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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
7 June 2012 (07.06.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/071626 A1

(51) International Patent Classification:
A61M 1/00 (2006.01) *A61M 27/00* (2006.01)
A61F 13/00 (2006.01)

(21) International Application Number:
PCT/AU2011/001568

(22) International Filing Date:
1 December 2011 (01.12.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/418,549 1 December 2010 (01.12.2010) US
2011900597 22 February 2011 (22.02.2011) AU

(72) Inventor; and
(71) Applicant : **KLEINER, Daniel Eduard** [AU/US]; 2454 Ivy Springs Lane, Charlottesville, Virginia 22901 (US).

(74) Agent: **ADAMS PLUCK**; Suite 3, Level 4, 20 George Street, Hornsby, New South Wales 2077 (AU).

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

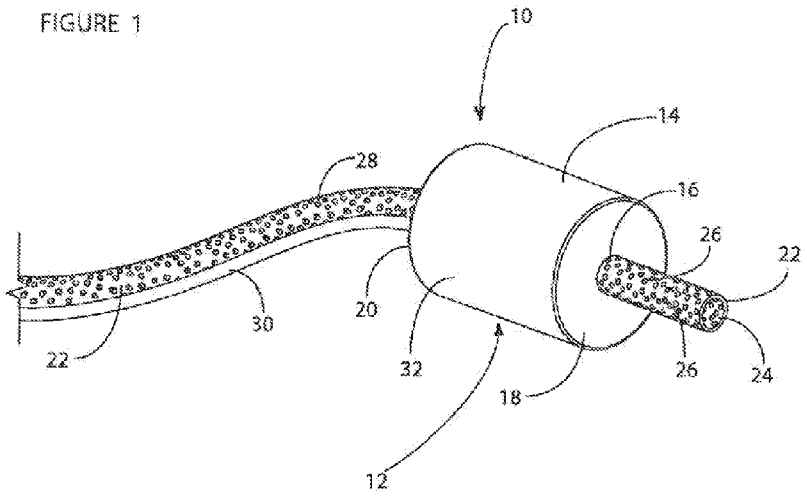
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR,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

Published:
— *with international search report (Art. 21(3))*

WO 2012/071626 A1

(54) Title: DEVICE FOR USE IN ENDOLUMINAL VACUUM THERAPY

FIGURE 1



(57) Abstract: The device (10, 36, 38, 42, 68) applies a negative pressure to an endoluminal surface in the body of a patient to facilitate healing of a wound in the endoluminal surface. The device comprises a flexible porous element (14) with a peripheral outer face (32) for contact with the wound, the outer face being defined between opposite proximal and distal ends of the porous element. A suction tube (30) for being connected to a suction source externally of the patient's body is provided in fluid communication with the porous element to apply a negative pressure to the wound via the outer face (32) of the porous element (14) upon operation of the suction source. The porous element (14) has at least one through passageway (16) extending from its proximal end to its distal end for passage of bodily substances of the patient through the porous element. The device can also include a drainage tube (22) for collection and drainage of the bodily substances from the patient, wherein the drainage tube is received in the through passageway of the porous element. The device is particularly suitable for assisted healing of anastomotic wounds but its use is not limited thereto.

DEVICE FOR USE IN ENDOLUMINAL VACUUM THERAPY

FIELD OF THE INVENTION

The invention relates to a device for facilitating healing of a wound in an endoluminal surface of a patient and a method for use of the device.

BACKGROUND OF THE INVENTION

Cancer remains one of the major modern day health issues and accounts for a large proportion of health and hospital costs. For example, in excess of 106,000 new cases of large bowel cancer are diagnosed each year in the United States alone. Of these, about 65,230 cases are colon cancer while the remainder of patients have cancer of the rectum. In the United States, approximately 49,920 people die from colorectal cancer (CRC) yearly, with about 1 in 17 people developing CRC during some stage of their life.

Surgery is the mainstay of care for CRC. Radiotherapy (for rectal cancer) and/or chemotherapy can also be administered. About 60% of rectal cancer patients have surgery as well as both radiotherapy and chemotherapy. Surgery involves resection of the affected region and rejoining of the bowel forming an anastomosis. Commonly, a colostomy involving attaching the top end of the colon to an opening (known as a stoma) made in the abdomen is performed to divert faecal matter away from the anastomosis to a collection bag arranged externally of the patient's body while the anastomosis is healing. Connection of the lower end of the small intestine (the ileum) to the stoma is known as an ileostomy. The colostomy or ileostomy is usually temporary requiring a subsequent reversal operation to be performed.

A patient who has a rectal cancer, for example, may have a Lower Anterior Resection (LAR). Of such patients in the United States, about 32% will undergo a temporary diverting loop ileostomy. A patient that has an LAR but not an ileostomy has a 10-30% risk of having an anastomotic leak which can be either symptomatic (10-15%) or asymptomatic. However, patients that suffer anastomotic leakage not only then require an ileostomy, an abscess can form at the site of the leakage which then requires

drainage, involving a yet further operation complicating the healing process. If the leakage is symptomatic the mortality rate is 6-22%.

The average time to surgical reversal of a colostomy or ileostomy is about 15 to 23 weeks. Immediately prior to the reversal, a contrast (e.g., barium) enema is performed to ensure that the anastomosis has healed. A routine reversal is not without its own risks, with the overall complication rate (e.g., wound infection etc) estimated at about 19.8%. About 3% of patients suffer an anastomotic leak associated with the reversal operation. Moreover, in the United States, the financial cost for the colostomy or ileostomy and subsequent reversal can be US$10,000 to $15,000 or more per patient.

As such, not only is there significant morbidity and mortality associated with anastomotic leakage arising from primary surgery for treatment of CRC, the risk of leakage is compounded by subsequent diverting colostomy/ileostomy procedures and reversal operations where performed, the latter treatments adding significantly to the financial burden involved in obtaining treatment.

The application of sub-atmospheric pressure to acute or chronic wounds to promote wound healing is known as negative pressure wound therapy (NPWT) or vacuum assisted closure (VAC). VAC therapy involves creating a negative-pressure in the local wound environment, drawing away bacteria, exudate, fluid and desiccated tissue from the wound site. Besides improving localised conditions and reducing oedema for wound healing, the negative pressure may draw wound edges together and increase the rate of healing by promoting blood flow and facilitating localised cell migration and proliferation. Indeed, it is believed VAC therapy can increase the rate of wound closure.

Conventionally, VAC therapy has been applied to wounds in the skin such as burns, grafts, surgical incisions, diabetic ulcers, pressure ulcers, venous stasis ulcers and wounds arising from trauma. These "wound VAC" devices comprise a pad of open-cell sponge like material or a porous mat for being placed on the wound. A vacuum is applied to the sponge via a drainage tube through which fluid and exudate from the wound that is drawn into the sponge or mat is drained away. A drape can be laid over the sponge or porous mat to facilitate sealing of the wound. Such devices are commercially available and, for example, are described in United States Patent Application No. 11/186,056, US 11/347,073, US 11/409,116, US 11/268,212,

US 12/233,211, and International Patent Application WO 93/09727. In more recent times, VAC devices comprising like porous sponges and mats have been used to drain seromas and fluids from internal bodily spaces following surgery and to facilitate the healing of wounds on outer surfaces of internal body organs and tissues, examples of which are described in WO 03/028786, United States Patent No. 5,437,651 and patent application US 11/646,918.

SUMMARY OF THE INVENTION

Broadly stated, the present invention relates to the provision and use of a vacuum assisted closure (VAC) type device to facilitate the healing of a wound in an endoluminal surface within the body of a patient. Whilst, in at least some forms, devices embodied by the invention have application in the treatment of anastomotic wounds resulting from surgery such as for colorectal cancer (CRC), the invention is not limited thereto.

In particular, in an aspect of the invention there is provided a device for applying a negative pressure to an endoluminal surface in the body of a patient to facilitate healing of a wound in the endoluminal surface, comprising:

a flexible porous element with a peripheral outer face for contact with the wound, the outer face being defined between opposite proximal and distal ends of the porous element; and

a suction tube for being connected to a suction source externally of the patient's body and which is in fluid communication with the porous element to apply a negative pressure to the wound via the outer face of the porous element upon operation of the suction source, the porous element having at least one through passageway extending from its proximal end to its distal end for passage of bodily substances of the patient through the porous element, and at least one of the proximal and distal ends of the porous element is otherwise adapted against egress of the bodily substances into the porous element.

Typically, both the proximal and distal ends of the porous body are otherwise adapted against egress of the bodily substances into the porous element.

The porous element can be cylindrical with a single longitudinal said through passage, the through passage being defined substantially centrally within the porous element.

In other embodiments, the porous element is funnel shaped with a projecting shaft for being inserted into a duct defined by the endoluminal surface, the through passageway extending longitudinally through the shaft. Typically, the device further comprises a drainage tube for drainage of the bodily substances that pass through the porous element from the body of the patient.

Typically, the drainage tube is received in the through passageway of the porous element and the interior of that portion of the drainage tube within the porous element is sealed from the surrounding porous element by the side wall of the drainage tube to ensure the suction is applied to the peripheral outer face of the porous element via the suction tube.

In at least some embodiments, the drainage tube projects from the proximal and distal ends of the porous element, wherein the interior of the drainage tube is defined by a peripheral side wall of the tube and a plurality of through openings are provided in the side wall forward of the proximal end of the porous element for entry of the bodily substances into the interior of the drainage tube. In at least some embodiments, a plurality of further through openings may also, or alternatively, be provided in the side wall of the drainage tube rearwardly of the distal end of the porous element.

A device embodied by the invention may also comprise an expandable element arranged for expanding the porous element to press the outer face of the porous element against the wound with expansion of the expandable element. In embodiments provided with a drainage tube, the expandable element can be disposed between the discharge tube and the porous element.

The expandable element can be an inflatable inner core of the porous element. Alternatively, the expandable element can be fabricated from a resilient material biased to an expanded normal resting state or, for example, comprise an expandable stent.

A device in accordance with the invention can also comprise a hollow locating tube for receiving the porous element within the interior of the locating tube to facilitate location of the porous element in position adjacent the endoluminal surface. In such embodiments, the expandable element is in a compressed deflated or collapsed state when the porous element is received within the locating tube, and expands (or is

expanded) upon the tube being withdrawn from about the porous element, or the porous element otherwise being ejected from the locating tube, to press the porous element against the wound.

Typically, the porous element is formed from an absorbent material. The absorbent material can, for instance, be a sponge.

In another aspect of the invention there is provided a method for facilitating healing of a wound in an endoluminal surface in a body of a patient, comprising:

providing a device for applying a negative pressure to the wound, the device having a flexible porous element with a peripheral outer face for contact with the wound, the outer face being defined between opposite proximal and distal ends of the porous element, the porous element having at least one through passageway extending from its proximal end to its distal end for passage of bodily substances of the patient through the porous element, and at least one of the proximal and distal ends of the porous element is otherwise adapted against egress of the bodily substances into the porous element;

locating the device in position such that the peripheral outer face of the porous element is in contact with the wound; and

applying a negative pressure to the endoluminal surface through the outer face of the porous element via a suction tube in fluid communication with the porous element.

In another aspect of the invention there is provided a method for treating, or reducing potential for, leakage from an anastomosis in an endoluminal surface in a body of a patient, comprising:

providing a device for applying a negative pressure to the anastomosis, the device having a flexible porous element with a peripheral outer face for contact with the anastomosis, the outer face being defined between opposite proximal and distal ends of the porous element, the porous element having at least one through passageway extending from its proximal end to its distal end for passage of bodily substances of the patient through the porous element, and at least one of the proximal and distal ends of the porous element is otherwise adapted against egress of the bodily substances into the porous element;

locating the device in position such that the porous element is in contact with the anastomosis; and

applying a negative pressure to the anastomosis through the outer face of the porous element via a suction tube in fluid communication with the porous element.

Besides wounds arising from surgical resection, other wounds that may be treated using a device embodied by the invention include those arising from diseases and physiological conditions, ablation, radiotherapy, chemotherapy or other medical treatments, and injuries due to accidents and trauma. Moreover, although at least some embodiments are particularly suitable for use in facilitating healing of an anastomotic or other wound in the endoluminal surface of the large bowel of the gastrointestinal tract as described above, devices in accordance with the invention may have application in other luminal structures such as those may be explored with an endoscope or similar type of viewing device.

In particularly preferred embodiments, the device can be mounted on an endoscope and located in position within the lumen with the use of the endoscope (or other suitable insertion or viewing device). A guide wire can also be inserted along the relevant lumen, a device embodied by the invention moved along the guide wire into position, and the guide wire then withdrawn leaving the device behind within the lumen. This can be done under e.g., ultrasound or fluoroscopic guidance. As the porous element of a device embodied by the invention is provided with a through passageway as described above, bodily substances present within the lumen may be diverted through the porous element essentially without reducing the suction applied to the wound as a result of the porous element becoming clogged or fouled by them. Moreover, in instances of surgery on the large bowel, as bodily substances (e.g., faecal matter) can pass through the porous element via the through passageway while the device is in position in use, the need for a diverting colostomy or ileostomy following resection of tissue for treatment of CRC may also be reduced or avoided altogether. By avoiding the need for a colostomy or ileostomy, not only may the significant financial burden associated with patient treatment be lessened, patient psychological stress and discomfort stemming from the need for the patient to wear a waste collection bag into which bodily waste is received via the stoma is also avoided.

In addition, the use of a device as described herein may in one or more embodiments of the invention increase the rate of healing of the wound in the endoluminal surface of the patient. The risk of anastomotic leakage and associated

morbidity and mortality may also be reduced in patients following surgery such as an LAR on whom a diverting loop ileostomy is not performed.

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers, integers or steps.

Any discussion of documents, acts, materials, devices, articles or the like that has been included in this specification is solely for the purpose of providing a context for the invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the invention as it existed in Australia or elsewhere before the priority date of this application.

The features and advantages of the invention will become further apparent from the following detailed description of embodiments thereof together with the accompanying drawings. At least some like components of different embodiments of devices of the invention are numbered the same for convenience in the following description.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 is a diagrammatic perspective view of a device embodied by the invention;

Figure 2 is a diagrammatic partial side view of a the device of Fig. 1 in position within a lumen in the body of a patient;

Figure 3 is a diagrammatic perspective view of another device embodied by the invention;

Figure 4 is a diagrammatic perspective view of another device embodied by the invention;

Figure 5 is a diagrammatic perspective view of yet another device embodied by the invention;

Figure 6 is a diagrammatic view of a further device embodied by the invention in position within a lumen in the body of a patient;

Figure 7 is a diagrammatic view of a further device embodied by the invention in position within the lumen in a body of a patient;

Figure 8 is a diagrammatic view of another device in accordance with the invention;

Figure 9 illustrates the device of Fig. 8 inserted in the pancreatic duct of a pancreas sutured to the jejunum of the small intestine in a pancreatojejunostomy; and

Figure 10 illustrates a pancreas sutured to the jejumum of the small intestine in a pancreatojejunostomy employing the "dunk technique".

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS OF THE INVENTION

A device 10 embodied by the invention (termed an endoVac herein) is shown in Fig. 1. The device comprises a porous element 12 in the form of a substantially cylindrical biocompatible sponge 14 with a peripheral outer face for contact with an endoluminal surface of a patient and having a central through passageway indicated by the numeral 16 that extends from a proximal end 18 of the sponge to its opposite distal end 20. A drainage tube 22 fabricated from a physiologically acceptable plastic material is received in the through passageway of the sponge. The drainage tube allows for passage of bodily substances through the sponge and drainage from the lumen of the patient in use as further described below.

As can be seen, the drainage tube protrudes from the proximal end of the sponge 14 and terminates in an open end 24 for entry of the bodily substances into the tube. Further openings 26 for entry of the bodily substances into the interior of the drainage tube are provided in the side wall of the tube forward of the sponge. As also indicated in Fig. 1, the drainage tube 22 extends from the distal end 20 of the sponge, and is of a length sufficient to extend from the patient's body. Additional openings 28 are provided in the side wall of the tube for entry of bodily substances into the interior of the tube rearwardly of the sponge. That portion of the drainage tube 22 within the sponge is unperforated thereby sealing the interior of the drainage tube from the surrounding sponge. The sponge is fixed to the drainage tube along its length so as to retain the sponge in position whilst the device 10 is being inserted into position within the lumen.

The sponge may be fixed to the tube by, for example, by the use of a suitable adhesive, or sonic or heat welding.

A suction tube 30 for connection to a suction source arranged externally of the patient's body is in fluid communication with the sponge 14 for application of a negative pressure to the sponge. Both the proximal and distal ends 18 and 20 of the sponge are essentially impermeable to gases and fluids, and so are adapted against egress of the bodily substances into the sponge under action of the suction applied to the sponge via the suction tube.

To seal the proximal and distal ends of the sponge against entry of the bodily substances, an occlusive barrier in the form of a ring of flexible plastic sheet material can be affixed to the respective ends in any suitable manner such as by an appropriate adhesive, heat or sonic welding, or other method. In this embodiment, the suction tube is sealingly received in, or terminates about, an opening provided in the ring of plastic sheeting affixed to the distal end of the sponge whereby the interior of the suction tube is in fluid communication with the sponge. Alternatively, the sponge can be provided with a flexible annular end cap formed from a suitable plastics material (e.g., a closed cell foam) that sealingly receives the suction tube and is affixed to the distal end of the sponge for application of the suction to the sponge via the suction tube. In such embodiments, the suction tube can open into a circumferential open channel defined in the underside of the annular cap wherein the open channel faces the distal end of the sponge for more even circumferential distribution of the applied suction to the sponge. Preferably, however, in other forms, the suction tube 30 extends into the sponge itself and has through openings in the side wall of that portion of the suction tube within the sponge. In still further embodiments, an essentially impermeable coating can be applied to the respective end(s) of the sponge to seal the proximal and/or distal end(s) of the sponge rather than employing sheet plastics material or end/caps for this purpose.

The interior of the drainage tube is separated from the sponge along the entire length of the tube within the through passageway by the side wall of the tube. That is, there are no through openings in the side wall of the drainage tube between the proximal and distal ends of the sponge 14 ensuring the suction is applied to the peripheral face

However, and with reference to Fig. 2, the peripheral outer face 32 of the sponge is in fluid communication with the suction tube through pores in the sponge, and is pressed against the wound 29 in the surrounding endoluminal surface 31 defining the

lumen 33 in which the device 10 is placed in use. When in position, suction from the external suction source is thereby applied to wound and surrounding endoluminal surface via the peripheral outer face of the sponge 14. This creates a localised area of negative pressure about the wound, the suction drawing surface fluid and any exudate that may be present away from the wound into the sponge.

Thus, besides providing suction to the sponge, the suction tube 30 acts as a second drainage tube for fluids drawn through the sponge from the wound. Moreover, by diverting bodily substances present in the lumen through the sponge via the through passageway 16 and thereby separating those substances from fluids drawn into the sponge from the wound, clogging and/or fouling of the sponge by the bodily substance(s) in the lumen and associated loss of suction applied to the wound via the suction tube may be reduced or avoided.

Other endoVAC devices embodied by the invention similar to that shown in Fig. 1 are also provided but which have an expandable element 34 disposed in the through passageway 16 of the sponge and more particularly, between the drainage tube 22 and the outer cylindrical layer of sponge 14. The expandable element is arranged to expand the sponge to press the peripheral outer face 32 of the sponge into firm with contact with the endoluminal surface, and can take various forms.

For instance, in the embodiment illustrated in Fig. 3, the expandable element 34 is in the form of a tubular insert fabricated from a resilient material (e.g., a foamed plastics material) that is maintained in a compressed state about the drainage tube by a hollow locating tube/sheath (not shown) in which the surrounding sponge 14 is received whilst the device 10 is being located in position with the lumen adjacent the wound to be treated. The resilient material is biased to a normally expanded resting condition, and expands to that condition to press the sponge against the wound and surrounding endoluminal surface upon the insertion tube or sheath being withdrawn from the sponge once the device has been positioned within the lumen.

In another form, a further suction tube can be provided for applying suction/negative pressure to the resilient insert to compress the insert without the need to use a locating tube. In this embodiment, the peripheral surface of the resilient insert facing the sponge is sealed from the sponge (e.g., by an impermeable coating). As with the sponge 14, the proximal and distal ends of the insert are also sealed either by, for example, an impermeable coating or barrier as described in relation to Fig. 1. As such,

withdrawal of the negative pressure applied to the resilient insert via the further suction tube allows the insert to expand to its normal resting condition and press the peripheral outer face of the sponge against the endoluminal surface.

As a still further alternative, the expandable element 34 can take the form of an inflatable insert such as a tubular balloon with an inflation tube for inflation of the balloon to expand the peripheral outer face of the sponge into pressed contact with the endoluminal surface as generally illustrated in Fig. 4. The inflation tube can, for example, be connected to a hand operated pump externally of the patient's body for effecting inflation of the balloon to a predetermined pressure. To avoid over inflation, the pump is provided with a pressure safety valve and/or in other forms, a pressure gauge for indicating the pressure applied to the balloon. Once suitably inflated, a valve of the pump is closed to retain the balloon in the inflated condition.

From the above it will be understood that the term "expandable element" as used herein encompasses elements that can expanded from a compressed, collapsed or deflated condition in use to press the peripheral outer surface of the sponge 14 against the endoluminal surface. As such, the expandable element may normally exist in an expanded condition. Further, it will be appreciated that collapsing or compressing the sponge (with or without the use of a locating tube or sheath as described above) may assist passage of the device along the relevant bodily lumen into position by minimising frictional contact with the endoluminal surface.

Whilst the provision of a drainage tube 22 is desirable, it is not essential and embodiments of devices of the invention can be provided without one as illustrated in Fig. 5. In this embodiment, bodily substances present within the lumen may simply pass through the through passageway 16 of the device 36 once the device is located in position.

When provided, the drainage tube can be connected to a programmable or other electric suction pump for drawing the relevant bodily substances through the device 10, 36 to assist drainage and sanitary collection of the substances from the patient for monitoring and/or subsequent disposal. The external suction source connected to the suction tube 30 may also be an electric pump although any suitable source of suction can be utilised. In embodiments of a device of the invention that is provided with a suction compressible resilient insert 34 as described above, that insert may be connected to the same or different suction source as the sponge 14. Typically, the suction applied to the

sponge 14 via the suction tube 30 will be in a range of from 11mm Hg to 140mm Hg and most usually, in a range of from 50-100 mm Hg.

Various types of sponge 14 suitable for use in a device of the invention are known, non-limiting examples of which may include open cell polyurethane and polyvinyl alcohol foams with or without a reticulated cell structure. The pores of the sponge may be in a range of from about 100 μM to about 1000 μM, more usually in a range of from about 200 μM to 600 μM and generally, in a range of from about 400 μM to 600 μM. Desirably, the foam employed is essentially non-adherent to the wound. Alternatively, the device can be removed from the patient before any deleterious adherence to the wound or tissue ingrowth into the sponge 14 occurs.

EndoVAC devices embodied by the invention have particular application in the treatment of anastomotic wounds following surgery of the large bowel of the gastrointestinal (GI) tract for removal of cancerous tissue and to provide clear tissue margins in colorectal cancer (CRC) patients. Prior to the surgery (e.g., 24 hours beforehand), the patient's bowel is cleared of stool by the administration of laxatives such as dipropylene glycol and/or anemas. For cancer of the cecum or ascending colon, for example, a right hemicolectomy may be performed, whilst an extended hemicolectomy may be performed for cancer of the transverse colon. In patients with cancer of the descending or sigmoid colon, the surgery typically involves a left hemicolectomy or sigmoidectomy. In each of these surgeries, an anastomotic wound is formed by joining resected tissues and may be treated in accordance with the invention.

To facilitate healing of the wound, the endoVAC device of the invention is inserted into position adjacent the wound in the large bowel via the anus. An endoscope type viewing device such as a rigid or semi-flexible sigmoidoscope or colonoscope with a slight curvature may be employed to locate the device in position. The endoVAC device may be mounted on the end of the endoscope and/or otherwise be moved along the lumen of the large bowel as the endoscope is inserted into the patient. When in position adjacent the wound, the endoscope or other locating tool is withdrawn from the patient, the sponge is expanded into pressed contact with the endoluminal surface of the large bowel as needed as described above, and suction is applied to the sponge 14 via connection of the sponge to the external sectional suction source by the suction tube 30. A guide wire or tendon may also be inserted along the lumen, and a device embodied by the invention then moved along the guide wire into position before the guide wire is

removed. To assist positioning, the location of the device can be monitored by ultrasound or, for example, a fluoroscopic technique employing a contrast agent by another surgeon or medical attendant.

The endoVAC device will generally be maintained in position and negative pressure applied to the anastomotic wound for 3 to 5 days while the wound heals. During this time, faecal matter, mucus, and other fluid bodily substances in the large bowel distally to the device can pass through the sponge via the through passageway 16 or drainage tube 22 when provided.

Besides the large bowel, an endoVAC device embodied by the invention may, for example, be utilised to assist healing of fallopian tube, tracheal, bronchial, oesophagus, esophagogastric, gastrojeuneal or pancreatojejunal wounds such as following esophagectomy or bariatric surgery. Indeed, it will be understood that the endoluminal surface can be any endoluminal surface amenable to treatment with a device as described herein. Moreover, besides wounds resulting from resection of tissue, a device as described herein has application to assisted healing of wounds resulting from, but not limited to, trauma, radiotherapy, radiofrequency ablation, ethanol ablation, cryosurgery, chemotherapy, polypectomies, and ulcers. Hence, the term "wound" as used herein is to be taken in its broadest context to encompass wounds inflicted by surgery and medical treatments, trauma caused by accidents, and wounds resulting from physiological diseases or conditions (e.g., a fistula). Further, the term "bodily substances" as used herein is to be taken to encompass air, gases, fluids, mucous and waste bodily products (e.g., faecal matter) that may be present within the relevant lumen of the patient.

Employing a device in accordance with the invention may, in one or more embodiments, allow for a colostomy or ileostomy associated with surgery of the large bowel such as for CRC (e.g., Lower Anterior Resection (LAR)), and the risk of anastomotic leakage connected with subsequent reversal of the colostomy or ileostomy, to be avoided. Likewise, by facilitating the healing of anastomotic wound, the risk of leakage and/or infection of the wound may be decreased. To further facilitate healing, in at least some embodiments, the sponge or other porous element 12 may be impregnated or coated with drugs or other therapeutic agents such as antibiotics for release at, or application to, the wound site. For instance, a silver ion releasing antimicrobial coating may be applied to the peripheral outer face of the sponge for application to the wound. Moreover, by providing an occlusive barrier to the proximal and/or distal ends of the

sponge 14 against the egress of gases, faecal matter and/or bodily fluids into the sponge 14 as described above, bacterial loading and "clogging" of the sponge 14 may be minimised.

An endoVAC device embodied by the invention may also be used to assist the healing of a fistula between e.g., the bowel and skin as generally illustrated in Fig. 6. In this embodiment, the device 38 is of the type having an expandable element 34 to press the surrounding sponge 14 into contact with the endoluminal surface of the bowel lumen 66 into which the fistula 64 opens. However, rather than the suction tube 30 applying suction to the distal end of the sponge or otherwise entering the distal end of the sponge, in this instance, the suction tube enters the device 38 through the side of the sponge and protrudes from the subject's body through the fistula. The suction tube can, for example, fork within the sponge such that one fork of the suction tube extends distally along within the sponge from the middle of the sponge and the other fork extends along within the sponge in the opposite direction to distribute the applied suction along the length of the sponge. The endoVAC device 38 can be inserted into position in the bowel through the fistula, and suction applied to the endoluminal surface around the fistula to promote healing. As healing of the fistula progresses and the tissue forming the opening of the fistula into the bowel is remodelled, the device 38 can be replaced with another device 38 of a smaller size by removing the previous device through the fistula and reinserting the smaller device in the same manner. Depending on the size of the fistula, this may be repeated on or more times.

In another embodiment, an endoVAC device 68 can be located in position within the bowel so as to cover the opening of a fistula 64 but wherein the suction tube 30 enters the bowel through a surgically made opening along from the fistula as illustrated in Fig. 7.

A yet further endoVAC device 42 in accordance with the invention is shown in Fig. 8. In this device the sponge 14 is funnel shaped wherein the drainage tube 22 and the suction tube 30 enter the distal face 44 of the sponge, the distal face 44 of the sponge being otherwise sealed against egress of gas and fluid into the sponge as described above. As shown, that portion of the suction tube 30 within the sponge is provided with a number of through openings along its side wall, and the outer diameter of the sponge generally decreases in the distal to proximal direction of the sponge forming a projection of the sponge in the form of a shaft 48 from which the drainage tube 22 extends. The

shaft 48 of the sponge can be inserted into a resected end of duct such as the pancreatic duct to assist healing in a pancreatojejunostomy in which the resected pancreas is surgically sutured to the middle region of the small intestine between the duodenum and ileum known as the jejunum. The pancreatic duct carries pancreatic juice from the pancreas to the small intestine. Pancreatic juice is alkaline and contains enzymes which act to break down fat, and so can cause significant damage outside of the intestine. The "leakage rate" for pancreatojejunostomies is in the order of about 15%.

An example of a pancreatojejunostomy technique in which the exposed opening of the pancreatic duct 50 in a resected end 52 of the pancreas generally indicated by the numeral 54 is sutured to the mucosa of the jejunum by sutures 56 such that the duct opens into the jejunum 58 through an opening surgically formed in the jejunum is illustrated in Fig. 9. In the embodiment shown, the endoVAC device 42 is located within the lumen of the jejunum and the projecting shaft 48 of the sponge 14 is inserted into the open end of the pancreatic duct 50. The suction applied to the sponge via the suction tube 30 may assist to not only facilitate healing of the resected end of the pancreatic duct but also the suturing injury to the mucosa of the jejunum. The side wall of the jejunum adjacent to the pancreatic duct would also be expected to approximate to the funnel shape of the sponge, the suction applied to the sponge by the suction tube assisting to retain the side wall of the jejunum against the sponge and the shaft 48 of the sponge in position within the pancreatic duct. That is, the outer peripheral face of the sponge and at least the endoluminal surface of the jejunum about the sponge would change shape under the effect of the applied suction to conform to each other as indicated by the double headed arrows.

In some embodiments, at least that portion of the drainage tube 22 within the sponge extending longitudinally through the shaft can comprise an expandable stent sealed from the surrounding through passageway of the sponge by an expandable sleeve or layer of a suitable plastics material. Alternatively, for instance, the through passageway of the sponge in which the stent is received may sealed from the stent in some other manner. As shown in Fig. 8 and Fig. 9, the shaft 48 of the sponge tapers in the distal to proximal direction. However, in other embodiments, the diameter of the sponge's shaft 48 may be essentially constant. Further, the proximal end of the shaft 48 may be sealed against egress of bodily fluids into the sponge although this is not essential in all embodiments of this type as the exposed proximal end of the shaft 48

when in position in the pancreatic or other duct and pressed against the surrounding endoluminal surface of the duct will typically be of minimal thickness.

A further pancreatojejunostomy technique in which the entire resected end portion of the pancreas is inserted into an opening 60 formed the side wall of the jejunum 58 whereby the opening in the side wall is sutured to the pancreas by sutures 62 is illustrated in Fig. 10. The shaft 48 of the endoVAC device 42 is again inserted into the resected opening of the pancreatic duct 58 to assist healing of the duct and resected face 52 of the pancreas, as well as the suturing injury to the pancreas and jejunum. As in the embodiment illustrated in Fig. 9, contact of the funnel shaped main body of the sponge 14 with the endoluminal surface of the jejunum and the resected face of the pancreas 54 under the action of the suction applied to the sponge via the suction tube 30 further assists to retain the sponge in position.

The invention will be described further below by way of a non-limiting Example of the use of an endoVAC device embodied by the invention.

EXAMPLE 1: Healing of rectal anastomotic leaks in a swine model.

A study was carried out to evaluate the use of a vacuum assisted closure (endoVAC) device embodied by the invention to heal low rectal anastomoses in a swine model. Low anterior resection has a leak rate from about 5-15% which carries significant morbidity. A diverting ileostomy is often used for high risk anastomoses but its creation and subsequent reversal carries additional morbidity and surgical risks. Thus, a VAC device of the invention was employed as an alternative method to manage rectal anastomic surgery.

After bowel preparation, 14 pigs underwent rectal resection with primary anastomosis. A 2-cm defect was then created in the staple line. In the treatment (VAC) group, the endoVAC device was inserted within the bowel and low continuous suction (at a respective value in a range of from 5.5-140 mmHg) was applied for 5 days. The control group had no device placed. During the study all pigs were kept NPO and given total parenteral nutrition. After 5 days, the anastomoses were examined by lower GI contrast fluoroscopy (BE), by gross necropsy, and histologically evaluated for mucosal integrity, location and density of inflammation.

The pigs were randomly assigned into the treatment (endoVAC) or control groups. All 10 endoVAC treated pigs completed the 5 day course of endoVAC therapy. Of these, 9 had complete closure of the 2 cm defect when evaluated by contrast fluoroscopy (BE), and one had a contained anastomotic leak. The pig with the contained leak was treated with 5.5 mmHg applied suction. Of the 4 control pigs, 3 had anastomotic leaks (2 contained, 1 uncontained). The Chi-square value for postoperative leakage was $p = 0.0410$. Three of the control pigs were euthanized prior to completion of the experiment due to symptoms of sepsis. On histology, the endoVAC group had minimal mucosal and serosal inflammation with early granulation and scar tissue formation. The control group had extensive mucosal damage with associated serositis.

The results show that the endoluminal vacuum therapy is well tolerated in swine. Moreover, the endoVAC therapy was successful in closing anastomotic defects in 90% of cases, and inhibition of leakage as evaluated by fluoroscopy reached statistical significance in this study.

In another study employing the same animal model described above, a low rectal anastomoses in a single pig was treated for 5 days with an endoVAC device that was not provided with a drainage tube 22. That is, the endoVAC device simply comprised an unsealed sponge without a longitudinal through passageway wherein suction was applied to the sponge by a suction tube 30. However, the sponge became contaminated with faecal matter and suction to the sponge was lost resulting in the anastomosis failing to heal and a consequential uncontained leak from the anastomosis.

Whilst various embodiments have been described above, it will be understood that numerous various and modifications can be made without departing from the invention. For example, embodiments may be provided in which the expandable element 34 is a stent (e.g., a wire or other suitable stent) that is in a collapsed state when the device is being located in position within the patient and is operably arranged to be expanded to press the outer sponge 14 into contact with the wound and surrounding endoluminal surface in use. The stent will normally be enclosed in an expandable plastic or other covering sealing the stent from the sponge. Any suitable such stent can be employed. Moreover, the internal diameter of the drainage tube 22 can be greater than that of the particular embodiments shown in the accompanying figures which follow and as such, the relative dimensions and proportions of an endoVAC device embodied by the

invention can vary and are not limited to those of the currently exemplified embodiments.

Accordingly, the above described embodiments are merely illustrative and not restrictive.

CLAIMS

1. A device for applying a negative pressure to an endoluminal surface in the body of a patient to facilitate healing of a wound in the endoluminal surface, comprising:

a flexible porous element with a peripheral outer face for contact with the wound, the outer face being defined between opposite proximal and distal ends of the porous element; and

a suction tube for being connected to a suction source externally of the patient's body and which is in fluid communication with the porous element to apply a negative pressure to the wound via the outer face of the porous element upon operation of the suction source, the porous element having at least one through passageway extending from its proximal end to its distal end for passage of bodily substances of the patient through the porous element, and at least one of the proximal and distal ends of the porous element is otherwise adapted against egress of the bodily substances into the porous element.

2. A device according to claim 1 further comprising a drainage tube for collection and drainage of the bodily substances from the patient, wherein the drainage tube is received in the through passageway of the porous element.

3. A device according to claim 2 wherein the drainage tube projects from the proximal and distal ends of the porous element, the interior of the drainage tube is defined by a surrounding side wall of the tube and a plurality of through openings are provided in the side wall forward of the proximal end of the porous element.

4. A device according to claim 3 wherein a plurality of further through openings are provided in the side wall of the drainage tube rearwardly of the distal end of the porous element.

5. A device according to any one of claims 1 to 4 wherein at least the proximal end of the porous element is otherwise adapted against egress of the bodily substances into the porous element.

6. A device according to claim 5 wherein the proximal and distal ends of the porous element are otherwise adapted against egress of the bodily substances into the porous element.

7. A device according to any one of claims 1 to 6 wherein the porous element is cylindrical with a single longitudinal said through passage, the through passage being defined centrally within the porous element.

8. A device according to any one of claims 1 to 4 wherein the porous element is funnel shaped with a projecting shaft for being inserted into a duct defined by the endoluminal surface, the through passageway extending longitudinally through the shaft.

9. A device according to claim 8 wherein the distal end of the porous element is otherwise adapted against egress of the bodily substances into the porous element.

10. A device according to any one of claims 1 to 7 further comprising an expandable element arranged for expanding the porous element to press the outer face of the porous element against the wound.

11. A device according to claim 10 wherein the expandable element is an inflatable inner core.

12. A device according to claim 10 wherein the expandable element is fabricated from a resilient material biased to an expanded normal resting state.

13. A device according to claim 12 further comprising a hollow locating tube for locating the porous element in position adjacent the endoluminal surface, the expandable element being received in the locating tube in a compressed state and expandable to its resting state externally of the tube.

14. A device according to any one of claims 1 to 13 wherein the porous element is formed from an absorbent material.

15. A device according to any one of claims 1 to 14 wherein the porous element is a sponge.

16. A method for facilitating healing of a wound in an endoluminal surface in a body of a patient, comprising:

providing a device for applying a negative pressure to the wound, the device having a flexible porous element with a peripheral outer face for contact with the wound, the outer face being defined between opposite proximal and distal ends of the porous element, the porous element having at least one through passageway extending from its proximal end to its distal end for passage of bodily substances of the patient through the porous element, and at least one of the proximal and distal ends of the

porous element is otherwise adapted against egress of the bodily substances into the porous element;

locating the device in position such that the porous element is in contact with the wound; and

applying a negative pressure to the wound through the outer face of the porous element via a suction tube in fluid communication with the porous element.

17. A method according to claim 16 wherein the device further comprises a drainage tube for collection and drainage of the bodily substances from the patient, and the drainage tube is received in the through passageway of the porous element, and wherein the bodily substances are drained from the subject through the drainage tube.

18. A method according to claim 17 wherein the bodily substances are drained from the subject through the drainage tube under suction applied to the drainage tube.

19. A method according to any one of claims 16 to 18 wherein both the proximal and distal ends of the porous element are otherwise adapted against egress of the bodily substances into the porous element.

20. A method according to any one of claims 16 to 19 wherein the porous element is cylindrical with a single longitudinal said through passage, the through passage being defined centrally within the porous element.

21. A method according to any one of claims 16 to 19 wherein the porous element is funnel shaped with a projecting shaft, and the shaft is inserted in a duct defining the endoluminal surface, the through passageway of the porous element extending longitudinally through the shaft.

22. A method according to any one of claims 16 to 20 wherein the device further comprises an expandable element arranged for expanding the porous element to press the outer face of the porous element against the wound, and the method further comprises expanding the expandable element to press the outer face of the porous element against the wound.

23. A method according to any one of claims 16 to 22 wherein the device is used to reduce or prevent leakage from the wound.

24. A method according to claim 24 wherein the wound is an anastomosis resulting from surgery.

25. A method according to any one of claims 16 to 24 wherein the wound is in an endoluminal surface of the bowel of the patient.

25. A method according to any one of claims 16 to 24 wherein the porous element is formed from an absorbent material.

26. A method according to any one of claims 16 to 25 wherein the porous element is a sponge.

27. A method for treating, or reducing potential for, leakage from an anastomosis in an endoluminal surface in a body of a patient, comprising:

providing a device for applying a negative pressure to the anastomosis, the device having a flexible porous element with a peripheral outer face for contact with the anastomosis, the outer face being defined between opposite proximal and distal ends of the porous element, the porous element having at least one through passageway extending from its proximal end to its distal end for passage of bodily substances of the patient through the porous element, and at least one of the proximal and distal ends of the porous element is otherwise adapted against egress of the bodily substances into the porous element;

locating the device in position such that the porous element is in contact with the anastomosis; and

applying a negative pressure to the anastomosis through the outer face of the porous element via a suction tube in fluid communication with the porous element.

28. A method according to claim 27 wherein both the proximal and distal ends of the porous element are otherwise adapted against egress of the bodily substances into the porous element.

FIGURE 1

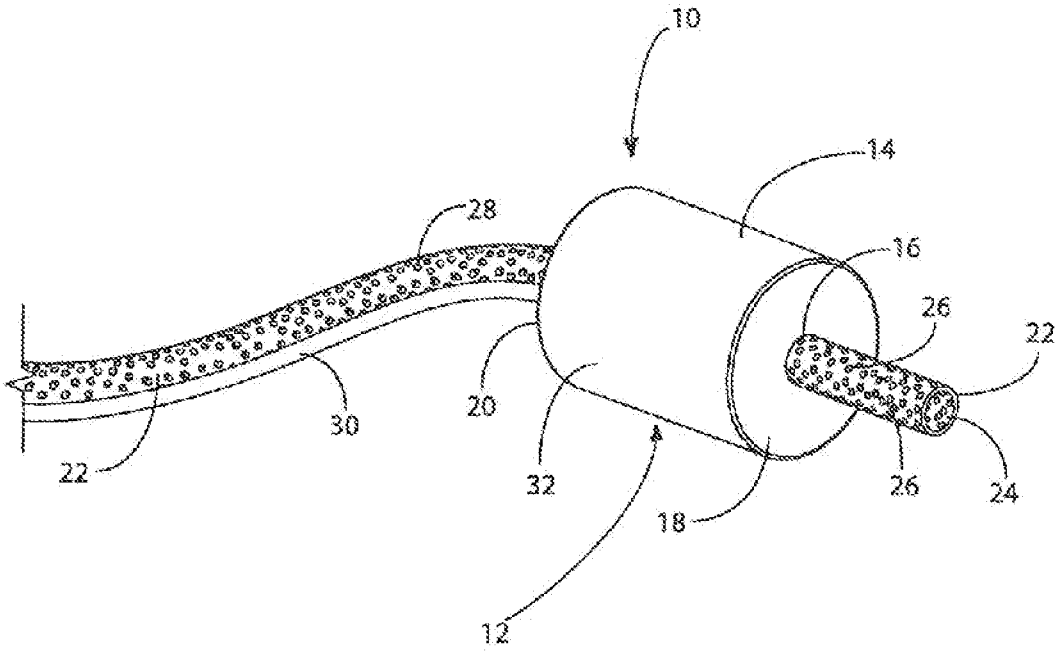


FIGURE 2

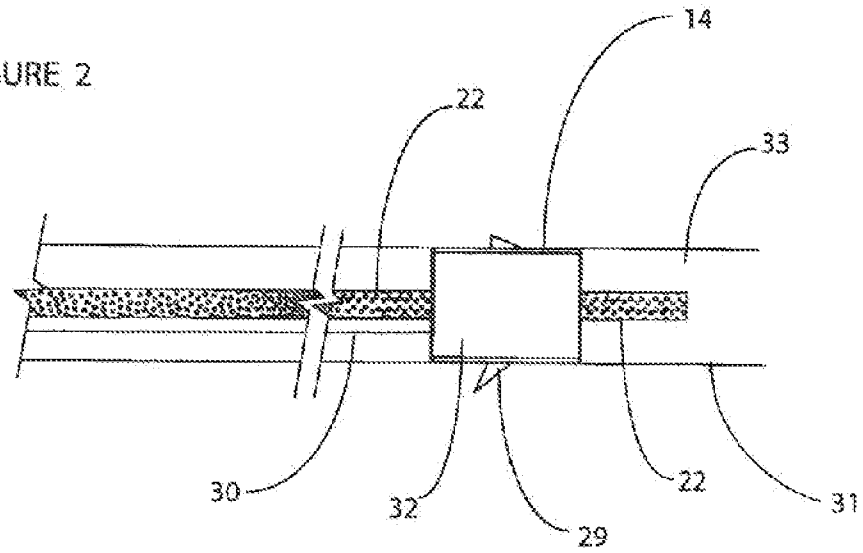


FIGURE 3

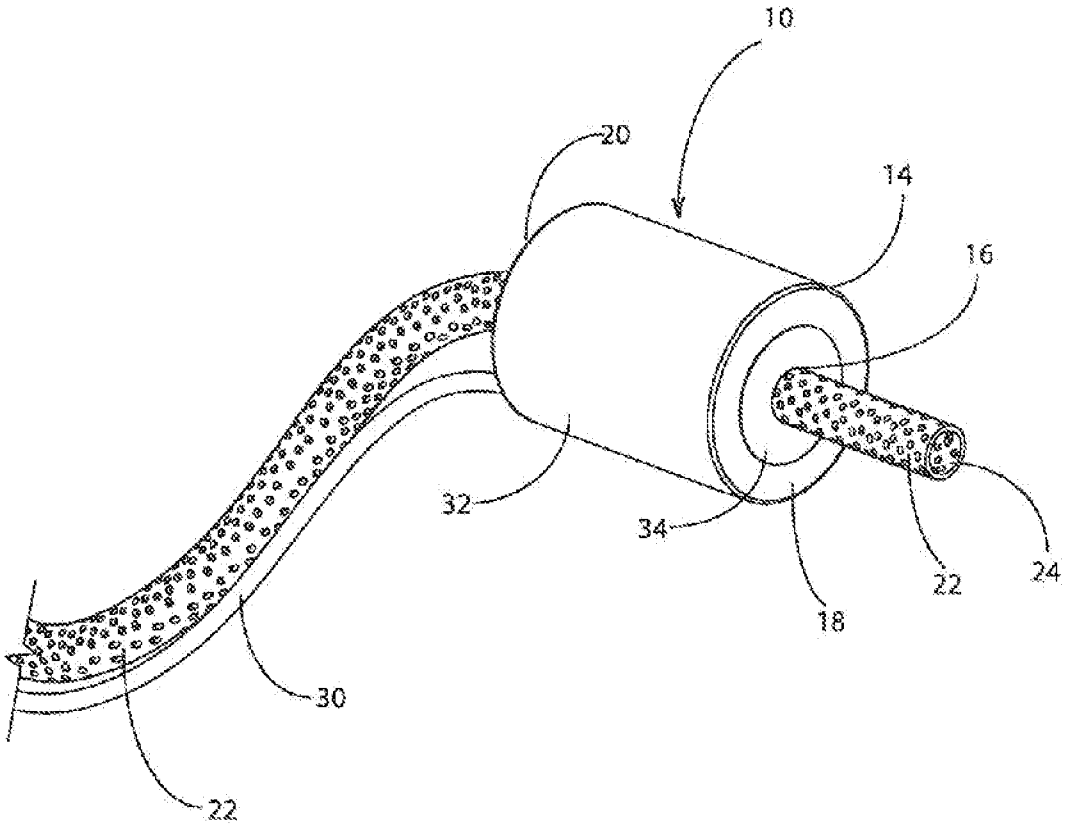


FIGURE 4

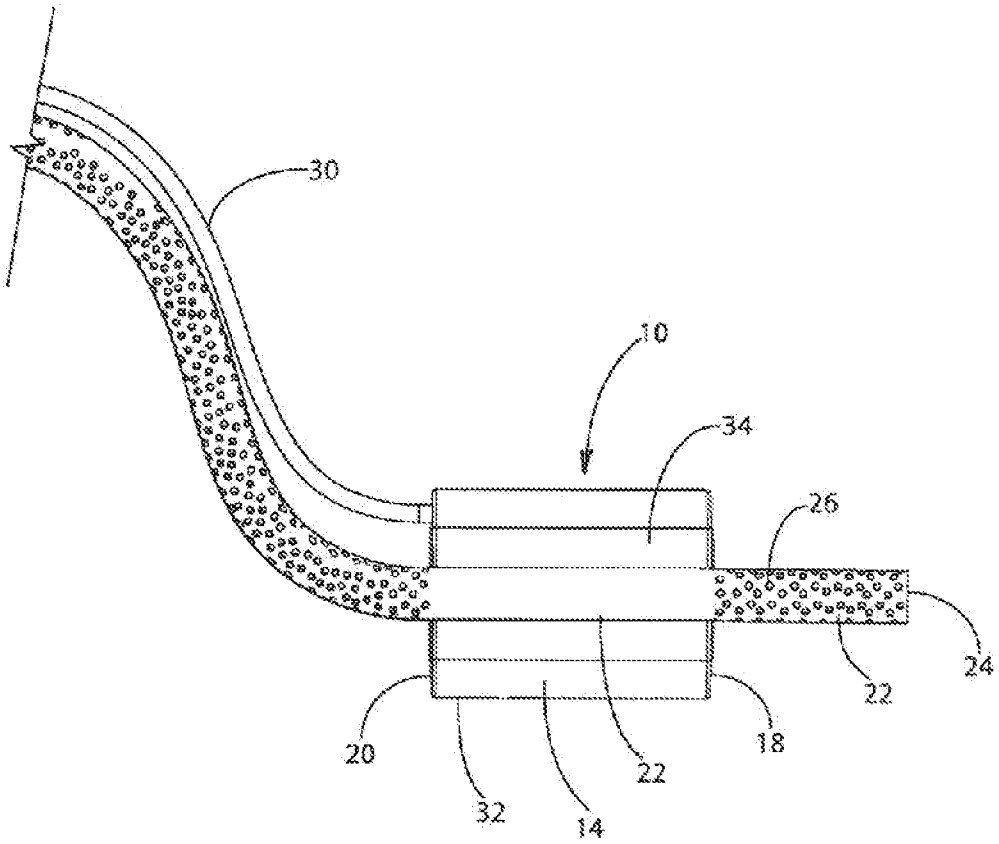


FIGURE 5

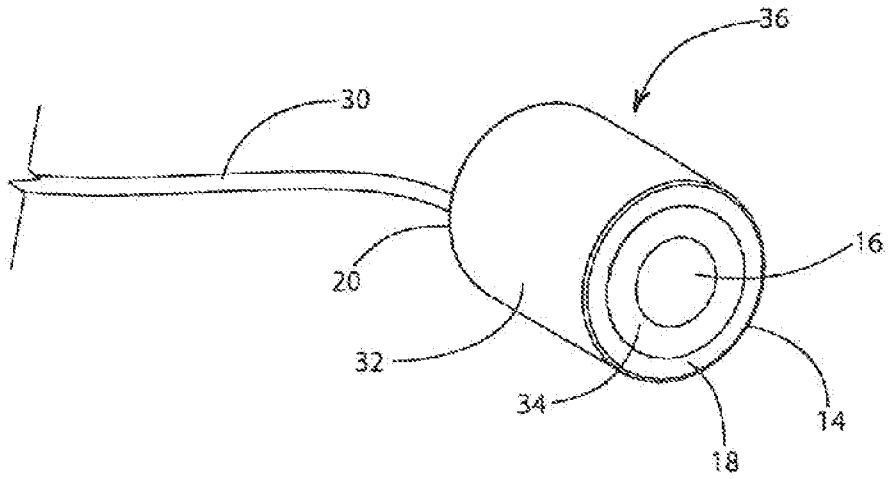


FIGURE 6

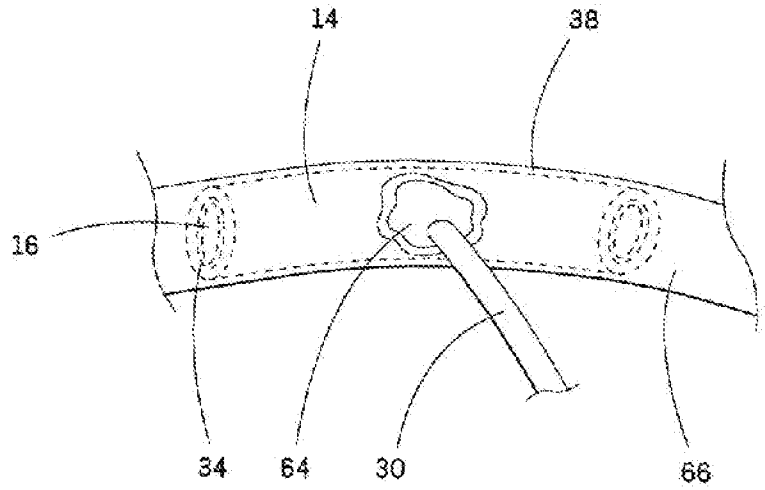


FIGURE 7

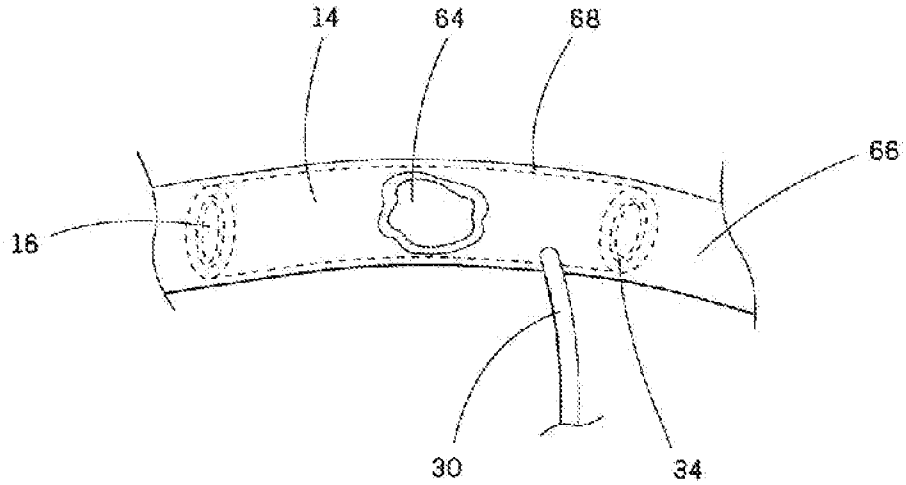


FIGURE 8

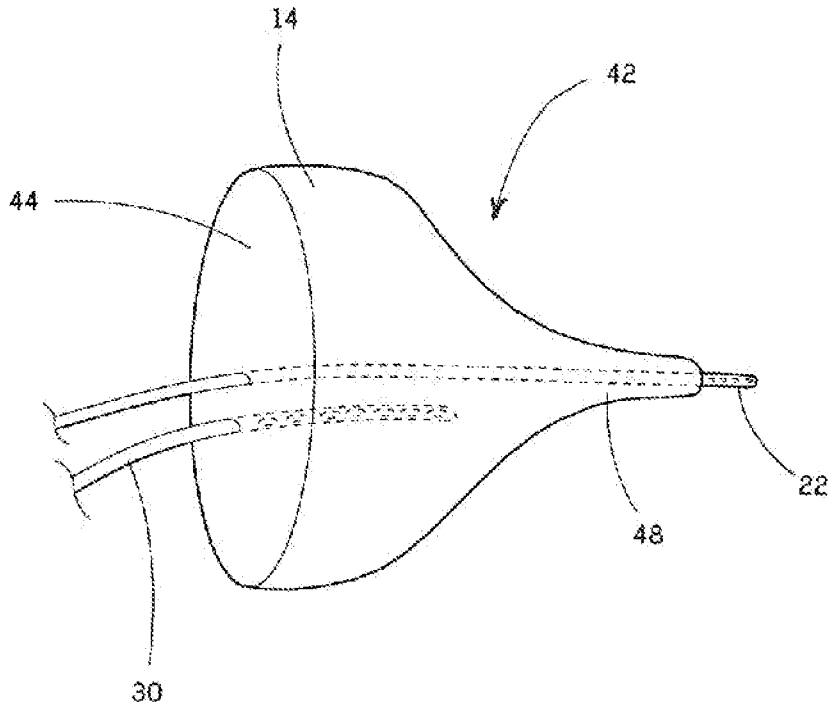


FIGURE 9

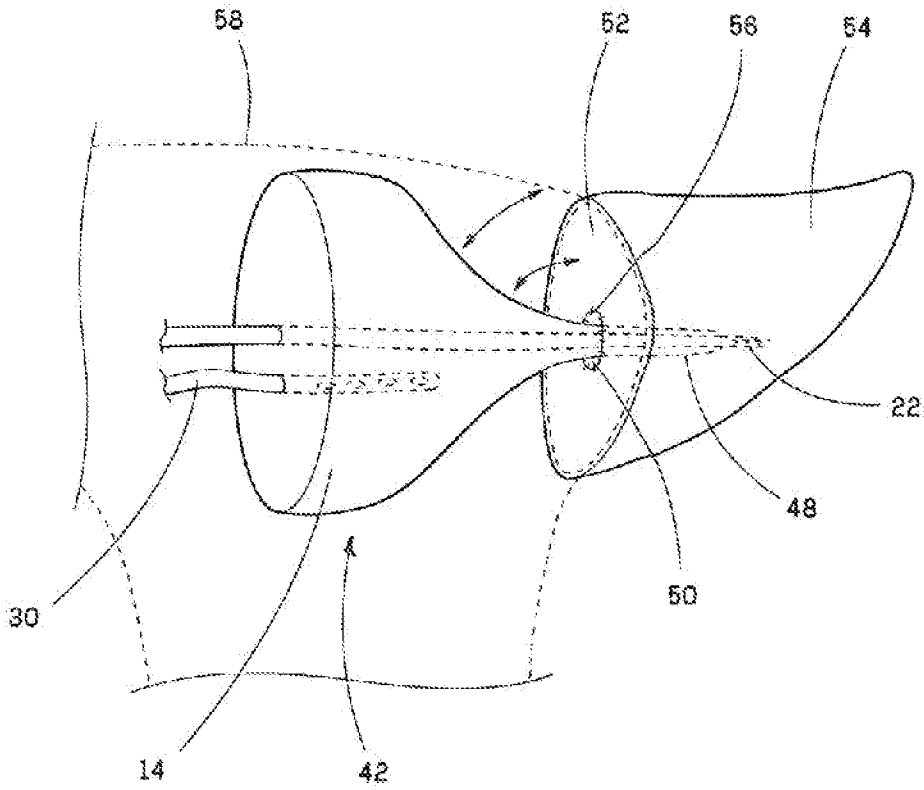
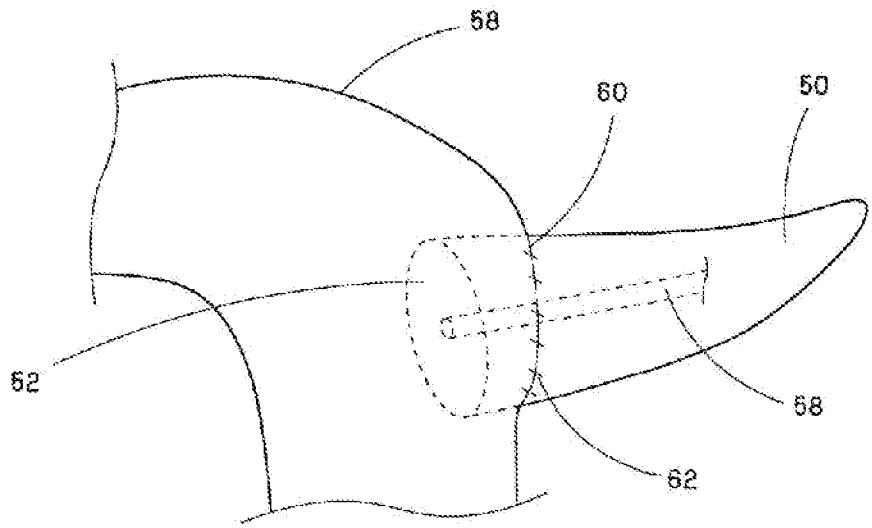


FIGURE 10



INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2011/001568

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 1/00 (2006.01) ***A61F 13/00*** (2006.01) ***A61M 27/00*** (2006.01)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPODOC, DWPI: IPC: EC: A61M1/-, A61M27/-, A61B17/- & A61F13/-, keywords: VAC, NPWT, THERAP+, POROUS, SUCTION, TUBE and similar terms or synonyms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0054338 A1 (BYBORDI et al.) 18 March 2004 see paragraphs [0006], [0008], [0012], [0021], [0026], [0030]-[0036], [0044] & [0052]; figs. 1A, 1C & 2-6	1-28
X	WO 2007/142688 A1 (BENGTSON et al.) 13 December 2007 see abstract; page 6, line 7 – page 7, line 34; page 9, line 9 – page 14, line 17; figs. 1-17	1-2, 5-9, 14-21 & 23-28
X	WO 2008/043067 A2 (INNOVATIVE THERAPIES, INC.) 10 April 2008 see abstract; paragraphs [1012]-[1017] & [1031]-[1082]; figs. 6-7 & 10-11	1-2, 5-9, 14-21 & 23-28
X	US 2005/0137539 A1 (BIGGIE et al.) 23 June 2005 see abstract; paragraphs [0032]-[0057]; figs. 1-5	1-2, 5-9, 14-21 & 23-28

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
05 March 2012	15 March 2012

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaustralia.gov.au
Facsimile No. +61 2 6283 7999

Authorized officer
MOUHAMMAD HABLAS
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No : +61 2 6225 6143

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2011/001568

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008/0300578 A1 (FREEDMAN) 04 December 2008 see whole document	
A	GB 2356148 B (KCI MEDICAL LIMITED) 09 June 2004 see whole document	
A	US 6695823 B1 (LINA et al.) 24 February 2004 see whole document	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2011/001568

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	2004054338	US	6979324	US	2005137539	US	7520872
		US	2005261643	US	7731702	US	2009204085
		US	8034038				
WO	2007142688	CA	2653961	EP	2029191	US	2007282310
		US	7699831	US	2007282309	US	2010179516
		WO	2007143179				
WO	2008043067	US	2008243096	US	2009093778		
US	2008300578	US	7967810	US	2011251571		
GB	2356148	AU	11639/01	BR	0015460	CA	2390513
		CN	1420792	CR	6634	EP	1227853
		EP	1920791	HK	1049124	IL	149509
		JP	2003513715	MX	PA02004652	NZ	518817
		RU	2002115287	US	7678102	US	2009312727
		WO	0134223	ZA	200203608		
US	6695823	AU	40785/00	CA	2367460	EP	1169071
		EP	2255837	JP	2003521962	US	2004006319
		US	7722582	US	2007219513	US	7758554
		US	2010022972	US	8096979	WO	0061206

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX