, the energy source may comprise a wireless energy transmitter adapted to wirelessly transmit energy from outside the patient's body to the energy storage means.

ENERGY TRANSMISSION FEEDBACK

[0044] A feedback subsystem, which can make part of a control device described subsequently, can advantageously be provided to wirelessly send feedback information related to the energy to be stored in the accumulator from inside the human body to the outside thereof. The feedback information is then used for adjusting the amount of wireless energy transmitted by the energy transmitter. Such feedback information may relate to an energy balance which is defined as the balance between an amount of wireless energy received inside the human body and an amount of energy consumed by the at least one energy consuming part. Alternatively, the feedback information may relate to an energy balance which is defined as the balance between a rate of wireless energy received inside the human body and a rate of energy consumed by the at least one energy consuming part.

[0045] Also, the transmission of energy from the energy storage means to the at least one energy consuming part may be performed wirelessly by means of an accordingly adapted wireless energy transmitter.

[0046] Preferably, in order to reduce the number of parts and possibly increase the system's efficiency, the energy consuming part can be adapted to directly transform the wirelessly transmitted energy into kinetic energy. Otherwise, it will be necessary to provide an implantable energy transforming device for transforming the wireless energy, preferably into electric energy. In this case, it is further preferred to set up the system such that the energy consuming part is driven with the electric energy, as said energy transforming device transforms the wireless energy into the electric energy.

[0047] The energy transmitter can be adapted to generate an electromagnetic field, a magnetic field or an electrical field. The wireless energy may be transmitted by the energy transmission device by at least one wireless signal. More specifically, the energy transmitter may be adapted to transmit the energy by at least one wireless energy signal, which may comprise an electromagnetic wave signal, including at least one of an infrared light signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, an X-ray radiation signal, and a gamma radiation signal. Also, the wireless energy signal may comprise a sound or ultrasound wave signal. Furthermore, the wireless energy signal may comprise a digital or analog signal or a combination thereof.

GALVANIC ENERGY TRANSMISSION

[0048] Where energy is not transmitted wirelessly, galvanic coupling elements should be provided at least between the energy source and the motor for transmitting energy to the motor in contacting fashion.

CONTROL UNIT

[0049] It is advantageous to provide a control unit adapted to directly or indirectly control one or more elements of the system, such as for controlling opening of the exit valve and/or closing of the entry valve, in particular in a manner such that when one of the two valves is closed, the respective other valve is open, and vice versa. The control unit can also be adapted to control actuation of the pump.

[0050] The control unit is preferably operable by the patient, e.g. particularly in order to empty the reservoir.

[0051] At least part of the control unit may be adapted to be implantable in the patient's body. For instance, a manually operable switch may be provided for activating the control unit, the switch preferably being arranged for subcutaneous implantation so as to be operable from outside the patient's body. Also, the control unit may comprise a first part adapted for implantation in the patient's body and a second part adapted to cooperate with the first part from outside the patient's body. In this case, the control unit can be adapted to transmit data from the external second part of the control unit to the implanted first part of the control unit in the same manner as energy is transmitted to the at least one energy consuming part.

[0052] That is, the second part of the control unit may be adapted to wirelessly transmit a control signal to the implantable first part of the control unit for controlling the at least one energy consuming part from outside the patient's body. Also, the implantable first part of the control unit may be programmable via the second part of the control unit. Furthermore, the implantable first part of the control unit may be adapted to transmit a feedback signal to the second part of the control unit.

SENSOR

[0053] Furthermore, a physical parameter sensor adapted to directly or indirectly sense a physical parameter of the patient can be provided. The physical parameter sensor may be adapted to sense at least one of the following physical parameters of the patient: a pressure within the artificial intestine section, a pressure within the patient's intestine, an expansion of the artificial intestine section, a distension of an intestinal wall of the patient's intestine, a movement of the intestinal wall.

[0054] Similarly, a functional parameter sensor adapted to directly or indirectly sense a functional parameter of the system can be provided, wherein the functional parameter sensor may be adapted to sense at least one of the following functional parameters of the system: a pressure against a part of the system such as the artificial intestine section, a distension of a part of the system such as a wall of the artificial intestine section, an electrical parameter such as voltage, current or energy balance, a position or movement of a movable part of the system.

[0055] Preferably, an indicator is coupled to the sensor or sensors, the indicator being adapted to provide a signal when a sensor senses a value for the parameter beyond a predetermined threshold value. The sensor signal may comprise at least one of the following types of signals: a sound signal, a visual signal.

INTESTINAL CONTENTS COLLECTING DEVICE (WITH "EXTERNAL" PUMP)

[0056] Where the artificial intestine piece comprises a reservoir, in a simple way, an intestinal contents collecting device may used to be temporarily applied from outside the patient's body when the reservoir is to be emptied. According to a preferred embodiment, the collecting device may comprise a front open end adapted to be applied towards the exit valve so as to provide a flow passage from the exit valve towards the collecting device. More specifically, the collecting device front open end is preferably adapted to be applied to the exit valve so as to open the valve and thereby provide said flow passage towards the collecting device. Where the exit valve is normally closed by resilient means, said front open end is adapted to be inserted through the central opening of the exit valve so as to urge apart the resilient means normally closing the central opening.

[0057] The collecting device preferably comprises a suction pump, which may comprise a piston-cylinder-arrangement. The suction pump may be adapted to be driven manually, in particular where it is intended for use as a back-up pump for a situation where the pump of the flow control device is out of operation. However, preferably a motor is connected to the suction pump for driving the pump automatically.

METHOD OF TREATMENT (IMPLANTATION)

[0058] The invention does not only relate to the artificial intestine section and systems described above, but also to a method of treating a patient having a disorder related to the patient's intestine.

LATERAL CONNECTION

[0059] Connecting at least the first open end portion of the artificial intestine section laterally to the patient's intestine involves the following steps of a surgical method of treating a patient:

- cutting the patient's skin and abdominal wall,
- dissecting an area of the patient's intestine,
- surgically creating at least one opening in a wall of the dissected intestinal area so as to create an artificial lateral intestinal opening,
- providing an artificial intestine section having a first open end portion and a second open end portion in flow communication with one another and affixing the first open end portion to the lateral intestinal opening so as to be in flow communication therewith, and
- suturing the abdominal wall and skin.

[0060] A corresponding laparoscopic surgical method of treating a patient would comprise the steps of:

- making a small opening in the patient's skin and abdominal wall,
- introducing a needle in the abdominal cavity,
- inflating the abdominal cavity with gas,
- inserting at least one trocar into the cavity,
- introducing a camera through the trocar,
- inserting at least one dissecting instrument preferably through a second trocar,
- dissecting an area of the intestine,
- surgically creating at least one opening in a wall of the dissected intestinal area so as to create an artificial lateral intestinal opening,
- providing an artificial intestine section having a first open end portion and a second open end portion in flow communication with one another and affixing the first open end portion to the lateral intestinal opening so as to be in flow communication therewith,
- extracting the instruments, camera and trocar, and in relation thereto
- suturing, if necessary, the abdominal wall and permanently closing the skin.

CLOSING THE INTESTINE BY SEWING

[0061] The dissected portion may be permanently closed at a location downstream of the lateral intestinal opening so as to create an upstream part of the intestine including the lateral intestinal opening and a downstream part of the intestine, and the second open end portion of the artificial intestine section may be affixed to the downstream intestinal part, preferably again to a lateral opening in the wall of the downstream intestinal part. The downstream intestinal part may be connected to a surgically created stomy or to the patient's rectum or anus or to tissue adjacent the

patient's anus. The step of permanently closing the patient's intestine preferably comprises sewing and/or stapling the intestinal wall so as to form a dead end.

DIVIDING THE INTESTINE

[0062] The patient's intestine may alternatively be divided and the artificial intestine piece may be placed between the resulting upstream and downstream intestinal parts. This would require the following steps:

- dissecting a portion of the dissected intestinal area downstream of the lateral intestinal opening such that intestinal mesentery connected to the dissected portion is opened in such a way that supply of blood through the mesentery to the dissected intestinal area is maintained as far as possible on both sides of the dissected portion,
- dividing the patient's intestine in the dissected portion so as to create an upstream part of the intestine with the lateral intestinal opening and a downstream part of the intestine, said downstream intestine part being separate from the upstream intestine part and having a cross-sectional opening at the upstream side thereof, wherein the mesentery maintains a tissue connection between the upstream and downstream intestine parts,
- affixing the second open end portion of the artificial intestine section to the downstream intestine part, and
- permanently closing the upstream intestine part at a location downstream of the lateral intestinal opening.

LATERAL FRONT AND LATERAL END CONNECTION (BY-PASS)

[0063] As mentioned before, preferably not only the first open end but also the second open end of the artificial intestine section are connected to a lateral opening in the patient's intestinal walls. This would involve the following steps to be performed on the downstream intestinal part:

- surgically creating an opening in a wall of the downstream intestinal part at an upstream end thereof so as to create a second artificial lateral intestinal opening, and
- affixing the second open end portion of the artificial intestine section to the second lateral intestinal opening so as to be in flow communication therewith.

[0064] The step of permanently closing the patient's intestine may then comprise sewing the intestinal wall with two rows of sutures or staples and cutting and dividing the intestine between the sutures or staples so as to form two dead ends.

[0065] Alternatively, where the method of implanting the artificial intestine section involves dividing the patient's intestine, the step of affixing the second open end portion of the artificial intestine section to the downstream intestinal part may comprise the steps of:

- surgically creating an opening in a wall of the downstream intestinal part at an upstream end thereof so as to create a second artificial lateral intestinal opening,
- affixing the second open end portion of the artificial intestine section to the second lateral intestinal opening so as to be in flow communication therewith, and
- permanently closing the cross-sectional opening at the upstream side of the downstream intestine part at a location upstream of the second lateral intestinal opening, e.g. by sewing and/or stapling.

LATERAL FRONT CONNECTION AND STRAIGHT END CONNECTION

[0066] However, the second open end portion of the artificial intestine section can likewise be affixed to a cross-sectional upstream opening of the downstream intestinal part of the divided intestine so as to be in flow communication therewith.

SLEEVE/BULGE CONNECTOR

[0067] The step of affixing the second open end portion of the artificial intestine section to a cross-sectional upstream opening of the downstream intestine part preferably comprises:
- inserting the second open end portion of the artificial intestine section into the upstream opening of the downstream intestine part, and
- placing a flexible sleeve so as to extend over both the downstream intestine part and second open end portion of the artificial intestine section such that the downstream intestine part is located intermediate the sleeve and the outer surface of the artificial intestine section.

[0068] Where the flexible sleeve is mounted on the outer surface of the second open end portion of the artificial intestine piece so as to be foldable upon itself, the step of placing the flexible sleeve so as to extend over both the downstream intestine part and second open end portion of the artificial intestine section comprises folding the flexible sleeve upon itself such that the downstream intestine part is located intermediate the folded sleeve.

[0069] Alternatively, or in addition, the step of affixing the second open end portion of the artificial intestine section to the cross-sectional upstream opening of the downstream intestine part may comprise:
- inserting the artificial intestine section having a bulge formed on the outside thereof into the upstream opening of the downstream intestine part so that the downstream intestine part extends over the bulge from one side of the bulge, and
- advancing a blocking ring over the downstream intestine part towards the bulge from the respective other side of the bulge such that the downstream intestine part is located intermediate the outer surface of the artificial intestine section and the blocking ring.

[0070] The afore-mentioned second open end portion of the artificial intestine section with a sleeve or with a bulge serve to improve the strength of the connection against axial forces which may e.g. result from the peristaltic movement of the intestine and tend to pull on the intestine. The second open end portion of the artificial intestine section may also combine a sleeve and a bulge.

EXIT THROUGH STOMA

[0071] As mentioned before, the downstream intestinal part may be connected to a surgically created stomy or to the patient's rectum or anus or to tissue adjacent the patient's anus. In the case of a connection to a stomy, this would involve the following steps:

- cutting the patient's skin and abdominal wall so as to create an opening for an intestinal stomy,
- dissecting the area of the stomy opening,
- dividing the intestine at a location downstream of the artificial intestine piece so as to create an upstream natural intestine section having a cross-sectional opening at the downstream end thereof and a downstream natural intestine section,
- dissecting the mesentery of the upstream natural intestine section in the area of the cross-sectional opening thereof to prepare for creating the intestinal stomy,
- advancing the downstream end of the upstream natural intestine section through the abdominal wall and skin, and
- suturing the cross-sectional opening of the upstream natural intestine section to the skin with the intestinal mucosa turned inside out, thereby achieving the intestinal stomy.

EXIT THROUGH ANUS

[0072] In the case of a connection to the patient's anus or to tissue adjacent the patient's anus, this would involve the following steps:

- dividing the intestine at a location downstream of the artificial intestine piece so as to create an upstream natural intestine section having a cross-sectional opening at the downstream end thereof and a downstream natural intestine section leading to the patient's anus,
- dissecting the area of the patient's anus and surgically separating the downstream natural intestine section from the patient's anus, whereas the steps of dividing the intestine and separating the intestine section leading to the patient's anus can alternatively be carried out in reversed order,
- dissecting the mesentery of the upstream natural intestine section in the area of the cross-sectional opening at the downstream end thereof to prepare for connecting the upstream natural intestine section to the patient's anus or tissue adjacent the patient's anus,

- advancing the downstream end of the upstream natural intestine section through the patient's anus, and
- suturing the cross-sectional opening of the upstream natural intestine section to the patient's anus or tissue adjacent the patient's anus.

[0073] Depending upon the circumstances, the step of dividing the intestine so as to form the upstream natural intestine section may be performed either on the patient's small intestine or on the patient's large intestine.

STRUCTURE OF ATTACHMENT

[0074] Where the first open end portion of the artificial intestine section and possibly also the second open end portion are to be affixed to the lateral intestinal opening so as to be in flow communication therewith, this may comprise the step of connecting the afore-mentioned shoulder portion, which is formed around the open end portion, to the patient's intestinal wall so as to surround the lateral intestinal opening. In particular, the step of affixing the open end portion to the intestine may comprise attaching the shoulder portion to the patient's outer intestinal wall.

[0075] Alternatively, where the shoulder portion is split into an upper and a lower shoulder portion with a gap between the upper and lower shoulder portions, the step of affixing the open end portion of the artificial intestine section to the lateral intestinal opening may comprise placing the lower shoulder portion inside the patient's intestine and the upper shoulder portion outside the patient's intestine such that the intestinal wall tissue is accommodated in the gap.

[0076] The step of affixing the open end portion of the artificial intestine section to the lateral intestinal opening may comprise gluing, sewing and/or stapling the open end portion to the patient's intestinal wall.

[0077] As a material for the first open end portion at least one biocompatible material from the following group of materials may be selected: titanium, stainless steel, ceramics, biocompatible polymer material, wherein the biocompatible polymer is preferably selected from the following group of polymers: polytetrafluoroethylene, silicone, polyurethane, expanded polytetrafluoroethylene (ePTFE).

[0078] More specifically, a multilayer material may be selected for the first open end, in particular one having a porous ingrowth layer allowing ingrowth of living tissue. The ingrowth layer is preferably chosen to have a net-like structure.

INTESTINAL CONTENT INTERACTING DEVICE WITHIN ARTIFICIAL INTESTINE PIECE / RESERVOIR / FLOW CONTROL DEVICE

[0079] As mentioned before, the artificial intestine section or system may comprise at least one element adapted to directly or indirectly interact with intestinal contents contained in the artificial intestine section between the first and second open end portions thereof. This element will be implanted along with the artificial intestine section. As also mentioned before, the element may comprise a reservoir for receiving and temporarily collecting therein intestinal contents supplied through the first open end portion and/or a flow control device adapted to control flow of intestinal contents from the artificial intestine section through the second open end portion.

[0080] Again, the flow control device may comprise an exit valve preventing intestinal contents flow through the second open end portion in its closed position and may additionally comprise an entry valve allowing intestinal contents to flow through the first open end portion into the artificial intestine section in its open position.

[0081] Alternatively or in addition, as also mentioned before, the flow control device may comprise a pump for advancing intestinal contents through the second open end portion to outside the artificial intestine section. Where the pump comprises a manually operable switch for activating the pump, the method of implantation may further comprise the step of implanting the switch subcutaneously so as to be operable from outside the patient's body.

MOTOR

[0082] Again, at least one motor may be implanted in the patient's body either separately or, more preferably, integrally with the artificial intestine section and may be arranged for automatically driving one or more energy consuming part of the flow control device. Where the motor comprises a manually operable switch for activating the motor, the method of implantation may further comprise the step of implanting the switch subcutaneously so as to be operable from outside the patient's body.

ENERGY SOURCE / ENERGY TRANSMISSION

[0083] The method of implantation may further comprise the step of implanting inside the patient's body an energy source, possibly comprising energy storage means such as a battery or an accumulator as described before, for supplying at least one of the energy consuming parts with energy.

[0084] Where energy is transmitted wirelessly, for instance from outside the patient's body to inside the patient's body either to an energy consuming part and/or to the accumulator or from the accumulator to the energy consuming part, it may further be necessary to implant an energy transforming device for transforming the

wireless energy into electric energy. Alternatively or in addition, galvanic coupling elements may be implanted, e.g. for transmitting energy to the energy consuming part in contacting fashion from outside the patient's body and/or from the implanted energy source.

CONTROL UNIT

[0085] Furthermore, as mentioned previously, at least a part of a control unit may be implanted inside the patient's body adapted to directly or indirectly control one or more of the elements that have also been implanted in the patient's body. Where the control unit comprises a manually operable switch for activating the control unit, the method of implantation may further comprise the step of implanting said switch subcutaneously so as to be operable from outside the patient's body.

SENSOR

[0086] As mentioned before, one or more physical and/or functional parameter sensors may be implanted to directly or indirectly sense physical and/or functional parameters inside the patient and in the system implanted inside the patient. Where the sensor is a pressure sensor, it may be placed in the artificial intestine section or the patient's natural intestine so as to sense the pressure within the artificial intestine section or patient's natural intestine, respectively. Where the sensor is a tension sensor, it may be placed in contact with the artificial intestine section or the patient's intestine so as to sense an expansion of the artificial intestine section or patient's natural intestine, respectively. Where the sensor is a movement sensor, it may be placed in contact with the artificial intestine section or the patient's natural intestine so as to sense movement of the artificial intestine section or patient's natural intestine, respectively. The functional sensor may be adapted to measure at least one of the following functional parameters of the system: an electrical parameter such as voltage, current or energy balance or a stimulation parameter in relation to the system.

USE

[0087] Once the artificial intestine section or system according to the invention has been properly installed, the flow control device can be used for emptying the reservoir implanted in the patient.

[0088] Accordingly, a method of treating a patient by means of the artificial intestine section which comprises at least one element adapted to directly or indirectly interact with intestinal contents contained in the artificial intestine section may comprise the step of actuating the at least one element so as to interact with the

intestinal contents contained in the artificial intestine section between the first and second open end portions thereof.

EXIT AND ENTRY VALVE

[0089] Where the at least one element comprises an exit valve preventing intestinal contents flow from the artificial intestine section through the second open end portion in its closed position, the method may further comprise the steps of opening the exit valve and then removing intestinal contents from the artificial intestine section. Furthermore, where the at least one element further comprises an entry valve allowing intestinal contents to flow through the first open end portion into the artificial intestine section in its open position, the method may further comprise the step of closing the entry valve before removing intestinal contents from the artificial intestine section.

[0090] In particular, the method of use may comprise the step of inserting a conduit from outside the patient's body into the artificial intestine section, thereby mechanically urging the exit valve to open.

PUMP

[0091] Where the at least one element interacting with intestinal contents inside the artificial intestine piece comprises a pump, the method of use may further comprise the step of advancing intestinal contents from the artificial intestine section through the second open end portion thereof to outside the artificial intestine section by means of the pump. The pump may be activated by manually operating a subcutaneously arranged actuator from outside the patient's body.

[0092] Alternatively, a flow passage may be provided to extend from the artificial intestine section to an external collecting device and intestinal contents may then be removed from the artificial intestine section by means of a suction pump.

MOTOR

[0093] The suction pump is preferably driven by means of a motor.

[0094] Furthermore, where the at least one element interacting with intestinal contents inside the artificial intestine piece comprises a motor, the method of use may further comprise the step of driving at least the exit valve between its closed and open positions and/or driving at least the pump by means of the motor. In either case, the motor is preferably activated by manually operating a subcutaneously arranged actuator from outside the patient's body.

ENERGY

[0095] As mentioned before, energy may be transmitted from outside the patient's body to at least one implanted energy consuming part of the system, preferably in the form of wireless energy. This may involve the following additional steps:

- transforming the wirelessly transmitted energy into electric energy by means of an energy transforming device,
- storing the transformed energy in an energy storage means, and
- supplying the stored energy from the energy storage means to at least one implanted energy consuming part of the system.

[0096] Again, energy may be transmitted wirelessly from the storage means to the energy consuming part.

[0097] Preferably, at least part of the wirelessly transmitted energy is transformed into electric energy and used for the energy consuming part of the system, as said part of the wirelessly transmitted energy is transformed into the electric energy.

CONTROL

[0098] Where a first part of a control unit for controlling at least one energy consuming part of the system is implanted inside the patient's body, the method of use may further comprise the step of using the external second part of the control unit to transmit data to the implanted first part of the control unit. Preferably, the data are transmitted to the implanted first part of the control unit in the same manner as energy is transmitted to the implanted energy consuming part. More particularly, the data are preferably transmitted wirelessly to the implanted first part of the control unit. This may involve a wireless control signal.

[0099] For instance, the implanted first part of the control unit can be programmed via the external second part of the control unit. Furthermore, a feedback signal may be transmitted from the implanted first part of the control unit to the external second part of the control unit.

SENSOR

[0100] Where one or more of the afore-mentioned sensors are provided, the method of use may comprise the step of sensing a physical parameter in the patient's body and/or a functional parameter of the artificial intestine piece or system in the patient's body, such as one or more of the following parameters: a pressure within the artificial intestine section, a pressure within the patient's natural intestine, an expansion of the artificial intestine section, a distension of an intestinal wall of the patient's natural intestine, a movement of the patient's intestinal wall, a pressure against a part of the system such as the artificial intestine section, a distension of a part of the system such as a wall of the artificial intestine section, an electrical

parameter such as voltage, current or energy balance, a position or movement of a movable part of the system.

[0101] A signal, such as a sound signal or a visual signal, may be provided when a value for the physical parameter sensed is beyond a predetermined threshold value.

[0102] The invention will now be described in more detail in context with some preferred embodiments of the invention as shown in the accompanying drawings.

Brief description of the drawings

[0103] Figure 1 shows a system according to the present invention with an artificial intestine section being implanted inside a patient's body and having a first open end portion connected to a surgically created lateral opening in a wall of the patient's intestine. The second open end portion exits the patient's abdominal wall forming a stomy. The artificial intestine section is here shown as a black box and may include an artificial reservoir for intestinal contents, a motor, one or more valves, a pump and/or any other flow control device.

[0104] The system shown in Figure 2 corresponds to the one shown in Figure 1, however, with the second open end portion of the artificial intestine section exiting the patient's anus.

[0105] Figure 3 shows a system where both the first and second open end portions of the artificial intestine section are attached to surgically created lateral openings in a wall of the patient's small and/or large intestine. The downstream part of the intestine exits the patient's abdominal wall forming a surgically created stomy. The downstream part of the intestine may as well exit through the patient's anus.

[0106] Figure 4 shows a similar system with the difference that the second open end portion is connected to a cross-sectional opening of the patient's intestine, further leading to the surgically created stomy. The downstream part of the intestine may as well exit through the patient's anus.

[0107] Figure 5 shows the structure of the first open end portion of the artificial intestine section for attaching the artificial intestine section to the lateral opening in the patient's intestine by means of a shoulder portion formed around the end portion. The end portion is sewn to the intestine and may additionally or alternatively be stapled and/or glued to the intestine.

[0108] Figure 6 shows an improved structure for lateral attachment to the intestine, wherein the shoulder portion is split into an upper and a lower shoulder portion forming a gap to accommodate intestinal wall tissue therein. The surface area of the upper shoulder portion is larger than the surface area of the lower shoulder portion.

[0109] Figure 7 shows an enlarged view of a ring-and-bulge connection by which the artificial intestine section and the patient's downstream intestinal part are connected, as shown in Figure 4.

[0110] Figures 8A and 8B show the ring-and-bulge connection of Figure 7 in combination with a sleeve. The sleeve is rolled upon itself and can be unrolled such that a part of the intestine is located intermediate the sleeve and the conduit. Thereafter, the ring is pushed over the sleeve against the bulge.

[0111] Figures 9A and 9B show a connection of the artificial intestine section to the cross-sectional opening of the patient's intestine similar to the connection shown in Figures 8A and 8B, however, without the bulge and the ring.

[0112] Figures 10A and 10B show an alternative to the connection in Figure 9A and 9B. Instead of unrolling the sleeve, it is simply pulled over the intestine.

[0113] Figures 11A and 11B show another sleeve connection. Here, the sleeve is mounted on the outer surface of the open end portion so as to be foldable upon itself. By folding the flexible sleeve upon itself, a part of the intestine is located intermediate the folded sleeve.

[0114] Figure 12 shows an embodiment of the artificial intestine section with an artificial reservoir and an entry valve and exit valve arranged upstream and downstream of the reservoir. The reservoir is mounted with a pump in a common housing and the pump and the entry and exit valves are controlled by means of a control device, of which a part is implanted inside the patient's body. Data are transmitted wirelessly between the external part and implanted part of the control unit. In addition, energy is wirelessly transmitted to the artificial intestine section or to an accumulator also implanted in the patient's body and galvanically connected here to the valves and pump.

[0115] Figures 13A and 13B show a first embodiment of the structure of Figure 12 in more detail. The pump comprises a moveable piston with a front end of the piston extending into the reservoir such that a volume of the reservoir is reduced upon advancement of the piston. The piston is spring loaded so as to urge the piston into a normally retracted position. Furthermore, entry and exit valves are here realized as

flap valves. The flap valves are controlled so that one valve is open while the other one is closed.

[0116] Figures 14A and 14B show a system similar to the one of Figures 13A and 13B. However, here the entry and exit valves comprise bellows acting on the intestine from the outside so as to close the intestine by compression. In Figure 14A the bellows of the exit valve are expanded to compress the artificial intestine section at the downstream side of the reservoir, whereas in Figure 14B the artificial intestine section is closed by means of the bellows of the entry valve upstream of the reservoir so that the reservoir can be emptied by advancing the piston of the pump.

[0117] Figure 15 shows an embodiment schematically, wherein the artificial intestine section by-passes a section of the patient's intestine, the intestine being closed by sewing so as to direct intestinal content towards the artificial intestine section. An exit valve is provided for controlling the flow of intestinal contents from the artificial intestine section. The enlarged area of the artificial intestine section represents any kind of element acting on the intestinal contents within the artificial intestine section, such as a reservoir, one or more valves, a pump or any other flow control device, possibly including a motor, and the like.

[0118] Figure 16 shows a by-passing artificial intestine section in action, further leading to a surgically created stoma. A pump or valve may be contained in the artificial intestine section.

[0119] Figure 17 shows the artificial intestine section of Figure 16 with a large reservoir and an exit valve downstream the reservoir.

[0120] Figure 18 shows the by-passing artificial intestine section including a pump and a valve incorporated therein. Furthermore, a battery implantable in the patient's body and preferably rechargeable provides the artificial intestine section with energy. The artificial intestine section is wirelessly controlled and the battery, if rechargeable, wirelessly charged. A sensor implanted on or within the intestine delivers data on the physical conditions within the intestine for controlling the artificial intestine section.

[0121] Figures 19A to 19C show an embodiment, where the artificial intestine section comprises a reservoir with a flexible wall. A pump is implanted in the patient's body separate but in close proximity to the reservoir and is used to empty the reservoir. The pump is actuated by means of a subcutaneously implanted, manually operable switch.

[0122] Figures 20A and 20B show a structure similar to the one of Figures 19A to 19C, however, with the pump and the reservoir being fixedly connected to one another. The reservoir is formed by a bellow having an end wall closing the bellow at one end thereof. The end wall makes part of the pump such that a volume of the bellow can be reduced upon advancement of the end wall. The bellow is made of a resilient material so as to urge the bellow into a normally extended position

[0123] Figures 21A and 21B show a variant to Figures 20A and 20B. Here, the pump and reservoir are integrally combined. The pump is manually operable and subcutaneously mounted so as to be operable from the outside of the patient's body.

[0124] Figures 22A and 22B likewise show a variant to the system shown in Figures 20A and 20B. While in the system of Figures 20A, 20B the pump is automatically driven, such as by an integrated motor, and activated via remote control, the system in Figures 22A and 22B is again manually operable in that the manually operable pump is mounted subcutaneously.

[0125] Figures 23A to 23C show a plurality of cooperating valves implanted inside the patient's body and outside the patient's intestine. These can be positioned behind and/or in front of the artificial intestine piece along the patient's natural intestine. Each of the valves comprises an electrical stimulation device adapted to electrically stimulate muscle or neural tissue of an intestine section so as to cause at least partial contraction of the intestine section. For that purpose, the stimulation device comprises at least one electrode adapted to apply electric pulses to the intestine section. While instead of the three stimulation devices shown, a single stimulation device would be sufficient for opening and closing the intestine, the arrangement of the plurality of stimulation devices is adapted to stimulate different portions of the intestine section over time. The function of the three stimulation devices may also be combined in one integral unit. The direction of natural intestinal contents flow is indicated by arrows. The different portions of the intestine section in a wavelike manner may be made in a direction opposite to the natural intestinal contents flow, as shown in Figures 23A to 23C, so as to close the intestine section. The stimulation in the wavelike manner may also be made in the direction of natural intestinal contents flow to support emptying of the intestine or reservoir.

[0126] Figures 24A to 24C show the stimulation devices of Figures 23A to 23C in combination with constriction devices, such as the bellow valves described in relation to Figures 14A and 14B, for at least partly constricting the intestine section mechanically. Complete constriction is obtained by additional electrical stimulation of the respective intestine sections. The constriction devices may be released in order to allow intestinal contents to flow through.

[0127] Figure 25 shows a sim system similar to the system of Figure 1, however, with a flow control device in the form of an exit valve being implanted within the artificial intestine section. An external manually driven suction pump is used for emptying the artificial intestine section, wherein a conduit on the front end of the pump is inserted from outside the patient's body into the intestine, thereby mechanically urging the exit valve to open.

CLAIMS

LATERALLY CONNECTED ARTIFICIAL INTESTINE SECTION

1. An artificial intestine section adapted to be implanted inside a patient's body, said intestine section having a first open end portion and a second open end portion in flow communication with one another, wherein at least the first open end portion is adapted to being connected to a surgically created lateral opening in a wall of the patient's intestine.

2. The artificial intestine section of claim 1, wherein the second open end portion is adapted to being connected to a surgically created stomy.

3. The artificial intestine section of claim 1, wherein the second open end portion is adapted to being connected to the patient's rectum or anus or to tissue adjacent the patient's anus.

4. The artificial intestine section of claim 1, wherein the second open end portion is adapted to being connected to a patient's small intestine.

5. The artificial intestine section of claim 1, wherein the second open end portion is adapted to being connected to a patient's large intestine.

BY-PASS ARRANGEMENT

6. The artificial intestine section of any of claims 1 to 3, wherein both the first and second open end portions are adapted to being connected to a surgically created lateral opening in a wall of the patient's intestine.

STRUCTURE OF ATTACHMENT

7. The artificial intestine section of any of claims 1 to 6, wherein at least the first open end portion comprises a shoulder portion formed around the end portion for lateral connection to the patient's intestinal wall.

8. The artificial intestine section of claim 7, wherein at least a part of the shoulder portion extends laterally from the artificial intestine section by 3 mm to 20 mm.

9. The artificial intestine section of any of claims 7 to 8, wherein the shoulder portion has a curved cross section, so as to generally conform to an intestinal wall when laterally attached thereto.

10. The artificial intestine section of any of claims 7 to 9, wherein the shoulder portion is split into an upper and a lower shoulder portion with a gap between the upper and lower shoulder portions adapted to accommodate intestinal wall tissue therein.

11. The artificial intestine section of claim 10, wherein the lower shoulder portion is adapted to being placed inside the patient's intestine through a surgically created lateral opening in the intestinal wall and wherein the upper shoulder portion is adapted to being placed outside the intestinal wall.

12. The artificial intestine section of claim 11, wherein the upper shoulder portion and the lower shoulder portion each have a surface area facing the intestinal wall, with the surface area of the upper shoulder portion being larger than the surface area of the lower shoulder portion.

13. The artificial intestine section of any of claims 1 to 12, wherein at least the first open end portion is adapted to being connected to the patient's intestinal wall by gluing.

14. The artificial intestine section of any of claims 1 to 13, wherein at least the first open end portion is adapted to being connected to the patient's intestinal wall by sewing.

15. The artificial intestine section of any of claims 1 to 13, wherein at least the first open end portion is adapted to being connected to the patient's intestinal wall by stapling.

16. The artificial intestine section of any of claims 1 to 14, wherein at least the first open end portion is made from a biocompatible material.

17. The artificial intestine section of claim 16, wherein the biocompatible material of the open end portion comprises at least one material of the following group of materials: titanium, stainless steel, ceramics, biocompatible polymer material.

18. The artificial intestine section of claim 17, wherein the biocompatible polymer material comprises at least one polymer of the following group of polymers: polytetrafluoroethylene, silicone, polyurethane, expanded polytetrafluoroethylene (ePTFE).

19. The artificial intestine section of any of claims 1 to 18, wherein at least the first open end portion comprises a multilayer material.

20. The artificial intestine section of any of claims 1 to 19, wherein at least the first open end portion comprises a porous ingrowth layer allowing ingrowth of living tissue.

21. The artificial intestine section of claim 20, wherein the ingrowth layer has a net-like structure.

22. The artificial intestine section of any of claims 20 to 21, wherein the ingrowth layer is made from Dacron®.

INTESTINAL CONTENT INTERACTING DEVICE WITHIN ARTIFICIAL INTESTINE SECTION

23. The artificial intestine section of any of claims 1 to 22, comprising at least one element adapted to directly or indirectly interact with intestinal contents contained in the artificial intestine section between the first and second open end portions thereof.

RESERVOIR

24. The artificial intestine section of claim 23, wherein the at least one element comprises an artificial reservoir between the first and second open end portions for receiving and temporarily collecting therein intestinal contents supplied through the first open end portion.

FLOW CONTROL DEVICE

25. The artificial intestine section of any of claims 23 to 24, wherein the at least one element comprises a flow control device adapted to control flow of intestinal contents from the artificial intestine section through the second open end portion.

26. The artificial intestine section of claim 25, wherein the flow control device is adapted to prevent flow of intestinal contents from the artificial intestine section through the second open end portion.

EXIT VALVE AS FLOW CONTROL DEVICE

27. The artificial intestine section of any of claims 25 to 26, wherein the flow control device comprises at least one valve, including an exit valve preventing

intestinal contents flow through the second open end portion in its closed position.

28. The artificial intestine section of claim 27, wherein the exit valve is a normally closed valve.

ENTRY VALVE AS AN ADDITITONAL PART OF THE FLOW CONTROL DEVICE

29. The artificial intestine section of any of claims 27 to 28, wherein the flow control device comprises an entry valve allowing intestinal contents to flow through the first open end portion into the artificial intestine section in its open position.

30. The artificial intestine section of claim 29, wherein the entry valve is a normally open valve.

31. The artificial intestine section of any of claims 29 to 30, wherein the exit valve and the entry valve are adapted to cooperate such that when one of the two valves is closed, the other valve is open, and vice versa.

VALVE TYPES

32. The artificial intestine section of any of claims 27 to 31, wherein the exit valve comprises a central opening which is normally closed by resilient means that can be urged apart mechanically by inserting a conduit through the central opening so as to open the central opening of the exit valve.

33. The artificial intestine section of any of claims 27 to 32, wherein the at least one valve comprises a compartment with a variable volume adapted to open and close the valve by changing the compartment's volume.

34. The artificial intestine section of claim 33, wherein the at least one valve comprises at least one passage for filling and emptying the compartment with hydraulic fluid.

35. The artificial intestine section of any of claims 33 to 34, wherein the compartment has at least one flexible wall defining an opening, the opening being adapted to close upon increase of the compartment's volume.

36. The artificial intestine section of any of claims 27 to 32, wherein the at least one valve is a flap valve.

37. The artificial intestine section of claim 36, wherein the flap valve comprises a rotatable disc.

EXTRA VALVE SEPARATE FROM ARTIFICIAL INTESTINE PIECE

38. The artificial intestine section of any of claims 1 to 37, further comprising at least one extra valve adapted to control flow of intestinal contents in a natural section of a patient's intestine upstream and/or downstream the artificial intestine section, wherein the extra valve is adapted to being implanted inside the patient's body outside a section of the patient's natural intestine and comprises at least one element adapted to act on the natural intestine section from the outside thereof so as to prevent intestinal contents flow through the natural intestine section.

39. The artificial intestine section of claim 38, wherein the extra valve comprises at least one electrical stimulation device adapted to electrically stimulate muscle or neural tissue of the natural intestine section so as to cause at least partial contraction of the natural intestine section.

40. The artificial intestine section of claim 39, wherein the stimulation device comprises at least one electrode adapted to apply electric pulses to the natural intestine section.

41. The artificial intestine section of any of claims 39 to 40, wherein the stimulation device is adapted to stimulate different portions of the natural intestine section over time.

42. The artificial intestine section of claim 41, wherein the stimulation device is adapted to stimulate, over time, the different portions of the natural intestine section in a wave like manner in a direction opposite to natural intestinal contents flow.

43. The artificial intestine section of any of claims 38 to 42, wherein the extra valve comprises a constriction device for at least partly constricting the natural intestine section mechanically.

44. The artificial intestine section of claim 43, including claim 39, wherein the stimulation device is combined with the constriction device so that the stimulation device and the constriction device act on the same natural intestine section.

45. The artificial intestine section of claim 44, wherein the constriction device in its normal condition constricts the natural intestine section only partly.

46. The artificial intestine section of any of claims 44 to 45, wherein the stimulation device is adapted to pump intestinal contents along the natural intestine section by, over time, stimulating the different portions of the natural intestine section in a wave like manner in a direction of natural intestinal contents flow.

PUMP AS PART OF THE IMPLANTABLE FLOW CONTROL DEVICE

47. The artificial intestine section of any of claims 25 to 46, wherein the flow control device comprises a pump for advancing intestinal contents through the second open end portion to outside the artificial intestine section.

48. The artificial intestine section of claim 47, including claim 24, wherein the pump is adapted for emptying the reservoir.

49. The artificial intestine section of claim 48, wherein the reservoir is formed by a bellow, said bellow having an end wall closing the bellow at one end thereof, said end wall making part of the pump such that a volume of the bellow is reduced upon advancement of said end wall.

50. The artificial intestine section of claim 49, wherein the bellow is made of a resilient material so as to urge the bellow into a normally expanded position.

51. The artificial intestine section of claim 48, wherein the pump comprises a movable piston, with a front end of the piston extending into the reservoir such that a volume of the reservoir is reduced upon advancement of the piston.

52. The artificial intestine section of claim 51, wherein the piston is spring loaded so as to urge the piston into a normally retracted position.

53. The artificial intestine section of claim 48, wherein the pump is adapted for being permanently arranged inside the reservoir.

54. The artificial intestine section of claim 48, wherein the reservoir has a flexible wall and the pump is adapted for emptying the reservoir by squeezing the reservoir.

55. The artificial intestine section of claim 54, wherein the pump includes a constriction device adapted to alternately constrict and release sections of the reservoir so as to pump intestinal contents along the reservoir by, over time, constricting different sections of the reservoir in a wave like manner.

56. The artificial intestine section of claim 55, wherein the reservoir has a tube-like form and the pump is a roller pump acting on the tube-like reservoir from the outside thereof.

MOTOR

57. The artificial intestine section of any of claims 25 to 56, wherein the at least one element comprises at least one motor arranged for automatically driving at least one energy consuming parts of the flow control device.

58. The artificial intestine section of claim 57, including the artificial intestine section of any of claims 27 to 46, wherein the at least one motor is arranged for driving at least one of the valve or valves, respectively, between closed and open positions.

59. The artificial intestine section of any of claims 57 to 58, including the artificial intestine section of any of claims 47 to 56, wherein the at least one motor is arranged for driving the pump.

60. The artificial intestine section of any of claims 57 to 59, comprising a manually operable switch for activating the at least one motor, the switch being arranged for subcutaneous implantation so as to be operable from outside the patient's body.

61. The artificial intestine section of any of claims 57 to 60, wherein the motor is arranged to be driven by electric or electromagnetic energy.

ENERGY SOURCE

62. A system comprising the artificial intestine section of any of claims 1 to 61 and further comprising an energy source for supplying energy directly or indirectly to at least one energy consuming part of the system.

63. The system of claim 62, wherein said energy source includes a battery as an energy storage means.

64. The system of claim 63, wherein said energy source includes an accumulator as an energy storage means.

65. The system of claim 64, wherein the accumulator comprises one or more of a rechargeable battery and a capacitor.

66. The system of any of claims 63 to 65, wherein the energy storage means is adapted for being implanted inside the patient's body.

67. The system of any of claims 63 to 66, wherein the energy storage means supplies energy for at least one energy consuming part of the at least one element.

WIRELESS ENERGY TRANSMISSION

68. The system of claim 62, wherein the energy source comprises a wireless energy transmitter adapted to wirelessly transmit energy from outside the patient's body to the at least one energy consuming part.

69. The system of any of claims 63 to 67, wherein the energy source comprises a wireless energy transmitter adapted to wirelessly transmit energy from outside the patient's body to the energy storage means.

70. The system of claim 69, comprising a feedback subsystem adapted to wirelessly send feedback information related to the energy to be stored in the accumulator from inside the human body to the outside thereof, wherein the system is adapted to use the feedback information for adjusting the amount of wireless energy transmitted by the energy transmitter.

71. The system of claim 70, wherein the feedback information is related to an energy balance which is defined as the balance between an amount of wireless energy received inside the human body and an amount of energy consumed by the at least one energy consuming part.

72. The system of claim 70, wherein the feedback information is related to an energy balance which is defined as the balance between a rate of wireless energy received inside the human body and a rate of energy consumed by the at least one energy consuming part.

73. The system of any of claims 69 to 72, comprising a wireless energy transmitter adapted to wirelessly transmit energy from the energy storage means to the at least one energy consuming part.

74. The system of any of claim 68 or 73, wherein the energy consuming part is adapted to directly transform the wirelessly transmitted energy into kinetic energy.

75. The system of any of claims 68 to 73, comprising an implantable energy transforming device for transforming wirelessly transmitted energy into electric energy.

76. The system of claim 75, wherein the energy consuming part is driven with the electric energy, as said energy transforming device transforms the wireless energy into the electric energy.

GALVANIC ENERGY TRANSMISSION

77. The system of any of claims 62 to 67, further comprising galvanic coupling elements between the energy source and the motor for transmitting energy to the motor in contacting fashion.

CONTROL UNIT

78. A system comprising an artificial intestine piece of any of claims 23 to 61, or the system of any of claims 62 to 77, further comprising a control unit adapted to directly or indirectly control one or more elements of the system.

79. The system of claim 78, including claim 27, wherein the control unit is adapted to control opening of the exit valve.

80. The system of any of claims 78 to 79, including claim 29, wherein the control unit is adapted to control closing of the entry valve.

81. The system of claim 80, wherein the control unit is adapted to control opening of the exit valve and closing of the entry valve such that when one of the two valves is closed, the other valve is open, and vice versa.

82. The system of any of claims 78 to 81, including claim 47, wherein the control unit is adapted to control actuation of the pump.

83. The system of any of claims 78 to 82, wherein the control unit is operable by the patient.

84. The system of any of claims 78 to 83, wherein at least part of the control unit is implantable in the patient's body.

85. The system of claim 84, comprising a manually operable switch for activating the control unit, the switch being arranged for subcutaneous implantation so as to be operable from outside the patient's body.

86. The system of any of claims 78 to 85, wherein the control unit comprises a first part adapted for implantation in the patient's body and a second part adapted to cooperate with the first part from outside the patient's body.

87. The system of claim 86, including claim 68, wherein the control unit is adapted to transmit data from the second part of the control unit to the implantable first part of the control unit in the same manner as energy is transmitted to the at least one energy consuming part.

88. The system any of claims 86 to 87, wherein the second part of the control unit is adapted to wirelessly transmit a control signal to the implantable first part of the control unit for controlling the at least one energy consuming part from outside the patient's body.

89. The system of any of claims 86 to 88, wherein the implantable first part of the control unit is programmable via the second part of the control unit.

90. The system of any of claims 86 to 89, wherein the implantable first part of the control unit is adapted to transmit a feedback signal to the second part of the control unit.

SENSOR

91. A system comprising an artificial intestine piece of any of claims 1 to 61, or the system of any of claims 62 to 90, further comprising a physical parameter sensor adapted to directly or indirectly sense a physical parameter of the patient.

92. The system of claim 91, wherein the physical parameter sensor is adapted to sense at least one of the following physical parameters of the patient: a pressure within the artificial intestine section, a pressure within the patient's intestine, an expansion of the artificial intestine section, a distension of an intestinal wall of the patient's intestine, a movement of the intestinal wall.

93. A system comprising an artificial intestine piece of any of claims 1 to 61, or the system of any of claims 62 to 92, further comprising a functional parameter

sensor adapted to directly or indirectly sense a functional parameter of the system.

94. The system of any of claims 93, wherein the functional parameter sensor is adapted to sense at least one of the following functional parameters of the system: a pressure against a part of the system such as the artificial intestine section, a distension of a part of the system such as a wall of the artificial intestine section, an electrical parameter such as voltage, current or energy balance, a position or movement of a movable part of the system.

95. The system of any of claims 91 to 94, comprising an indicator coupled to the sensor, the indicator being adapted to provide a signal when the sensor senses a value for the parameter beyond a predetermined threshold value.

96. The system of claim 95, wherein the signal comprises at least one of the following types of signals: a sound signal, a visual signal.

INTESTINAL CONTENTS COLLECTING DEVICE (WITH "EXTERNAL" PUMP)

97. A system comprising an artificial intestine piece of any of claims 1 to 61, or the system of any of claims 62 to 96, further comprising an intestinal contents collecting device to be temporarily applied from outside the patient's body.

98. The system of claim 97, including claim 27, wherein the collecting device comprises a front open end adapted to be applied towards said exit valve so as to provide a flow passage from the exit valve towards the collecting device.

99. The system of claim 98, wherein the collecting device front open end is adapted to be applied to said exit valve so as to open the valve and thereby provide the flow passage towards the collecting device.

100. The system of claim 99, including claim 32, wherein said front open end is adapted to be inserted through the central opening of said exit valve so as to urge apart the resilient means normally closing the central opening.

101. The system of any of claims 97 to 100, wherein the collecting device comprises a suction pump.

102. The system of claim 101, wherein the suction pump comprises a piston-cylinder-arrangement.

103. The system of claim 102, wherein the suction pump is adapted to be driven manually.

104. The system of any of claims 97 to 103, further comprising a motor connected to the suction pump for driving the pump automatically.

105. The system of any of claims 97 to 104, including any of claims 47 to 56, wherein the suction pump is provided as a back-up pump for a situation where the pump of the flow control device is out of operation.

METHOD OF TREATMENT (IMPLANTATION)

LATERAL CONNECTION

106. A surgical method of treating a patient, comprising the steps of:
- cutting the patient's skin and abdominal wall,
- dissecting an area of the patient's intestine,
- surgically creating at least one opening in a wall of the dissected intestinal area so as to create an artificial lateral intestinal opening,
- providing an artificial intestine section having a first open end portion and a second open end portion in flow communication with one another and affixing the first open end portion to the lateral intestinal opening so as to be in flow communication therewith, and
- suturing the abdominal wall and skin.

107. A laparoscopic surgical method of treating a patient, comprising the steps of:
- making a small opening in the patient's skin and abdominal wall,
- introducing a needle in the abdominal cavity,
- inflating the abdominal cavity with gas,
- inserting at least one trocar into the cavity,
- introducing a camera through the trocar,
- inserting at least one dissecting instrument preferably through a second trocar,
- dissecting an area of the intestine,
- surgically creating at least one opening in a wall of the dissected intestinal area so as to create an artificial lateral intestinal opening,
- providing an artificial intestine section having a first open end portion and a second open end portion in flow communication with one another and affixing the first open end portion to the lateral intestinal opening so as to be in flow communication therewith,
- extracting the instruments, camera and trocar, and in relation thereto

- suturing, if necessary, the abdominal wall and permanently closing the skin.

CLOSING THE INTESTINE BY SEWING

108. The method of any of claims 106 to 107, comprising the steps of:
- permanently closing the patient's intestine in the dissected portion at a location downstream of the lateral intestinal opening so as to create an upstream part of the intestine including the lateral intestinal opening and a downstream part of the intestine,
- affixing the second open end portion of the artificial intestine section to the downstream intestinal part.

109. The method of claim 108, wherein the step of permanently closing the patient's intestine comprises sewing or stapling, or sewing and stapling, the intestinal wall so as to form a dead end.

DIVIDING THE INTESTINE

110. The method of any of claims 106 to 107, comprising the steps of:
- dissecting a portion of the dissected intestinal area downstream of the lateral intestinal opening such that intestinal mesentery connected to the dissected portion is opened in such a way that supply of blood through the mesentery to the dissected intestinal area is maintained as far as possible on both sides of the dissected portion,
- dividing the patient's intestine in the dissected portion so as to create an upstream part of the intestine with the lateral intestinal opening and a downstream part of the intestine, said downstream intestine part being separate from the upstream intestine part and having a cross-sectional opening at the upstream side thereof, wherein the mesentery maintains a tissue connection between the upstream and downstream intestine parts,
- affixing the second open end portion of the artificial intestine section to the downstream intestine part, and
- permanently closing the upstream intestine part at a location downstream of the lateral intestinal opening.

LATERAL FRONT AND LATERAL END CONNECTION (BY-PASS)

111. The method of any of claims 108 to 109, wherein the step of affixing the second open end portion of the artificial intestine section to the downstream intestinal part comprises the steps of:
- surgically creating an opening in a wall of the downstream intestinal part at an upstream end thereof so as to create a second artificial lateral intestinal opening, and

- affixing the second open end portion of the artificial intestine section to the second lateral intestinal opening so as to be in flow communication therewith.

112. The method of claim 111, wherein the step of permanently closing the patient's intestine comprises sewing the intestinal wall with two rows of sutures or staples and cutting and dividing the intestine between the sutures or staples so as to form two dead ends.

113. The method of claim 110, wherein the step of affixing the second open end portion of the artificial intestine section to the downstream intestinal part comprises the steps of:
- surgically creating an opening in a wall of the downstream intestinal part at an upstream end thereof so as to create a second artificial lateral intestinal opening,
- affixing the second open end portion of the artificial intestine section to the second lateral intestinal opening so as to be in flow communication therewith, and
- permanently closing the cross-sectional opening at the upstream side of the downstream intestine part at a location upstream of the second lateral intestinal opening.

LATERAL FRONT CONNECTION AND STRAIGHT END CONNECTION

114. The method of claim 110, wherein the step of affixing the second open end portion of the artificial intestine section to the downstream intestinal part comprises the step of:
- affixing the second open end portion of the artificial intestine section to the cross-sectional upstream opening of the downstream intestine part so as to be in flow communication therewith.

SLEEVE/BULGE CONNECTOR

115. The method of claim 114, wherein the step of affixing the second open end portion of the artificial intestine section to the cross-sectional upstream opening of the downstream intestine part comprises:
- inserting the second open end portion of the artificial intestine section into the upstream opening of the downstream intestine part, and
- placing a flexible sleeve so as to extend over both the downstream intestine part and second open end portion of the artificial intestine section such that the downstream intestine part is located intermediate the sleeve and the outer surface of the artificial intestine section.

116. The method of claim 115, wherein the flexible sleeve is mounted on the outer surface of the second open end portion of the artificial intestine piece so as to be foldable upon itself and wherein the step of placing the flexible sleeve so as to extend over both the downstream intestine part and second open end portion of the artificial intestine section comprises folding the flexible sleeve upon itself such that the downstream intestine part is located intermediate the folded sleeve.

117. The method of claim 114, wherein the step of affixing the second open end portion of the artificial intestine section to the cross-sectional upstream opening of the downstream intestine part comprises:
- inserting the artificial intestine section having a bulge formed on the outside thereof into the upstream opening of the downstream intestine part so that the downstream intestine part extends over the bulge from one side of the bulge, and
- advancing a blocking ring over the downstream intestine part towards the bulge from the respective other side of the bulge such that the downstream intestine part is located intermediate the outer surface of the artificial intestine section and the blocking ring.

EXIT THROUGH STOMA

118. The method of any of claims 106 to 117, further comprising the steps of:
- cutting the patient's skin and abdominal wall so as to create an opening for an intestinal stomy,
- dissecting the area of the stomy opening,
- dividing the intestine at a location downstream of the artificial intestine piece so as to create an upstream natural intestine section having a cross-sectional opening at the downstream end thereof and a downstream natural intestine section,
- dissecting the mesentery of the upstream natural intestine section in the area of the cross-sectional opening thereof to prepare for creating the intestinal stomy,
- advancing the downstream end of the upstream natural intestine section through the abdominal wall and skin, and
- suturing the cross-sectional opening of the upstream natural intestine section to the skin with the intestinal mucosa turned inside out, thereby achieving the intestinal stomy.

EXIT THROUGH ANUS

119. The method of any of claims 106 to 117, further comprising the steps of:

- dividing the intestine at a location downstream of the artificial intestine piece so as to create an upstream natural intestine section having a cross-sectional opening at the downstream end thereof and a downstream natural intestine section leading to the patient's anus,
- dissecting the area of the patient's anus and surgically separating the downstream natural intestine section from the patient's anus, whereas the steps of dividing the intestine and separating the intestine section leading to the patient's anus can alternatively be carried out in reversed order,
- dissecting the mesentery of the upstream natural intestine section in the area of the cross-sectional opening at the downstream end thereof to prepare for connecting the upstream natural intestine section to the patient's anus or tissue adjacent the patient's anus,
- advancing the downstream end of the upstream natural intestine section through the patient's anus, and
- suturing the cross-sectional opening of the upstream natural intestine section to the patient's anus or tissue adjacent the patient's anus.

120. The method of any of claims 118 to 119, wherein the natural intestine section is selected from the patient's small intestine.

121. The method of any of claims 118 to 119, wherein the natural intestine section is selected from the patient's large intestine.

STRUCTURE OF ATTACHMENT

122. The method of any of claims 106 to 121, wherein the step of affixing the first open end portion of the artificial intestine section to the lateral intestinal opening so as to be in flow communication therewith comprises connecting a shoulder portion, which is formed around the first open end portion of the artificial intestine section, to the patient's intestinal wall so as to surround the lateral intestinal opening.

123. The method of claim 122, wherein the step of connecting the shoulder portion comprises attaching the shoulder portion to the patient's outer intestinal wall.

124. The method of claim 122, wherein the shoulder portion is split into an upper and a lower shoulder portion with a gap between the upper and lower shoulder portions, and wherein the step of affixing the first open end portion of the artificial intestine section to the lateral intestinal opening comprises placing the lower shoulder portion inside the patient's intestine and the upper shoulder portion outside the patient's intestine such that intestinal wall tissue is accommodated in the gap.

125. The method of any of claims 122 to 124, wherein the step of affixing the first open end portion of the artificial intestine section to the lateral intestinal opening comprises gluing the first open end portion to the patient's intestinal wall.

126. The method of any of claims 122 to 125, wherein the step of affixing the first open end portion of the artificial intestine section to the lateral intestinal opening comprises sewing the first open end portion to the patient's intestinal wall.

127. The method of any of claims 122 to 126, wherein the step of affixing the first open end portion of the artificial intestine section to the lateral intestinal opening comprises stapling the first open end portion to the patient's intestinal wall.

128. The method of any of claims 122 to 127, comprising the step of selecting for the first open end portion at least one biocompatible material from the following group of materials: titanium, stainless steel, ceramics, biocompatible polymer material.

129. The method of claim 128, comprising the step of selecting for the first open end at least one biocompatible polymer from the following group of polymers: polytetrafluoroethylene, silicone, polyurethane, expanded polytetrafluoroethylene (ePTFE).

130. The method of any of claims 122 to 129, comprising the step of selecting for the first open end a multilayer material.

131. The method of any of claims 122 to 130, comprising the step of providing the first open end portion with a porous ingrowth layer allowing ingrowth of living tissue.

132. The method of claim 131, comprising the step of choosing the ingrowth layer to have a net-like structure.

BLACK BOX WITHIN ARTIFICIAL INTESTINE PIECE

133. The method of any of claims 106 to 132, comprising the step of implanting along with the artificial intestine section at least one element adapted to directly

or indirectly interact with intestinal contents contained in the artificial intestine section between the first and second open end portions thereof.

RESERVOIR

134. The method of claim 133, wherein the at least one element comprises an artificial reservoir between the first and second open end portions for receiving and temporarily collecting therein intestinal contents supplied through the first open end portion.

FLOW CONTROL DEVICE

135. The method of any of claims 133 to 134, wherein the at least one element comprises a flow control device adapted to control flow of intestinal contents from the artificial intestine section through the second open end portion.

EXIT VALVE

136. The method of claim 135, wherein the flow control device comprises an exit valve preventing intestinal contents flow through the second open end portion in its closed position.

ENTRY VALVE

137. The method of any of claims 135 to 136, wherein the flow control device comprises an entry valve allowing intestinal contents to flow through the first open end portion into the artificial intestine section in its open position.

PUMP

138. The method of any of claims 135 to 137, wherein the flow control device comprises a pump for advancing intestinal contents through the second open end portion to outside the artificial intestine section.

139. The method of claim 138, wherein the pump comprises a manually operable switch for activating the pump, the method further comprising the step of implanting the switch subcutaneously so as to be operable from outside the patient's body.

MOTOR

140. The method of any of claims 135 to 138, wherein the at least one element comprises at least one motor arranged for automatically driving one or more energy consuming part of the flow control device.

141. The method of claim 140, wherein the motor comprises a manually operable switch for activating the motor, the method further comprising the step of

implanting the switch subcutaneously so as to be operable from outside the patient's body.

ENERGY SOURCE / ENERGY TRANSMISSION

142. The method of any of claims 106 to 141, further comprising the step of implanting inside the patient's body an energy source for supplying at least one energy consuming part with energy.

143. The method of claim 142, wherein the energy source comprises energy storage means.

144. The method of any of claims 142 to 143, further comprising the step of implanting an energy transforming device for transforming wireless energy into electric energy.

145. The method of any of claims 142 to 144, further comprising the step of implanting galvanic coupling elements for transmitting energy to the energy consuming part in contacting fashion.

CONTROL UNIT

146. The method of any of claims 106 to 145, further comprising the step of implanting inside the patient's body at least a part of a control unit adapted to directly or indirectly control one or more elements implanted in the patient's body.

147. The method of claim 146, wherein the control unit comprises a manually operable switch for activating the control unit, the method further comprising the step of implanting said switch subcutaneously so as to be operable from outside the patient's body.

SENSOR

148. The method of any of claims 106 to 147, further comprising the step of implanting a physical parameter sensor adapted to directly or indirectly sense a physical parameter inside the patient.

149. The method of any of claims 106 to 148, further comprising the step of implanting a functional parameter sensor adapted to directly or indirectly sense a functional parameter of the system inside the patient.

150. The method of any of claims 148 to 149, wherein the sensor is a pressure sensor and is placed in the artificial intestine section or the patient's natural

intestine so as to sense the pressure within the artificial intestine section or patient's natural intestine, respectively.

151. The method of any of claims 148 to 150, wherein the sensor is a tension sensor and is placed in contact with the artificial intestine section or the patient's intestine so as to sense an expansion of the artificial intestine section or patient's natural intestine, respectively.

152. The method of any of claims 148 to 151, wherein the sensor is a movement sensor and is placed in contact with the artificial intestine section or the patient's natural intestine so as to sense movement of the artificial intestine section or patient's natural intestine, respectively.

153. The method of any of claims 149 to 152, wherein the sensor is adapted to measure at least one of the following functional parameters: an electrical parameter such as voltage, current or energy balance or a stimulation parameter in relation to the system.

USE

154. A method of treating a patient by means of the artificial intestine section of claim 23, comprising the step of actuating the at least one element so as to interact with intestinal contents contained in the artificial intestine section between the first and second open end portions thereof.

EXIT AND ENTRY VALVE

155. The method of treating a patient according to claim 154, wherein the at least one element comprises an exit valve preventing intestinal contents flow from the artificial intestine section through the second open end portion in its closed position, the method further comprising the steps of opening the exit valve and then removing intestinal contents from the artificial intestine section.

156. The method of treating a patient according to claim 155, wherein the at least one element comprises an entry valve allowing intestinal contents to flow through the first open end portion into the artificial intestine section in its open position, the method further comprising the step of closing the entry valve before removing intestinal contents from the artificial intestine section.

157. The method of treating a patient according to any of claims 155 to 156, comprising the step of inserting a conduit from outside the patient's body into the artificial intestine section, thereby mechanically urging the exit valve to open.

PUMP

158. The method of any of claims 154 to 157, wherein the at least one element comprises a pump, the method further comprising the step of advancing intestinal contents from the artificial intestine section through the second open end portion thereof to outside the artificial intestine section by means of the pump.

159. The method of claim 158, further comprising the step of activating the pump by manually operating a subcutaneously arranged actuator from outside the patient's body.

160. The method of any of claims 154 to 157, further comprising the steps of providing a flow passage so as to extend from the artificial intestine section to an external collecting device and removing intestinal contents from the artificial intestine section by means of a suction pump.

MOTOR

161. The method of claim 160, comprising the step of driving the suction pump by means of a motor.

162. The method of any of claims 155 to 157, wherein the at least one element comprises a motor, the method further comprising the step of driving at least the exit valve between its closed and open positions by means of the motor.

163. The method of claim 158, wherein the at least one element comprises a motor, the method further comprising the step of driving at least the pump by means of the motor.

164. The method of any of claims 162 to 163, further comprising the step of activating the motor by manually operating a subcutaneously arranged actuator from outside the patient's body.

ENERGY

165. The method of any of claims 154 to 164, further comprising the step of transmitting energy from outside the patient's body to at least one implanted energy consuming part.

166. The method of claim 165, wherein in the step of transmitting energy from outside the patient's body to the energy consuming part, the energy is transmitted wirelessly.

167. The method of any of claims 154 to 164, further comprising the steps of:
- transmitting energy wirelessly,
- transforming the wirelessly transmitted energy into electric energy by means of an energy transforming device,
- storing the transformed energy in an energy storage means, and
- supplying the stored energy from the energy storage means to at least one implanted energy consuming part.

168. The method of claim 167, wherein in the step of supplying the energy from the storage means to the energy consuming part, the energy is transmitted wirelessly.

169. The method of any of claims 167 to 168, comprising the step of transforming at least part of the wirelessly transmitted energy into electric energy and supplying said part of transformed energy to the energy consuming part, as said part of the wirelessly transmitted energy is transformed into the electric energy.

CONTROL

170. The method of any of claims 154 to 169, wherein a first part of a control unit for controlling at least one implanted energy consuming part is implanted inside the patient's body, the method further comprising the step of using an external second part of the control unit adapted to cooperate with the first part from outside the patient's body to transmit data to the implanted first part of the control unit.

171. The method of claim 170, including claim 165, wherein the data are transmitted to the implanted first part of the control unit in the same manner as energy is transmitted for driving the implanted energy consuming part.

172. The method of any of claims 170 to 171, wherein the data are transmitted wirelessly to the implanted first part of the control unit.

173. The method of any of claims 170 to 172, wherein the data are transmitted wirelessly via a wireless control signal.

174. The method of any of claims 170 to 173, comprising the step of programming the implanted first part of the control unit via the external second part of the control unit.

175. The method of any of claims 170 to 174, comprising the step of transmitting a feedback signal from the implanted first part of the control unit to the external second part of the control unit.

SENSOR

176. The method of any of claims 154 to 175, comprising the step of sensing a physical parameter in the patient's body.

177. The method of claim 176, wherein the step of sensing a physical parameter in the patient's body comprises sensing at least one of the following physical parameters of the patient: a pressure within the artificial intestine section, a pressure within the patient's natural intestine, an expansion of the artificial intestine section, a distension of an intestinal wall of the patient's natural intestine, a movement of the patient's intestinal wall.

178. The method of any of claims 154 to 177, comprising the step of sensing a functional parameter of the system in the patient's body.

179. The method of claim 178, wherein the step of sensing a functional parameter of the system in the patient's body comprises sensing at least one of the following parameters: a pressure against a part of the system such as the artificial intestine section, a distension of a part of the system such as a wall of the artificial intestine section, an electrical parameter such as voltage, current or energy balance, a position or movement of a movable part of the system.

180. The method of any of claims 176 to 179, comprising the step of providing a signal when a value for the physical parameter sensed is beyond a predetermined threshold value.

181. The method of claim 180, wherein the step of providing a signal includes at least one of the following types of signals: a sound signal, a visual signal.

FIG 1

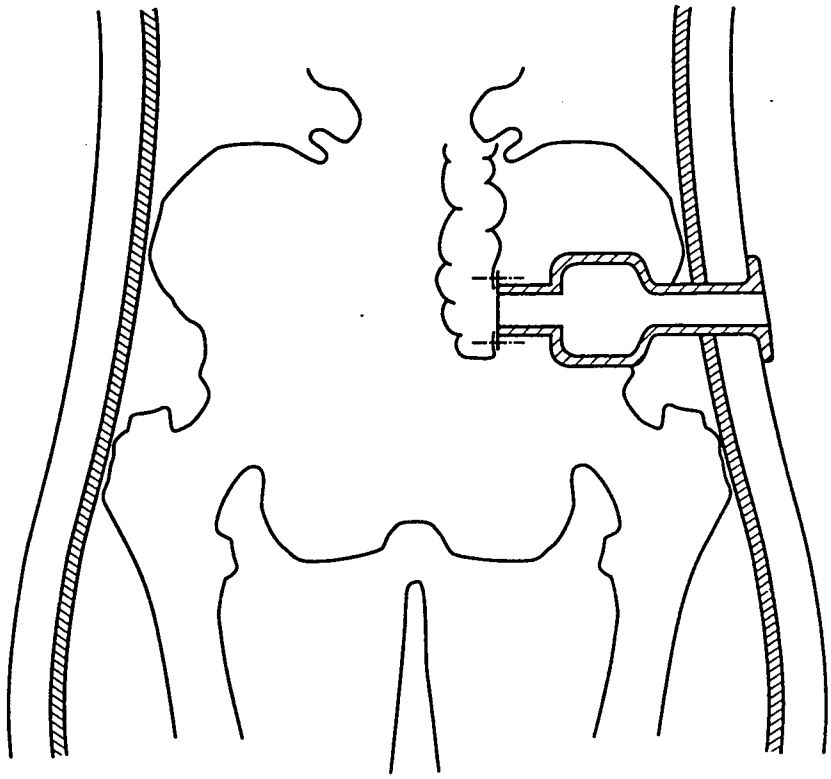


FIG 2

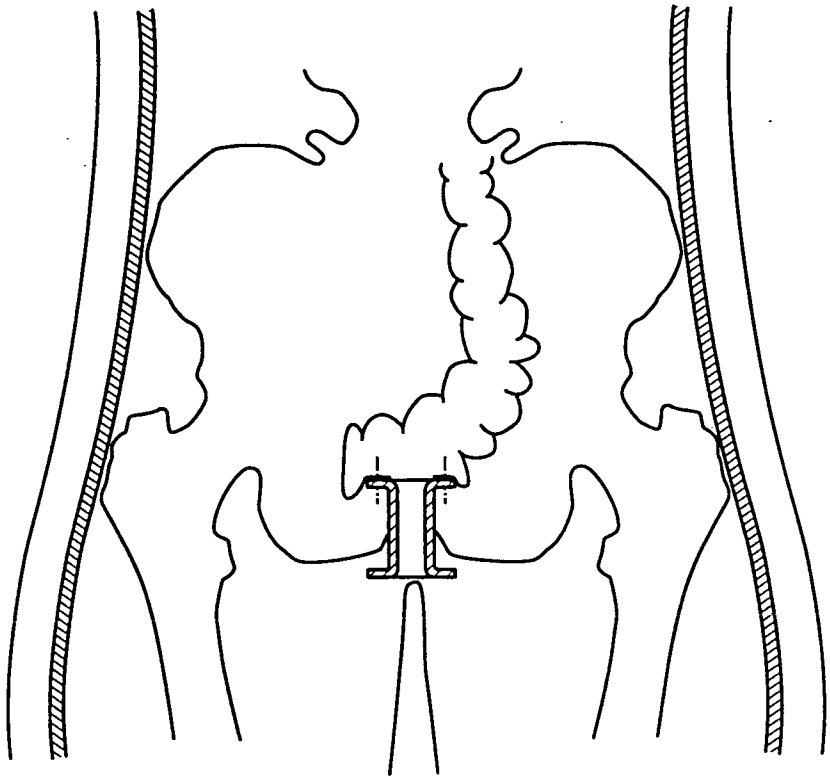


FIG 3

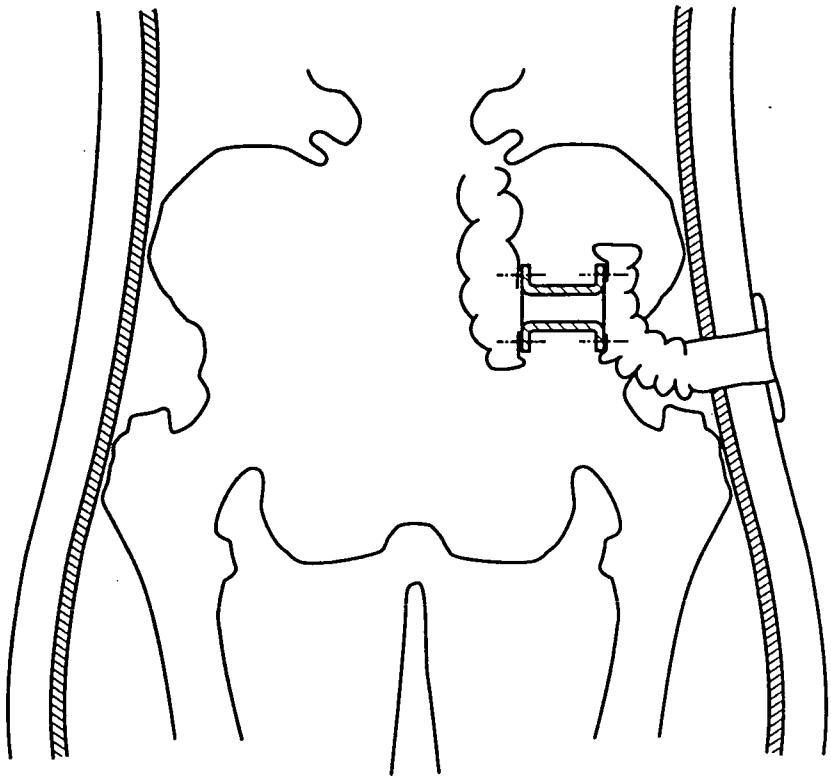


FIG 4

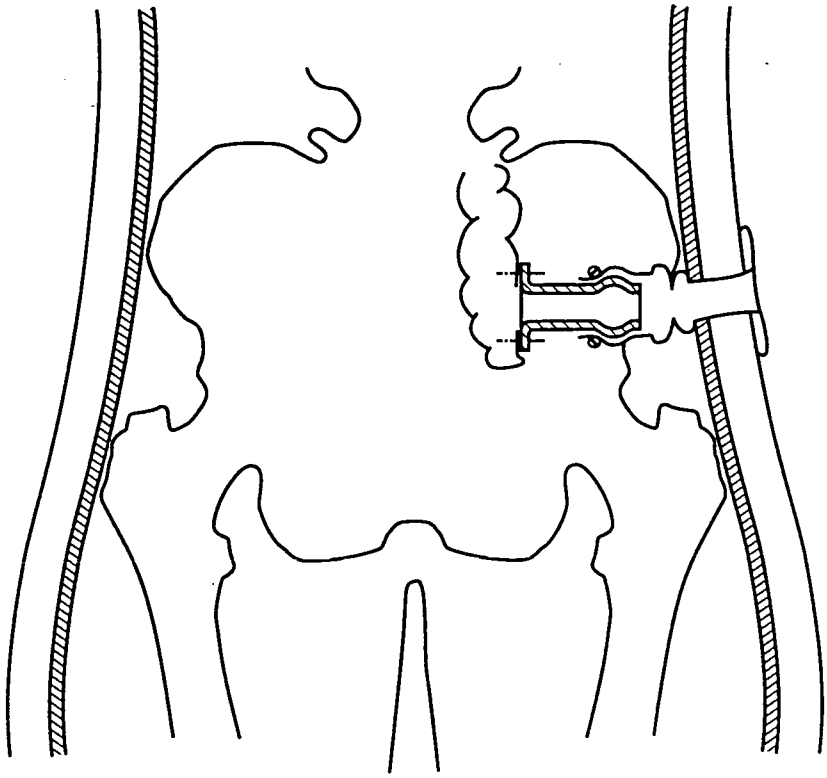


FIG 5

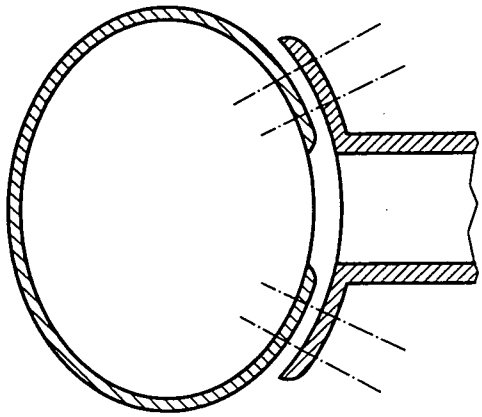


FIG 6

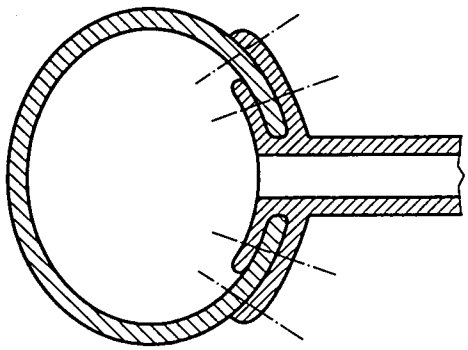


FIG 7

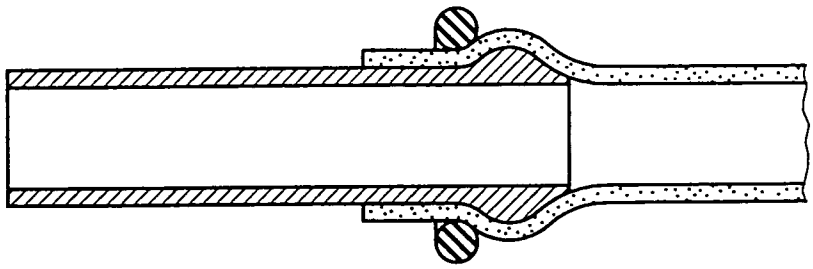


FIG 8A

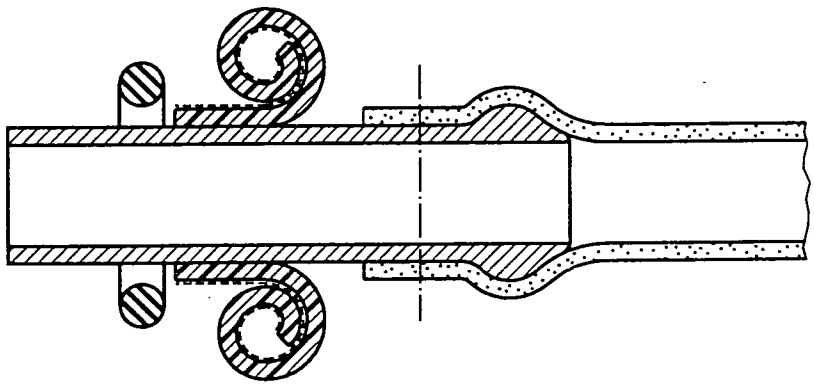


FIG 8B

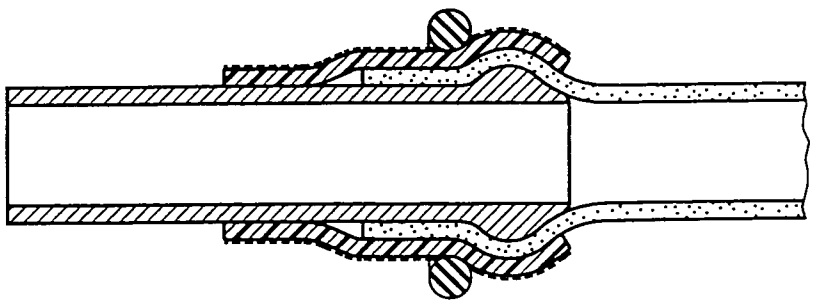


FIG 9A

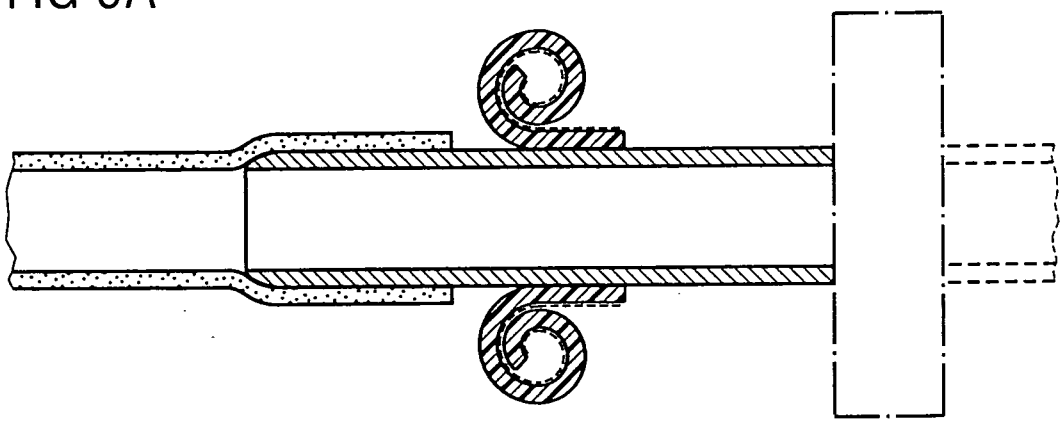


FIG 9B

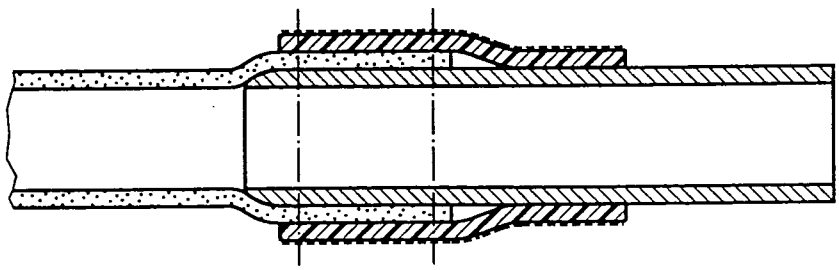


FIG 10A

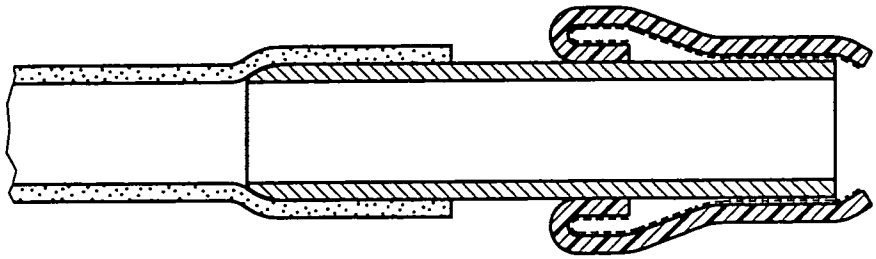


FIG 10B

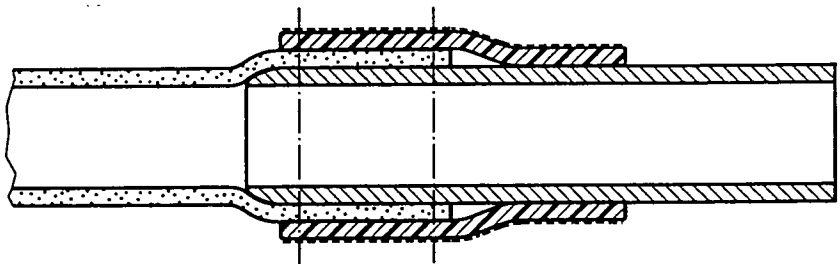


FIG 11A

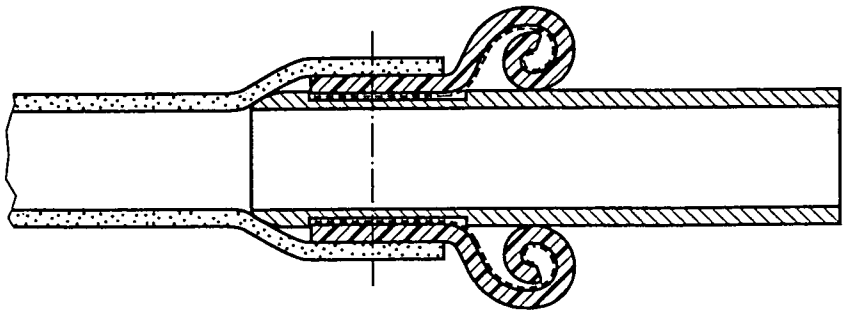


FIG 11B

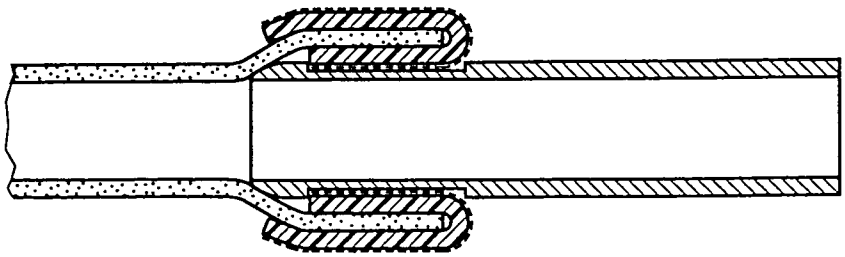
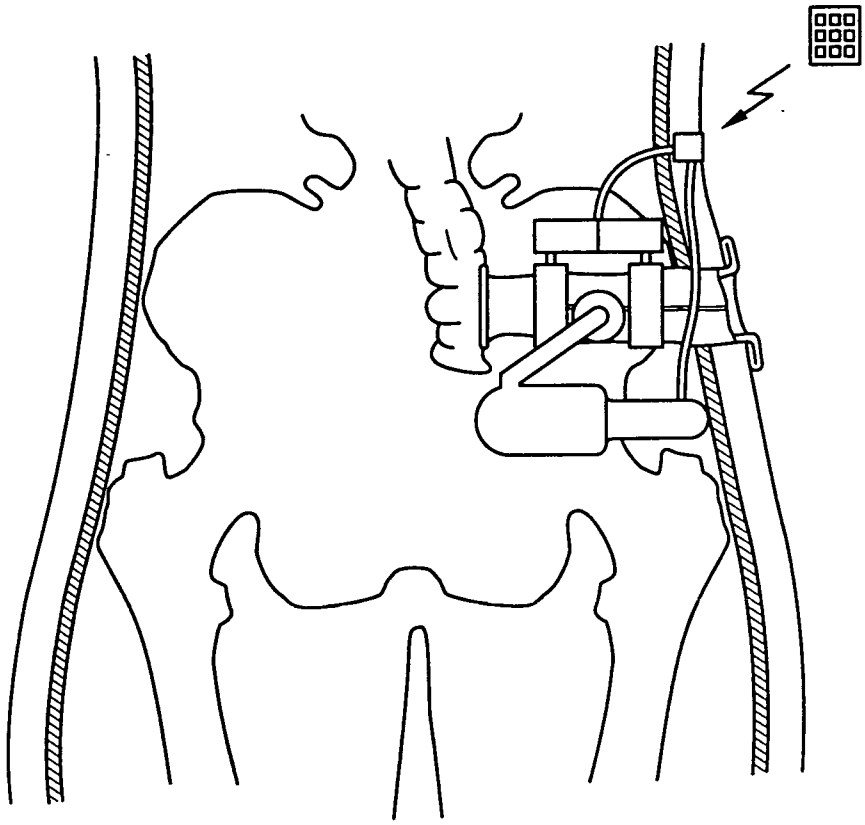


FIG 12



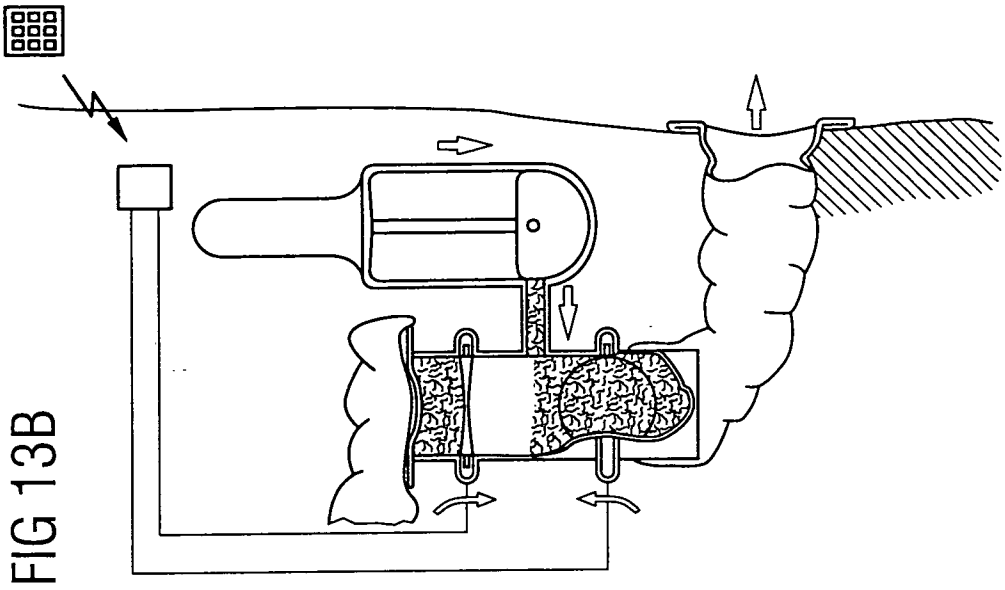


FIG 13B

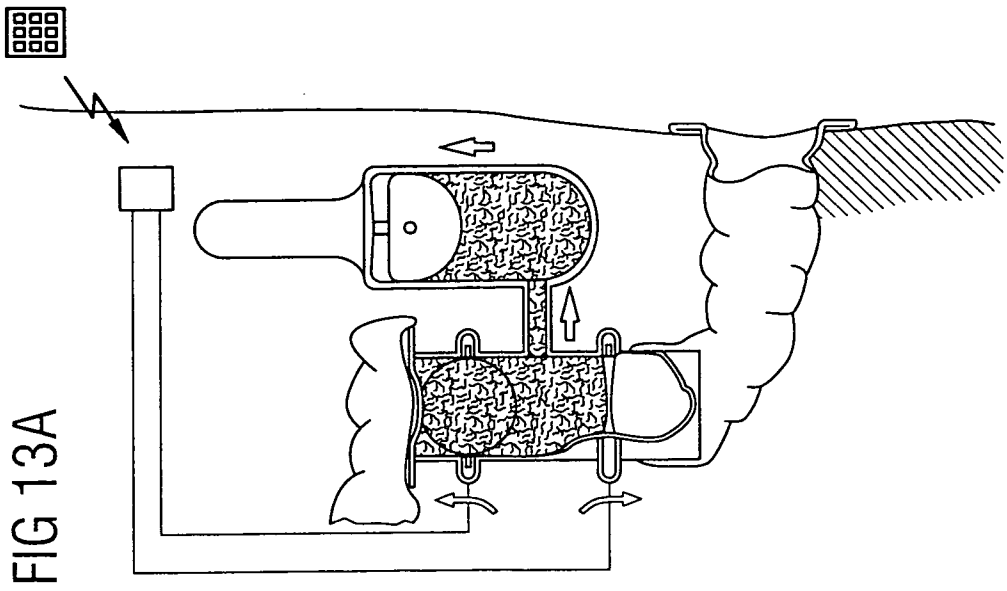


FIG 13A

FIG14A

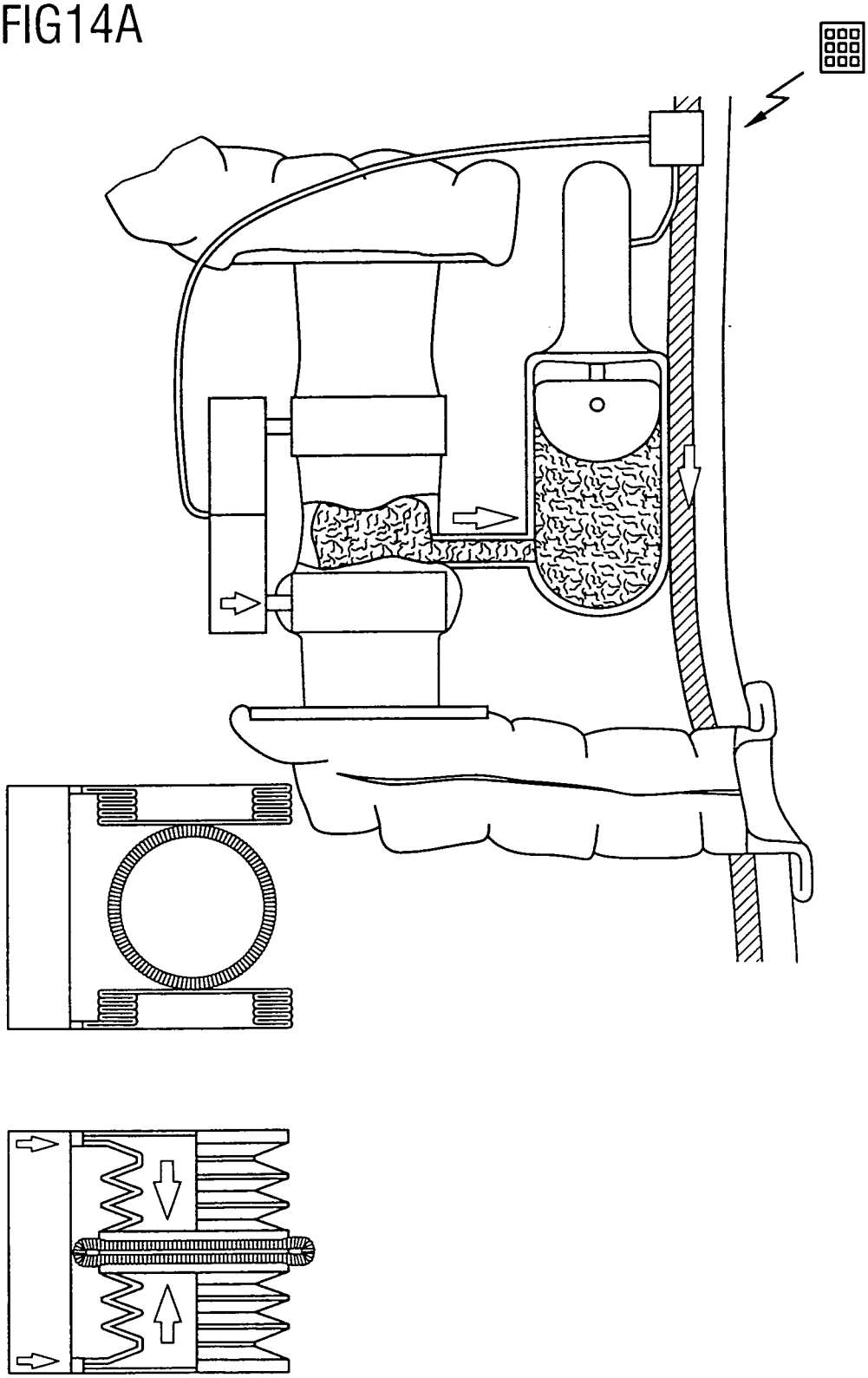


FIG 14B

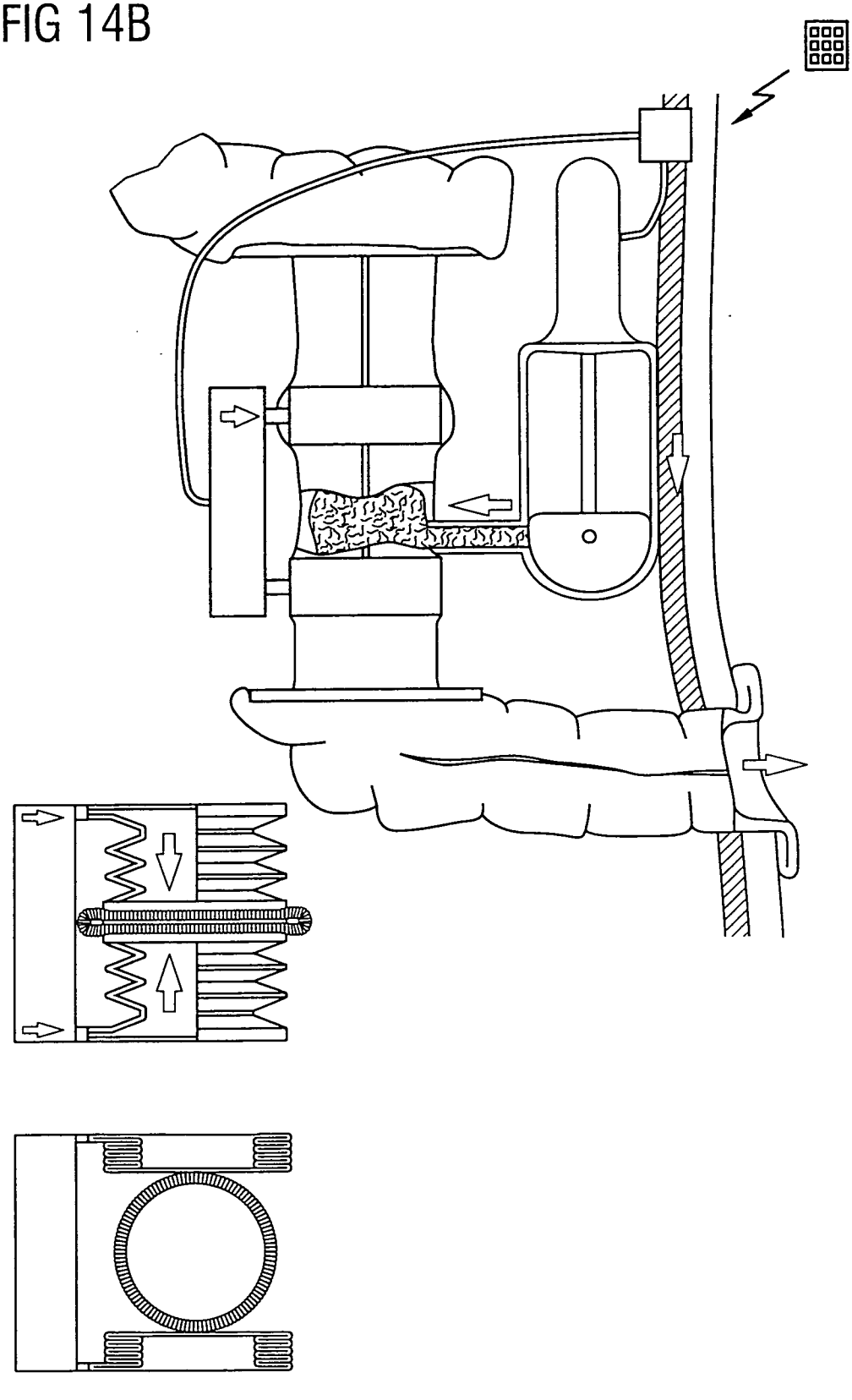


FIG 15

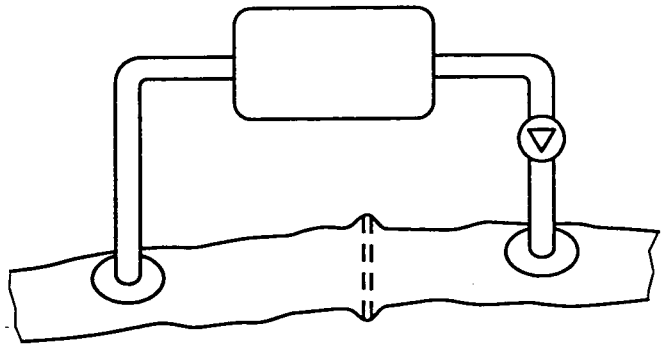


FIG 16

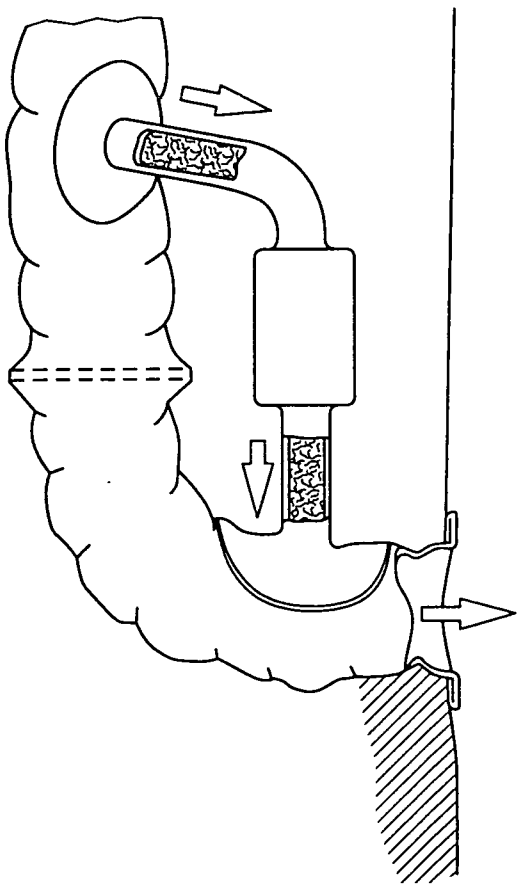


FIG 17

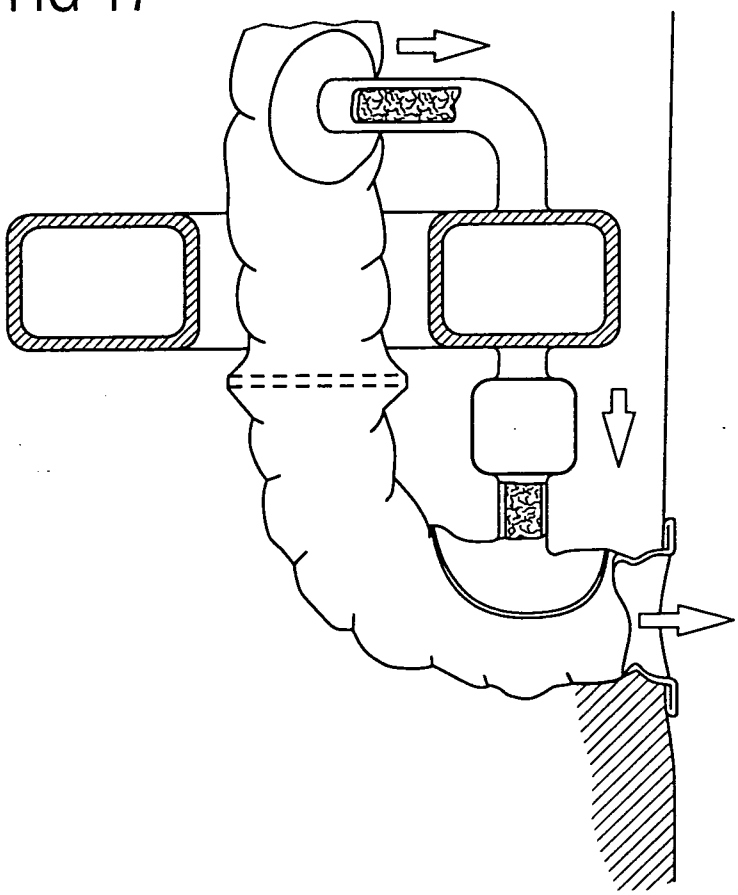
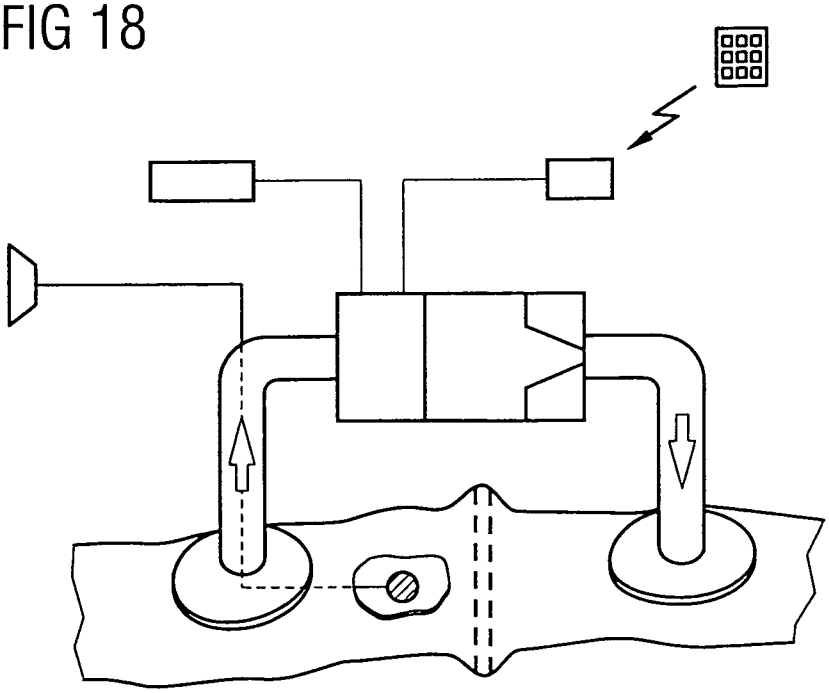


FIG 18



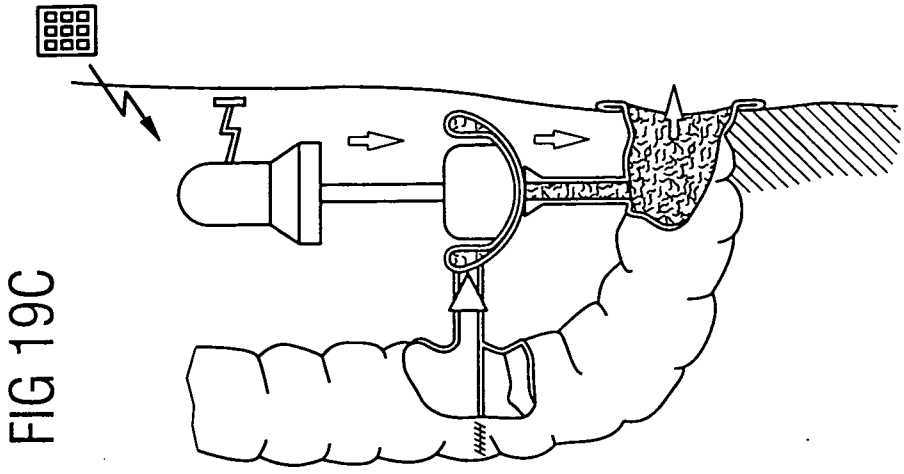


FIG 19C

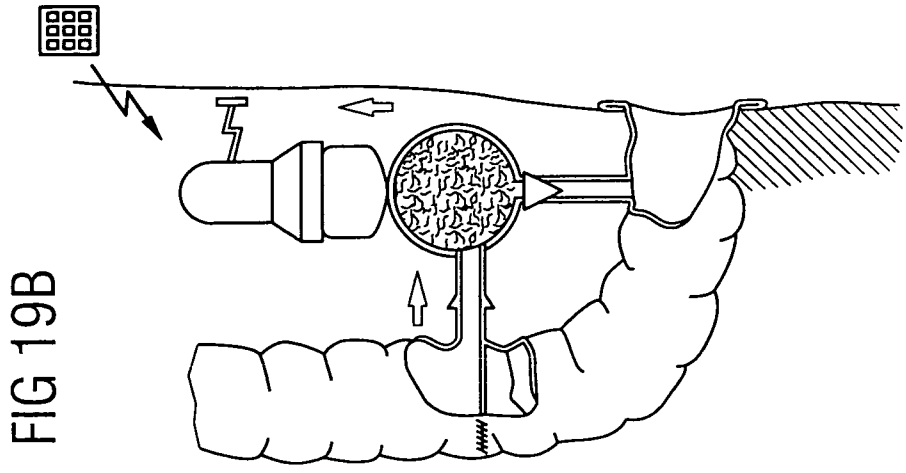


FIG 19B

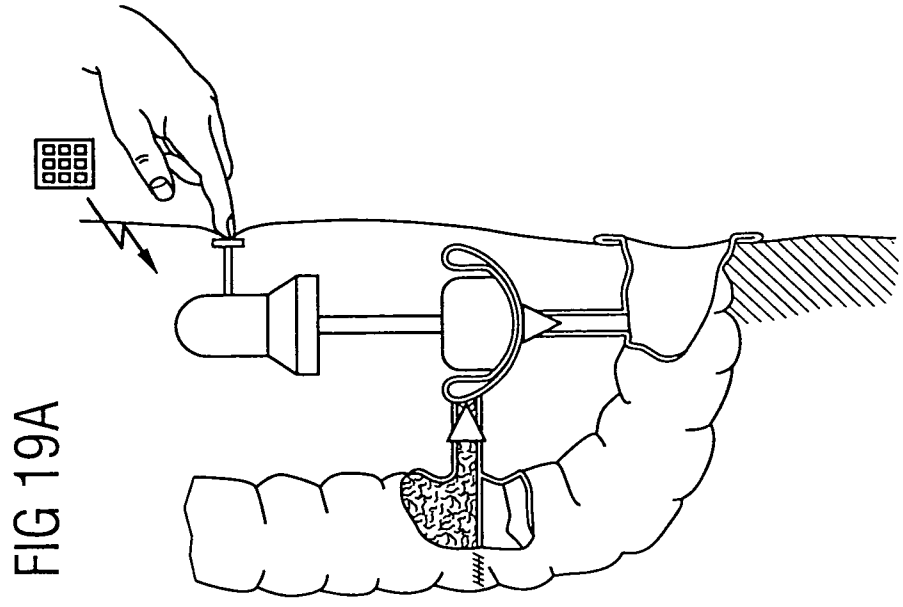


FIG 19A

FIG 20A

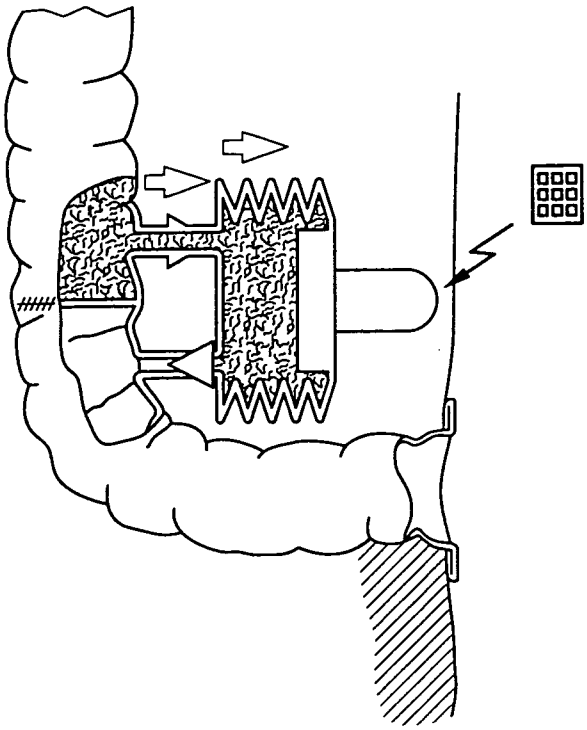


FIG 20B

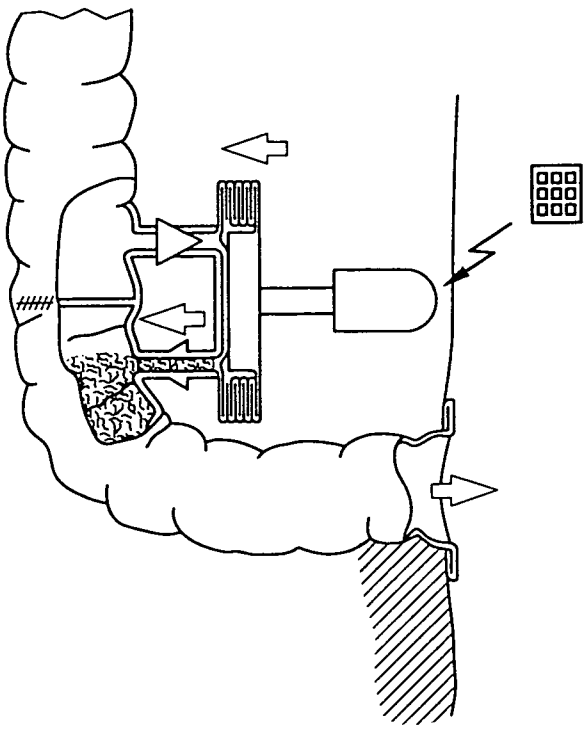


FIG 21A

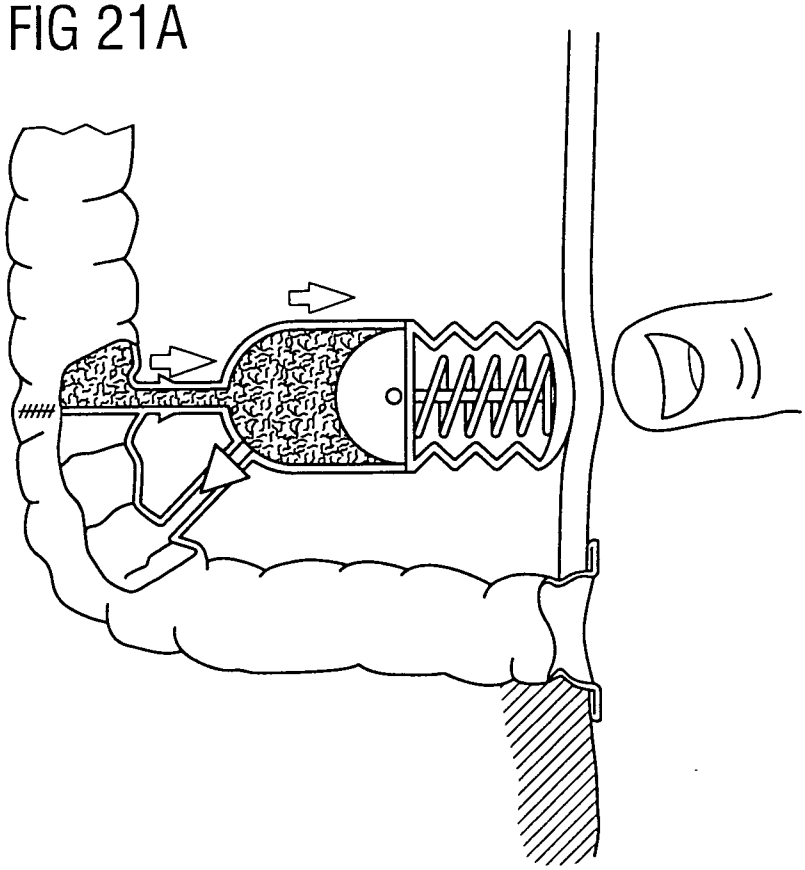


FIG 21B

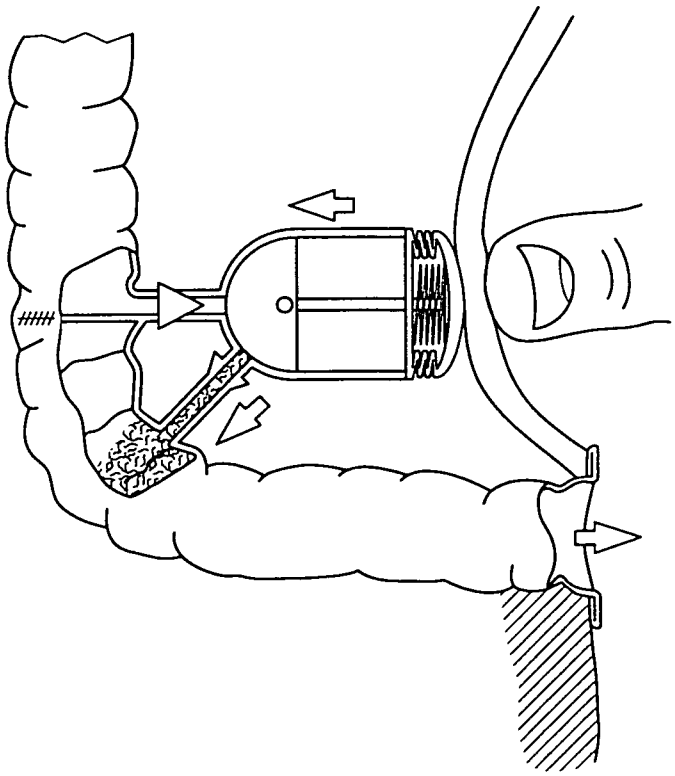


FIG 22A

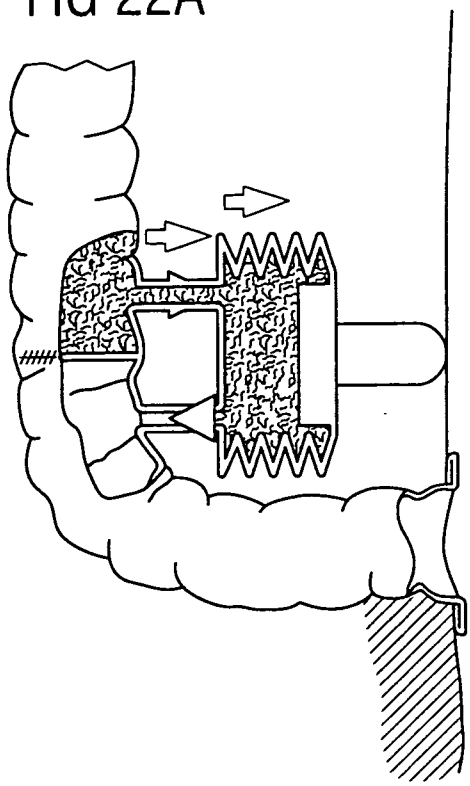
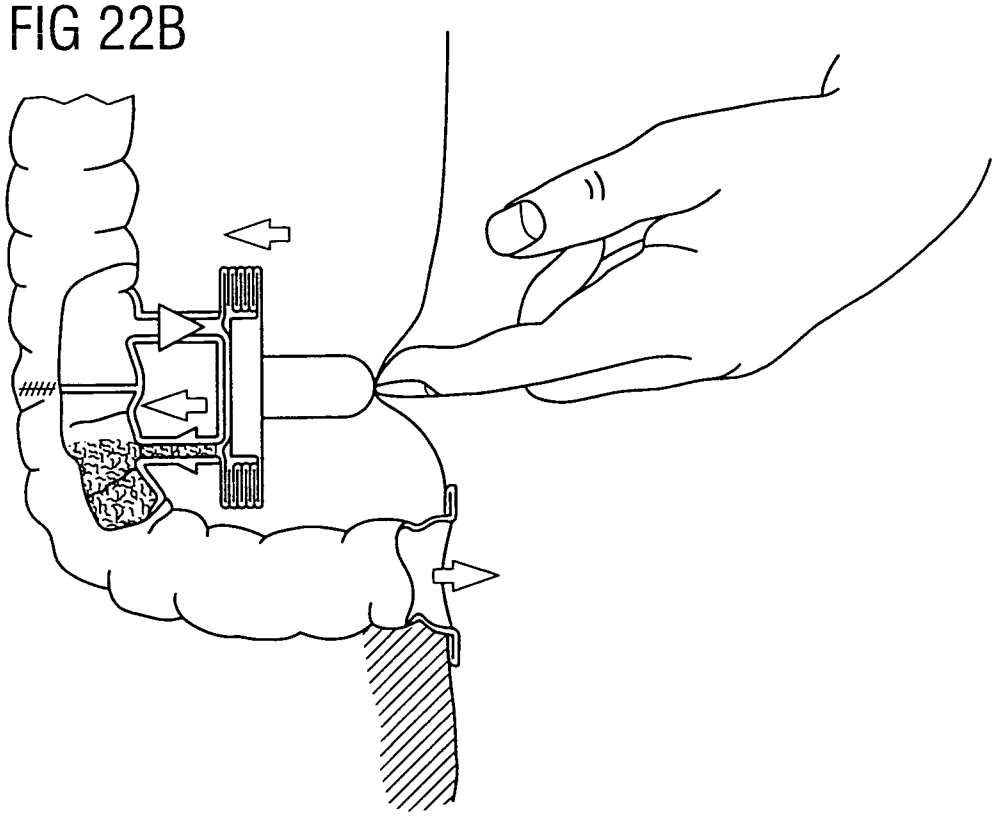


FIG 22B



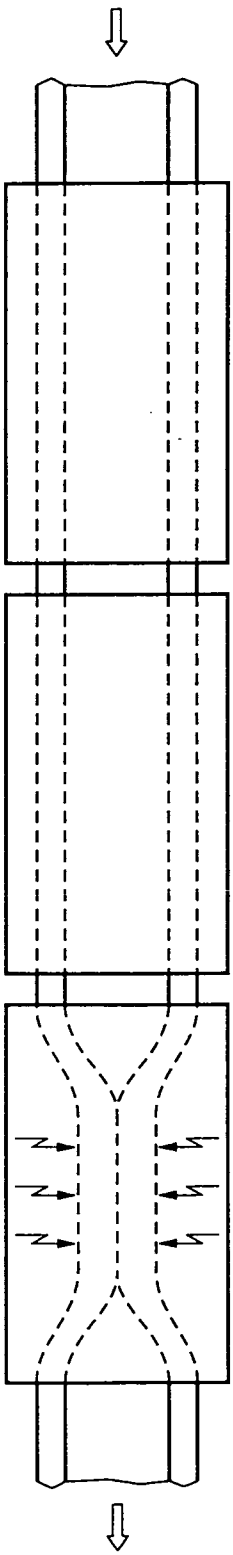


FIG 23A

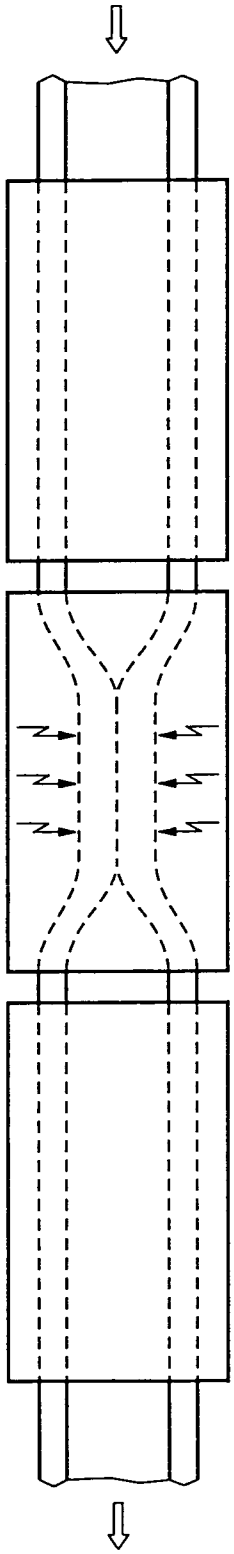


FIG 23B

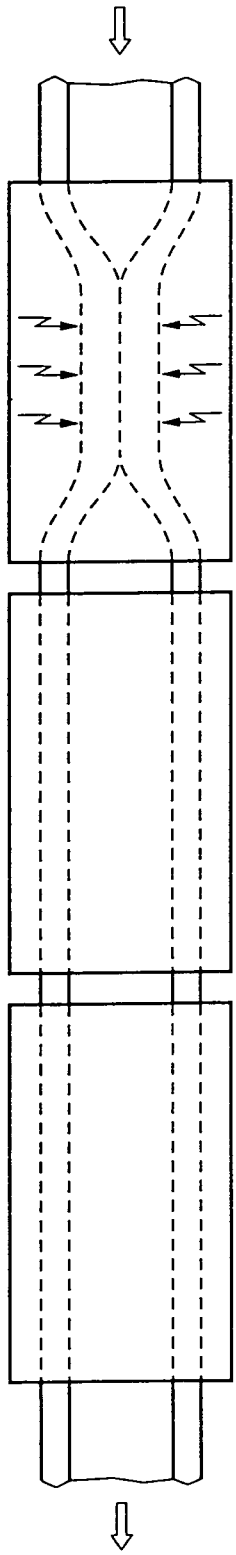


FIG 23C

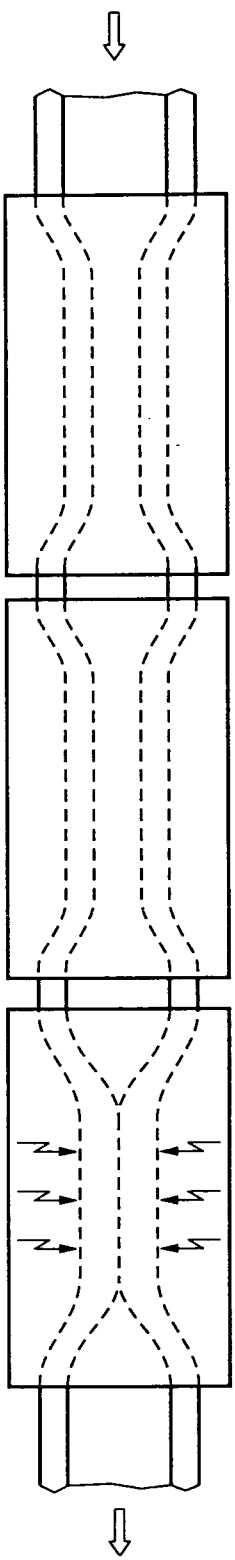


FIG 24A

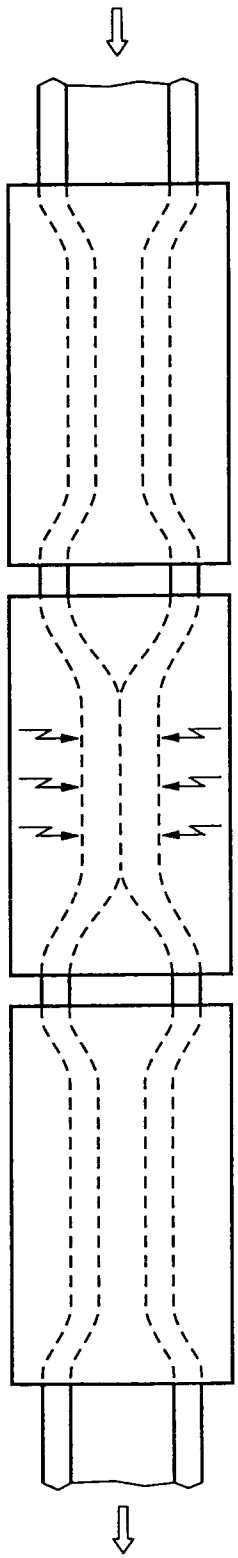


FIG 24B

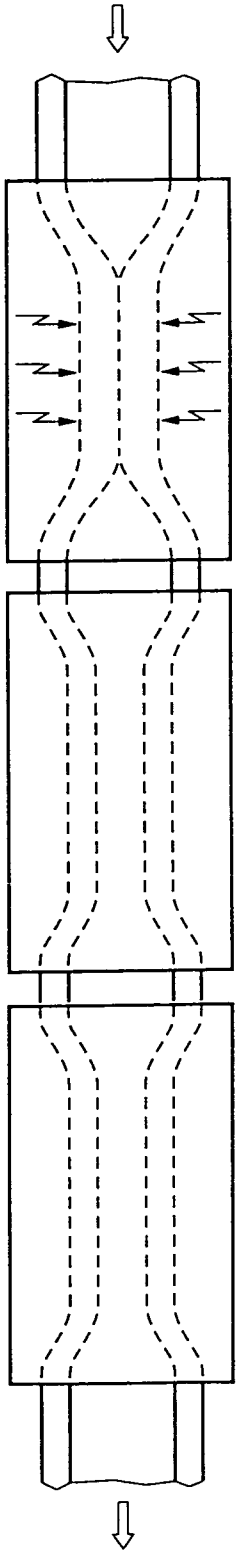


FIG 24C

FIG 25

