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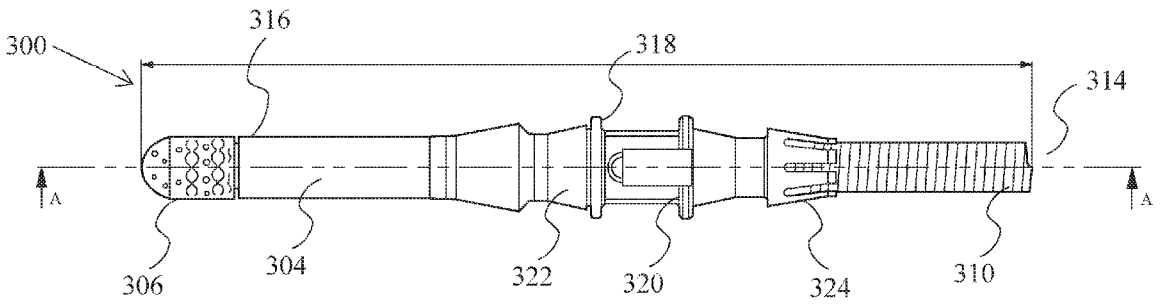

Fig. 4A

(57) Abstract: A catheter for treatment of a defect internal of a human or animal body. The catheter may comprise a tube adapted for insertion into the body; an applicator disposed within and moveable relative to the tube; and a porous medium attached to the applicator; wherein the porous medium is capable of fitting inside the tube, whereby the applicator can be controlled at a proximal end of the tube to deploy the porous medium from a distal end of the tube so as to treat the defect.

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APPARATUS FOR THE TREATMENT OF DEFECTS INTERNAL OF THE BODY

The invention relates to the treatment of defects internal of the human or animal body, such as abscesses and abscess cavities.

More specifically, the invention provides apparatus and methods for treating such internal defects through the application of a negative pressure at the site of the defect, for example to assist closure of an abscess cavity and/or to remove bodily fluids that may have accumulated at the defect.

Abscess cavities may include breaches in the continuity of the wall of the upper and lower gastrointestinal (GI) tract, which can create internal defects known as 'leak cavities'. Such breaches may be a result of anastomotic leak or spontaneous / iatrogenic perforation, which can often result in severe sepsis. Traditionally, open surgery and/or radiological drainage is required to treat such defects, though this approach is often associated with high rates of morbidity and mortality, and furthermore may not always be feasible. It is estimated that around 50% of patients who have a leak from the upper gastrointestinal (GI) tract that requires surgical intervention do not recover.

Abscesses occurring in the peritoneal and pleural cavities usually occur due to bacterial infection within that cavity, for example following visceral perforation in the peritoneal cavity, such as perforated appendicitis or perforated diverticulitus, or following pneumonia or other insult such as penetrating trauma in the pleural cavity. It is recognised that drainage of the cavity (i.e. removing contaminants) can help to control infection at these internal defects, though drainage by way of surgery is associated with increased morbidity and mortality.

It is desirable to provide an apparatus and method for treating such internal defects that may avoid the need for open surgery.

According to an aspect of the invention there is provided a catheter for treatment of a defect internal of a human or animal body, the catheter comprising: a tube adapted for insertion into the body; an applicator disposed within and moveable relative to the tube; and a porous medium attached to the applicator; wherein the porous medium is capable of fitting inside the tube, whereby the applicator can be controlled at a proximal end of

the tube to deploy the porous medium from a distal end of the tube so as to treat the defect.

The defect may be an abscess cavity, possibly caused by a breach in the wall of the lower or upper gastrointestinal (GI) tract, including in the pharynx and oesophagus, whereby the catheter may be adapted for insertion into the body to access the defect endoluminally.

Alternatively, the defect may be an abscess in the peritoneal and pleural cavity, possibly caused by bacterial infection, whereby the catheter may be adapted for insertion into the body to access the defect percutaneously, and optionally using radiological guidance.

The apparatus may further be suitable for drainage, such as for drainage of an abscess cavity, whether in the abdominal or thoracic cavity, optionally wherein the catheter is arranged to be inserted percutaneously.

Thus, the catheter may be utilised to place the porous medium into the defect, optionally under endoscopic visualisation or radiological guidance, depending on the defect. By attaching the porous medium to the moveable applicator, instead of the tubing, it may be possible to deliver the end of tube to the site of a defect before deploying the porous medium, and then subsequently deploying the porous medium. The porous medium may also be retracted back into the tube using the applicator to allow it to be removed at the end of the treatment. In addition, it may be possible to use the applicator to control and adjust the extent to which the porous medium is deployed, e.g. into a defect cavity, once the catheter is *in situ*.

Optionally, the porous medium may be capable of being deformed such that it can fit inside the tube, and the porous medium may be arranged to return to its pre-deformed shape when deployed from the tube. Optionally, the porous medium may initially, prior to deployment, be contained within the tube, for example in a deformed (for example, compressed or ‘non-expanded’) state.

Optionally, the tube may be arranged to provide a fluid conduit, for example for application of a negative pressure to the deployed porous medium and/or for flushing of liquid into the cavity and/or for drainage purposes. Optionally, the applicator may be

arranged to provide structural support to the tube, for example to inhibit the tube from collapsing and/or kinking.

Optionally, the applicator may be moveable in a longitudinal direction, for example wherein the amount of movement may be varied to control the amount of porous medium deployed. Optionally, the applicator may be a guidewire, for example a coiled guidewire having an internal bore. Optionally, the porous medium may be attached to the distal end of the applicator.

Optionally, the porous medium may be attached to the end of the applicator by a cord, thread, adhesive, heat-shrink wrap, or other suitable attachment means, whereby a first end of the cord may be secured to the porous medium and a second end of the cord may be secured to the applicator at a position spaced from the porous medium, such that the cord extends at least partway along the length of the applicator. Optionally, the second end of the cord may be attached to the applicator at a position that is external to the tube. Optionally, the porous medium may be attached to the end of the applicator by a suture.

Optionally, the porous medium may comprise a foam material such as an open-cell foam, which may comprise polyurethane. For example, a suitable open-cell foam may be a ‘vacuum assisted closure’ foam, VAC (REGISTERED TRADEMARK).

Optionally, the porous medium may comprise bio-active material, for example a bio-active collagen. The porous medium may be carried on the applicator and held in place either by friction, or by an additional binding such as an adhesive, or by wrapping it around the applicator or by mechanical fixing means, for example. Optionally, the porous medium may comprise a material designed to treat a cavity and/or restore continuity of a wall.

Optionally, the porous medium may be a tangled mesh of wire capable of being unravelled, stretched or drawn out into one or more single strands, the wire being arranged to have resilience causing it to reform the mesh when not restrained and/or under tension. Optionally, the porous medium may comprise a nickel titanium alloy, for example nitinol.

Optionally, the distal end of the tube may be arranged to provide a flared opening, for example a conical-shaped opening. Optionally, the tube may comprise fluorinated ethylene propylene (FEP). Optionally, the tube may be configured for nasogastric intubation.

Optionally, the catheter may further comprise an adaptor arranged to fit the applicator and provide a detachable fluid connection between the tube and a fluid flow generator capable of applying a negative pressure to the tube, for example a vacuum apparatus or a pumping apparatus. Optionally, the adaptor is arranged to provide a luer-lock connection with the fluid flow generator. The adaptor may also be used to couple a fluid source to the lumen of the catheter, for example to supply a fluid such as saline to the working (distal) end of the catheter to flush the defect and/or for example to deliver antibiotics.

Optionally, for insertion endoluminally, the catheter (or tube) may have an outer diameter arranged to fit within the working channel of an endoscope. For example, an endoscope having a working channel of 2.8mm diameter would, preferably, require a catheter to have an outer diameter of less than 2.8mm. For example, an endoscope having a working channel of 3.7mm would, preferably, require a catheter having a working channel of less than 3.7mm. Preferably, a clearance gap is required to allow movement of the catheter within the working channel of an endoscope – which typically has an internal diameter of about 3.7mm or 2.8mm – otherwise even so-called 'low friction' plastics (such as PVC, for example) may present a problem due to the length of channel and catheter. Optionally, for endoluminal insertion, the catheter (or tube) exterior may comprise a very smooth, preferably 'ultra-smooth', and/or a low-friction material, such as PVC (e.g. a material having a low friction coefficient), at least on its exterior surface.

Optionally, the length of the catheter may be at least 50% longer, and preferably at least 100% longer, than the length of the endoscope. Preferably, the catheter is flexible, and optionally it is sufficiently flexible to undergo a 1cm diameter 180 degrees bend.

Optionally, for percutaneous insertion, the catheter may be arranged to be deployed along a guidewire arranged to guide the catheter into position within the body. The guidewire may be introduced to the body using a needle (or cannula). Preferably, the outer diameter of catheter is not specifically restricted for percutaneous use, such as

may be necessary if the catheter is for endoluminal insertion, for example. Optionally, however, if the catheter is to be placed into a deep cavity between other structures, the catheter (or tube) may have an outer diameter similar to the outer diameter of the catheter for endoluminal insertion, and, for example, less than about 5mm. The catheter for percutaneous insertion may have a similar rigidity to the endoscopic catheter. Optionally, the catheter may have a length of between about 20 and about 50cm. Optionally, the catheter may comprise a low-friction material similar to the material of the catheter for endoluminal insertion.

Optionally, the catheter may be radio-opaque to aid x-ray guided visualisation of its insertion. Optionally, at least part of the applicator may be radio-opaque, for example if it comprises a metal or another suitably radio-opaque material.

According to another aspect of the invention there is provided a method for treating a defect, such as a leak cavity caused by a breach in a wall, of the lower or upper gastrointestinal (GI) tract internal of a human or animal body, the method comprising: introducing a catheter containing a deployable porous medium into the body, for example via endoluminal insertion; positioning the catheter at the defect (for example in an opening of a leak cavity, or adjacent the opening and preferably close enough to allow the porous medium to be deployed into a leak cavity); deploying the porous medium from the catheter; placing the porous medium into the defect; and applying a continuous negative pressure via the catheter to treat the defect.

Optionally, the catheter may be positioned using endoscopic visualisation. Optionally, the porous medium may be applied to the wall of the gastro-intestinal tract outside of the defect. Negative pressure can then be applied to the wall of the gastro-intestinal tract around the defect whereby to close the defect and/or inhibit the entry of bowel contents and other contaminants into the defect so as to assist healing.

According to another aspect of the invention there is provided a method for treating a defect, such as an abscess in a peritoneal or pleural cavity internal of a human or animal body, the method comprising: inserting a guidewire into the body, the guidewire being positioned at the site of a defect (for example at an abscess or infection having collection of fluid); inserting a catheter containing a deployable porous medium into the body percutaneously, wherein the catheter is deployed along the guidewire arranged to

position the catheter at the defect; deploying the porous medium from the catheter; placing the porous medium into the defect; and applying a continuous negative pressure via the catheter to treat the defect.

Optionally, imaging guidance, for example ultrasound, may be used to position the guidewire at the defect. Optionally, the positioning of the guidewire may be checked using imaging, for example radiology.

Optionally, the porous medium may be initially contained within the catheter in a deformed state, whereby deployment of the porous medium causes it to return to its pre-deformed state.

Optionally, the catheter may comprise an applicator controllable to deploy the porous medium, the method further comprising controlling the applicator at a proximal end of the catheter to deploy the porous medium at a distal end of the catheter.

Optionally, the negative pressure applied may be less than 125mm Hg, for example less than 100mm Hg, for example less than 85mm Hg.

According to another aspect of the invention there is provided a method of treating a defect, comprising using a catheter as described above with a method as described above.

According to another aspect of the invention there is provided a system for treating a defect internal of a human or animal body, the system comprising: a catheter as described above; and a fluid flow generator adapted to provide a fluid connection with the catheter, such that, when fluidly connected, a negative pressure can be applied by the fluid flow generator, via the catheter, to treat the defect.

According to another aspect of the invention there is provided a system for treating a defect internal of a human or animal body, the system comprising: a catheter, an elongate element disposed within and moveable relative to the catheter, and a porous substrate attached to an end of the elongate element, such that the porous substrate can be deployed from the catheter by advancing the elongate element at a position remote from the porous substrate; and a vacuum apparatus adapted to be fluidly

connected to the catheter whereby to apply a negative pressure via the catheter to treat the defect.

Optionally, the system further comprises an endoscope capable of positioning the catheter at the defect under endoscopic visualisation.

Optionally, the system further comprises visualisation means for positioning the catheter at the defect.

Optionally, the system may be arranged such that the catheter is deployed alongside the endoscope, for example wherein the catheter may be attachable to the endoscope, such that it can be positioned at a defect with the endoscope. Alternatively, the catheter may be arranged to fit within the lumen of the endoscope, such that it can be positioned at a defect with the endoscope.

Optionally, the system further comprises a guidewire and insertion needle (or cannula) arranged to insert the guidewire into the body.

Optionally, the system may be arranged such that the catheter is deployed along a guidewire introduced into the body percutaneously so as to position the catheter at a defect.

Optionally, the guidewire may pass through the catheter or it may run alongside the catheter.

A fluid source may be connectable to the lumen of the catheter, for example to supply a fluid such as saline to the working (distal) end of the catheter to flush the defect and/or for example to deliver antibiotics.

Miniaturisation may allow the catheter to be used in other areas of the body.

According to another aspect of the invention there is provided a kit of parts for a catheter, comprising an applicator and a porous medium attached to an end of the applicator.

Optionally, in the kit, the applicator may be a guidewire, for example a coiled guidewire having an internal bore. Optionally, in the kit, the porous medium may be attached to the end of the applicator by a suture. Optionally, in the kit, a first end of the suture thread (or cord) may be secured to the porous medium and a second end of the suture thread (or cord) may be secured to the applicator at a position spaced from the porous medium, such that the suture thread (or cord) may extend at least partway along the length of the applicator.

Optionally, the kit may further comprise a tube arranged to fit over the applicator so as to provide a fluid conduit. Optionally, the kit may further comprise an adaptor for coupling the tube to a vacuum apparatus, the adaptor arranged to allow the applicator to pass therethrough.

Optionally, the kit may further comprise a guidewire and a needle or cannula for inserting the guidewire into a body, preferably wherein the guidewire is arranged so as to pass through the applicator whereby to enable percutaneous insertion of the catheter into the body via the guidewire.

According to another aspect of the invention there is provided a substrate for delivering bio-active material into an internal wound in a human or animal body, the substrate (for example, an extensible substrate) carrying a bio-active material, wherein the substrate is configured at least partially to shed the bio-active material into a wound.

Optionally, the substrate may be flexible. Preferably, the substrate is more flexible than the bio-active material such that flexure of the substrate causes shedding of the bio-active material.

Optionally, the substrate is elongate and configured to form a mesh when not restrained and/or under tension. Optionally, the elongate substrate may be arranged to form a resilient mesh when not restrained and/or under tension. Optionally, the substrate may comprise a wire or tape. Optionally, the substrate may comprise a memory metal, such as nitinol. Optionally, the bio-active material may comprise collagen.

Optionally, the bio-active material may be water soluble. Optionally, the bio-active material may be adhered to the substrate by a water-soluble adhesive.

According to another aspect of the invention there is provided a method of delivering bio-active material into an internal wound in a human or animal body, comprising: positioning a catheter at the wound; and deploying an extensible substrate from the catheter into the wound; wherein said substrate carries the bio-active material and is configured to at least partially shed the bio-active material into the wound.

Optionally, the substrate may be deployed from a distal end of the catheter positioned at the wound. Optionally, deployment of the substrate may be controlled from a proximal end of the catheter. Optionally, the substrate may shed bio-active material while extended from the catheter, for example during deployment or during retraction.

Optionally, the distal end of the catheter may be configured to cause at least some of the bio-active material to shed from the substrate into the wound as the wire is retracted back into the catheter, for example wherein the distal end has serrations. Optionally, the substrate is elongate and configured to form a mesh when not restrained by the catheter and/or under tension.

Optionally, the elongate substrate may be arranged to form a resilient mesh when not restrained by the catheter and/or under tension. Optionally, the substrate may comprise a wire or tape. Optionally, the substrate may comprise a memory metal, such as nitinol. Optionally, the bio-active material may comprise collagen.

Optionally, the substrate may be flexible. Preferably, the substrate is more flexible than the bio-active material such that flexure of the substrate causes shedding of the bio-active material.

Optionally, the bio-active material may be water soluble. Optionally, the bio-active material may be adhered to the substrate by a water-soluble adhesive.

As used herein, the term “abscess” preferably connotes a drainable, infected fluid collection.

As used herein, the terms “vacuum apparatus” and “fluid flow generator” preferably include apparatus arranged to generate a vacuum, or at least a negative pressure (i.e. suction) via a tube or catheter.

As used herein, the term “proximal” preferably connotes situated nearer to a point of attachment, to an apparatus for example. In contrast, the term “distal” preferably connotes situated away (or remote) from a point of attachment, to an apparatus for example.

As used herein, means plus function features may be expressed alternatively in terms of their corresponding structure.

Any apparatus feature as described herein may also be provided as a method feature, and vice versa. Furthermore, any feature in a particular aspect of the invention may be provided independently and/or applied to other aspects of the invention, in any appropriate combination.

An exemplary embodiment of the invention will now be described with reference to the accompanying figures, in which:

Figure 1 shows different stages of endoscopic vacuum therapy (EVT);
Figure 2 shows a basic device for use with EVT;
Figure 3 shows an example of a catheter;
Figures 4A and 4B show a side view and a cross-sectional side view (A-A) of the catheter;
Figure 5 shows a detailed view (C) of a porous medium secured to a distal end of the catheter;
Figure 6 shows a system for EVT; and
Figure 7 shows an exemplary embodiment of a porous medium.

Endoscopic vacuum therapy (EVT) is a relatively new technique for treating defects, such as oesophageal perforation and certain other post-operative leakages. EVT is a minimally invasive, alternative method of treatment to traditional surgery, utilising vacuum-assisted closure (VAC) techniques.

EVT involves placing a polyurethane sponge into a defect cavity under endoscopic visualization and then applying a continuous negative pressure, causing the cavity to collapse around the sponge. The sponge is typically changed every 48-72 hours until the cavity shrinks and stable granulation tissue forms a barrier.

Devices used for EVT are typically 'homemade' and therefore quite crude in their construction, and could be improved. For example, one treatment method involves a nasogastric tube first being inserted through the nose under general anaesthesia, and then the distal end pulled out through the mouth, and attached to a polyurethane sponge which has been cut to size. The polyurethane sponge may be secured to the nasogastric tube by suture. The sponge is then delivered (attached to the tube) to a defect by a tripod-equipped endoscope, under direct endoscopic visualisation.

Referring to Figure 1, a schematic diagram of an oesophagus 100 is used to show an example of three different stages (i) – (iii) of endoscopic vacuum therapy (EVT) being used to treat a gastrointestinal defect. In this example, EVT is being used to treat a defect 102 in the oesophagus 100, as illustrated in (i). To treat the defect 102, a tube 104 may be inserted through the nose and then directed to the defect 102 under direct endoscopic visualisation, as illustrated in (ii). A sponge 106 attached to the tube 104 may be placed in the defect cavity. A negative pressure, such as -125mm Hg for example, may then be applied, causing the defect 102 cavity to collapse around the sponge 106 to aid healing, as illustrated in (iii). This treatment may also be referred to as endoscopic 'transluminal' or 'intraluminal' vacuum therapy.

Referring to Figure 2, a basic apparatus 200 for use in endoscopic vacuum therapy may include a sponge 206 attached to an end of a tube 204 using a suture 208. The tube 204 may be 12-16F nasogastric (feeding) tube. The sponge 206 may be polyurethane. The suture 208 may be made using '0 silk'. Due to the sponge 206 being in an expanded state, it cannot be passed down the working (or 'tool') channel of an endoscope but rather has to be secured to the outside of the endoscope for placement into a defect cavity, meaning placement of the sponge 206 can be difficult.

Referring now to Figure 3, a catheter 300 may include a porous medium 306 secured to a distal end 312 (shown in Figure 4B) of an applicator 310. The applicator 310 may be disposed at least partially within a tube 304. The tube 304 may have a distal end 316

and a proximal end 318 (as shown in Figure 4B). The distal end 316 of the tube 304 and the distal end 312 of the applicator 310 may be substantially coincident.

The proximal end 318 of the tube 304 may be secured to an adaptor 320. The applicator 310 may be arranged to pass through the adaptor 320 into the tube 304. A distal end 314 of the applicator 310 may be arranged to extend out from the other side of the adaptor 320. The adaptor 320 may be arranged to provide a fluid connection with a vacuum apparatus (not shown). When the adaptor 320 is connected to a vacuum apparatus, a negative pressure may be applied to the porous medium 306 via the tube 304.

Figures 4A and 4B show the catheter 300 in side profile. Figure 4B is a cross-sectional view of the catheter taken along line A-A as indicated in Figure 4A.

The applicator 310 may be elongate. The applicator 310 may be sufficiently elongate (and of suitable diameter) that it can be inserted through a patient's nose. The applicator 310 may be arranged to provide flexibility without creating sharp kinks. The applicator 310 may be flexible while substantially maintaining an inner bore that can act as a fluid conduit. The applicator 310 may be metal, for example a stainless steel such as 304 or 316 stainless steel. The applicator 310 may have a diameter of less than 3.7mm or 2.8mm, so that it can fit inside a standard endoscope having an internal diameter of 3.7mm or 2.8mm. The applicator 310 may have a perforate or foraminous wall. The applicator 310 may be a guidewire. The guidewire may be a guide coil.

The applicator 310 may be moveable relative to the tube 304 in a longitudinal direction. The applicator 310 may also be moveable relative to the tube 304 in a rotational sense. The porous medium 306 may be deployed from a distal end 316 of the tube 304 by moving the applicator 310 in a longitudinal direction relative to the tube 304. The applicator 310 may be moved relative to the tube 304 by controlling the applicator 310 at a region of the applicator 310 that is not disposed within the tube 304 or adaptor 320. The applicator 310 may be controlled at a proximal end 314 of the applicator 310. The extent to which the porous medium 306 is deployed from the tube can be controlled by the applicator 310. The applicator 310 may have a measurement guide disposed on at least its proximal end 314 to aid deployment of the porous medium 306.

The tube 304 may fit closely over the applicator 310. The tube 304 may provide a fluid conduit between the adaptor 320 and the porous medium 306. The tube 304 may provide a fluid tight seal between the adaptor 320 and the porous medium 306. The tube 304 may be supported structurally by the applicator 310 to maintain a fluid conduit through the tube 304.

The distal end 316 of the tube 304 may be flared open (not shown) to aid retraction of the porous medium 306 back into the tube 304. The tube may have an external diameter that allows it to fit (and have relative movement) inside the working channel of a standard endoscope, preferably either less than 2.8mm or less than 3.7mm, depending on the endoscope.

The tube 304 may be a thin-walled polymer. The tube 304 may be a low-friction polymer, compared to silicon and/or PTFE. The tube 304 may have greater elasticity than PTFE. The tube 304 may be arranged to be resistant to kinking. The tube 304 may be capable of twisting or bending with a curvature of about 1cm radius. The tube may be capable of bending greater than 90 degrees without rupturing or kinking. The applicator 310 may provide structural support that helps the tube 304 from kinking. The tube 310 may be formed from fluorinated ethylene propylene (FEP).

The adaptor 320 may have a first connector 322 (not shown) for connecting to the tube 304. The first connector 322 may be a “Christmas tree” connector. The first connector 322 may have one or more barbs 326. The tube 304 may be capable of being stretched to fit over the barbs 326 and sufficiently elastic that upon retraction it crimps over the barbs 326 to secure the tube 304 to the adaptor 320. The adaptor 320 may have a second connector 324 for connecting to a vacuum apparatus (not shown). The second adaptor 324 may be a ‘luer lock’ type connector. The adaptor may be substantially straight so that the first connector 322 and second connector 324 are substantially in-line. The adaptor 320 may be made from nylon or polycarbonate.

The porous medium 306 may be ‘bullet-shaped’. Alternatively, the porous medium 306 may be “teardrop-shaped”. Indeed, the porous medium 306 could take the form of many different 3D shapes, such as a cuboid, pentagonal prism and cylinder for example. The porous medium 306 may be resiliently deformable from a first state to a second state. The porous medium 306 may be deformable to the second state, and may further be

maintained in that second state, under a compression force, provided by squeezing the porous medium by hand, for example. The porous medium 306 may return to the first state when the compression force is removed.

The porous medium 306 may be polyurethane foam. Alternatively, the porous medium 306 may be an expandable mesh, preferably a wire mesh. The mesh may be capable of being unravelled, stretched out, or drawn out into a single thread of wire and to return to its mesh form when released. The mesh may be formed of a shape-memory material. The mesh may be formed from a nickel titanium alloy. The mesh may be formed from nitinol.

Alternatively, the porous medium 306 may be formed from a bio-active material, such as bio-active collagen. The bio-active material may be arranged to degrade itself after a predetermined period of time. The bio-active material may be capable of being wrapped around the applicator 310 (or otherwise attached) to create a porous, sponge- or foam-like medium.

Prior to deployment, the porous medium 306 may be compressed within the tube 304. Upon deployment, a portion of the porous medium 306 that is no longer contained within the tube may expand or undeform back to its pre-deformed state.

Referring to Figure 5, the porous medium 306 may be secured to the distal end 312 of the applicator 310 by way of a suture 308. The suture 308 may be secured to the applicator 310 at a point that is spaced-apart from the porous medium 306. The suture 308 may be secured to the applicator 310 at a point along the length of the applicator 310 that is not disposed within the tube 304 or adaptor 320, with the suture 308 passing either alongside or through the applicator 310. Alternatively, the porous medium 306 may be glued or otherwise secured to the applicator 310.

The catheter 300 as shown in Figures 3 – 5 is not shown to scale. The tube 304 may be of sufficient length to extend from outside of a patient's body to the defect 102 inside the patient's body. The tube 304 may have a length of between about 0.5m and 1.5m. The applicator 310 may be at least as long as the tube 304. In use, the adaptor 320 may be located outside of the patient's body. The portion of the applicator 310 that extends out of the adaptor 320 may be of sufficient length to be controlled to allow relative

longitudinal movement within the tube 304 to allow deployment of the porous medium 306 from the distal end 316 of the tube 304. The applicator 310 may be allowed to move relative to the tube 304 a longitudinal distance of between 1-10mm, for example. The size of the defect 102 will to a great extent dictate the amount of porous medium 306 to be deployed. Accordingly, the applicator 310 may be required to move longitudinally within the tube 304 by up to 50mm, perhaps further.

For small defects 102, the porous medium 306 may be deployed within the lumen of a delivery endoscope, which may then be placed adjacent the defect 102 and a negative pressure applied to cause the wall tissue at the defect to be sucked into the lumen for treatment of the defect 102.

A skilled person will appreciate that the apparatus 200 shown in Figure 2 differs from the catheter 300 shown in Figure 3 at least because the apparatus 200 has a sponge 206 secured to the outside of the tube 204, which is therefore not a porous medium capable of fitting inside the tube 204, and further because there is no applicator disposed within the tube 204.

The catheter 300 may be inserted by attaching it to the outside of an endoscope. Alternatively, the catheter 300 may be deployed from within the working channel of an endoscope.

Once the catheter 300 has been inserted into a patient and correctly positioned, the porous medium 306 may be deployed from the distal end 316 of the tube 304 into a defect cavity 102 by advancing the applicator 310. A vacuum apparatus may then be connected to the adaptor 320 and a continuous negative pressure (i.e. suction) applied to the porous medium 306 via the tube 304. The negative pressure causes the defect cavity to collapse around the porous medium 306 to aid healing of the defect 102, as discussed above. Importantly, the porous medium 306 need only be deployed from the tube 304 once the catheter 300 has been correctly placed at a defect 102 after inserted into the patient's body.

The catheter 300 also allows the defect cavity 102 to be flushed out with fluid, if required and/or suction applied to remove bodily (or other) fluids, i.e. for drainage purposes, for example to remove contaminants from the defect cavity.

The endoscope may be removed while leaving the catheter 300 in-situ for a predetermined period of time. The applicator 310 may then be used again to retract the porous medium 306 back into the tube 304 before the catheter 300 is withdrawn from the patient's body. The catheter 300 can then be replaced, as required.

Thus, the applicator 310 may function as both a reinforcement mechanism to the tube 304 and a deployment mechanism providing controlled deployment of the porous means 306.

When the endoscope is withdrawn, the catheter 300 may be left extending out of a patient's mouth. In order to retract the catheter 300, a plastic tube may be inserted through the nose and reattached to the catheter 300, which can then be fed back up through and out from nose.

The porous medium 306 may not fill the defect cavity 102 entirely. Only a small amount of porous medium 306 may be required to initiate collapse of the defect cavity 102 and hence aid healing.

Standard endoscopes are generally available in two sizes: 2.8mm and 3.7mm diameter. The 2.8mm diameter version is the more common type of endoscope, but this reduces the amount of porous medium 306 that can be deployed, hence using collagen for the porous medium 306, as described above, is of particular interest.

The catheter 300 is not limited for intraluminal treatment of the upper gastro-intestine (GI). The catheter 300 may also be used in treatment of the lower gastro-intestine (GI), such as for colonoscopy, for example, and for other parts of the body.

Alternatively, the catheter 300 may be introduced to a patient's body via percutaneous insertion, i.e. through the skin, similar to the method of inserting an intercostal chest drain, for example by performing a direct cut down, or using the 'Seldinger' technique. Thus the catheter 300 may be used to perform percutaneous drainage, for example to treat an abscess in the peritoneal or pleural cavity, and the abdominal or thoracic cavity, in addition to being used to treat internal defects, such as leak cavities, as discussed above.

The applicator 310 and/or porous medium 310 and/or tube 304 may be provided together in kit form for assembly when required.

Figure 6 shows a system 400 for treating a defect according to an embodiment of the invention. The system 600 includes a catheter 400 and a vacuum apparatus 500 arranged to be fluidly connected together such that a negative pressure can be applied by the vacuum apparatus 500 via the catheter 400.

The catheter 400 includes an adaptor 420 provided with a luer lock connector 424 for coupling with the vacuum apparatus 500. The adaptor 420 is provided with a further connector 422, which is substantially in-line with the luer lock connector 424, for coupling with a flexible tube 404, formed from FEP. The further connector 422 is provided with barbs, which the flexible tube 404 is stretched over so as to provide a secure fluid-tight coupling.

Disposed within the tube, but not visible in this figure (refer to Figure 3) is an applicator 410 that passes through the adaptor 420 and extends towards a distal end 416 of the tube 404. A porous medium 406, which is just about visible in Figure 6, is secured, via suture, to the end of the applicator 410.

In this exemplary embodiment, the applicator 410 is a coiled guidewire, and the porous medium 406 is a teardrop-shaped polyurethane foam, which is sufficiently compressible to allow it to be compressed to fit within the tube 404 and sufficiently resilient that it can resume its uncompressed shape when deployed from (and hence no longer constrained within) the tube 404.

The applicator 410 is moveable in a longitudinal direction relative to the tube 404. The applicator 410 can therefore be controlled to advance the porous medium 406 towards the distal end 416 of the tube 404 and hence deploy it. As the porous medium 406 is deployed from the tube 404, it expands.

Thus, once the catheter 400 has been positioned at a defect cavity, and prior to connecting the catheter 400 to the vacuum apparatus 500, the applicator 410 can be controlled to deploy the porous medium 406. The vacuum apparatus 500 is arranged to

connect to the luer lock connector 424 on the catheter 400 to provide a fluid connection to the porous medium 406 at the distal end of the catheter 400.

In use, once the catheter 400 has been inserted into a patient's body, via the nasal canal for example, and positioned by the defect, and the porous medium 406 deployed, the vacuum apparatus 500 may be attached to the catheter 400, via the adaptor 420, and a negative pressure (or 'suction') applied to the porous medium 406 via the tube 404, which is structurally supported by the coiled guidewire acting as the applicator 410.

Figure 7 shows various different stages of a porous medium 706 being formed of an expandable mesh (in an exemplary embodiment), which is capable of being unravelled, stretched out or drawn out into a single thread of wire 728 and of returning to its original mesh form 706 when released, being deployed from the distal end 716 of a tube 704 of a catheter.

As shown in the first (i) view, the wire 728 has been unravelled and is being held under tension in the tube 704 by the applicator 710. In the second view (ii) an amount of wire 728 has been released by advancement of the applicator 710 and allowed to deploy from the distal end 716 of the tube 704, where it is beginning to form a mesh 730. In the third (iii) view, a substantial amount of wire 728 has been released by further advancement of the applicator 710 and a mesh 730 has formed at the distal end 716 of the tube 704, suitable to provide a porous medium 706.

Where the porous medium 706 is provided by such a wire 728, the distance that the applicator 710 may be required to move within the tube 704 will of course be much further than if the porous medium 706 were a foam sponge, for example. Indeed, the applicator 710 may be required to travel substantially the entire length of the tube 704. The wire 728 may alternatively be a tape, or similar elongate element.

In another embodiment (not shown), a catheter (or other suitable apparatus) may contain an extensible substrate coated in a bio-active material, such as collagen. The bio-active material may be arranged to shed from the substrate, such that at least a portion of it can be deposited into an internal wound when the substrate positioned there by the catheter. The bio-active material may be particularly suitable for treating wounds or otherwise helping them to heal.

Similar to the arrangement described above, the substrate may comprise a wire, tape or similar elongate element that is formed into a mesh configuration. Furthermore, the substrate may be sufficiently resilient that if drawn or stretched out (such that the mesh is deformed) it will return to a resilient mesh configuration, or otherwise undergo flexure of some description, when no longer under tension and/or restrained within the catheter. The substrate may comprise a memory metal, such as nitinol. The substrate is, preferably, more flexible than the bio-active material coated onto it, such that flexure of the substrate causes the bio-active material to be shed. The bio-active material may be coated onto the substrate using a water-soluble adhesive. The bio-active material may itself be water-soluble.

A distal end through which the substrate can be deployed into a wound may be configured to cause the substrate to flex as it is either deployed or retracted. The distal end may be configured for example to cause the substrate to flex, or it may have features that cause the bio-active coating to shed, such as serrations. As described above, deployment of the substrate may be controlled from a proximal end of the catheter. The bio-active coating may shed either during deployment of the substrate into the wound or retraction of the substrate into the catheter. Indeed, the bio-active coating may shed during both procedures.

It will be understood that the present invention has been described above purely by way of example, and modifications of detail can be made within the scope of the invention.

Claims

1. A catheter for treatment of a defect internal of a human or animal body, the catheter comprising:

a tube adapted for insertion into the body;

an applicator disposed within and moveable relative to the tube; and

a porous medium attached to the applicator;

wherein the porous medium is capable of fitting inside the tube,

whereby the applicator can be controlled at a proximal end of the tube to deploy the porous medium from a distal end of the tube so as to treat the defect.

2. The catheter of Claim 1, wherein the porous medium is capable of being deformed such that it can fit inside the tube, and wherein the porous medium is arranged to retain its pre-deformed shape when deployed from the tube.

3. The catheter of Claim 1 or 2, wherein the porous medium is initially, prior to deployment, contained within the tube, for example in a deformed state.

4. The catheter of any preceding claim, wherein the tube is arranged to provide a fluid conduit, for example for application of a negative pressure to the deployed porous medium and/or for flushing of liquid into the cavity and/or for drainage purposes.

5. The catheter of any preceding claim, wherein the applicator is arranged to provide structural support to the tube, for example to inhibit the tube from collapsing and/or kinking.

6. The catheter of any preceding claim, wherein the applicator is moveable in a longitudinal direction relative to the tube, for example wherein the amount of movement can be varied to control the amount of porous medium deployed.

7. The catheter of any preceding claim, wherein the applicator is a guidewire, for example a coiled guidewire having an internal bore.

8. The catheter of any preceding claim, wherein the porous medium is attached to the distal end of the applicator.

9. The catheter of Claim 8, wherein the porous medium is attached by a thread or cord, whereby a first end of the thread or cord is secured to the porous medium and a second end of the thread or cord is secured to the applicator at a position spaced from the porous medium, such that the thread or cord extends at least partway along the length of the applicator.

10. The catheter of Claim 9, wherein the second end of the thread or cord is attached to the applicator at a position along the applicator that is external to the tube.

11. The catheter of any preceding claim, wherein the porous medium comprises a bio-active material, for example comprising collagen.

12. The catheter of any of Claims 1 to 8, wherein the porous medium is a tangled mesh of wire capable of being unravelled into one or more single strands, the wire being arranged to have resilience causing it to reform the mesh when not restrained and/or under tension.

13. The catheter of Claim 12, wherein the wire comprises a nickel titanium alloy, for example nitinol.

14. The catheter of any preceding claim, wherein the distal end of the tube is arranged to provide a flared opening, for example a conical-shaped opening.

15. The catheter of any preceding claim, wherein the tube comprises fluorinated ethylene propylene (FEP).

16. The catheter of any preceding claim, further comprising an adaptor arranged to fit over the applicator and provide a detachable fluid connection between the tube and a fluid flow generator, for example a vacuum apparatus or a pumping apparatus.

17. The catheter of Claim 16, wherein the adaptor is arranged to provide a Luer-lock connection with the fluid flow generator.

18. The catheter of any preceding claim, wherein the tube is configured for endoluminal insertion, for example wherein the tube is at least 50% of the length of an endoscope that inserts it, in use.

19. The catheter of Claim 18, having an outer diameter of less than 2.8mm and/or less than 3.7mm.

20. The catheter of any of Claims 1 to 17, wherein the tube is configured for percutaneous insertion, for example wherein the tube is between about 20 and about 50cm in length.

21. The catheter of Claim 20, further arranged to be deployed along a guidewire, for example that has been introduced into a body percutaneously.

22. A method for treatment of a defect in the lower or upper gastrointestinal (GI) tract of a human or animal body, the method comprising:

introducing a catheter containing a deployable porous medium into the body, for example via endoluminal insertion;

positioning the catheter adjacent the defect;

deploying the porous medium from the catheter;

placing the porous medium into the defect; and

applying a continuous negative pressure via the catheter to treat the defect.

23. The method of Claim 22, further comprising positioning the catheter using endoscopic visualisation.

24. A method for treatment of a defect in a peritoneal or pleural cavity of a human or animal body, the method comprising:

inserting a guidewire into the body, the guidewire being positioned at the site of a defect;

inserting a catheter containing a deployable porous medium into the body percutaneously, wherein the catheter is deployed along the guidewire arranged to position the catheter at the defect;

deploying the porous medium from the catheter; placing the porous medium into the defect; and

applying a continuous negative pressure via the catheter to treat the defect.

25. The method of Claim 24, further comprising using imaging guidance to position the guidewire at the defect.

26. The method of any of Claims 22 to 25, wherein the porous medium is initially contained within the catheter in a deformed state, whereby deployment of the porous medium allows it to return to its pre-deformed state.

27. The method of any of Claims 22 to 26, wherein the catheter comprises an applicator controllable to deploy the porous medium, the method further comprising controlling the applicator at a proximal end of the catheter to deploy the porous medium at a distal end of the catheter.

28. A method for treatment of a defect in a human or animal body according to any of Claims 22 to 27, using a catheter according to any of Claims 1 to 21.

29. A system for treatment of a defect internal of a human or animal body, the system comprising:

a catheter according to any of Claims 1 to 21; and

a fluid flow generator adapted to provide a fluidly connection with the catheter;

such that, when fluidly connected, a negative pressure can be applied by the vacuum apparatus, via the catheter, to treat the defect.

30. A system for treatment of a defect internal of a human or animal body, the system comprising:

a catheter, an elongate element disposed within and moveable relative to the catheter, and a porous substrate attached to a distal end of the elongate element, such that the porous substrate can be deployed from the catheter by controlling a proximal end of the elongate element; and

a vacuum apparatus adapted to be fluidly connected to the catheter,

such that, when fluidly connected together, a negative pressure can be applied by the vacuum apparatus, via the catheter, to treat the defect.

31. The system of Claim 29 or 30, further comprising an endoscope capable of positioning the catheter into the defect under endoscopic visualisation.

32. The system of Claim 31, wherein the catheter is arranged to fit within the lumen of the endoscope.

33. The system of Claim 29 or 30, further comprising a guidewire and means for inserting the guidewire into the body percutaneously, wherein the catheter is arranged to be deployed along a guidewire so as to guide the catheter to the defect.

34. A kit of parts for a catheter, comprising an applicator and a porous medium attached to an end of the applicator.

35. The kit of parts of Claim 34, wherein the applicator is a guidewire, for example a coiled guidewire having an internal bore.

36. The kit of parts of Claim 34 or 35, wherein the porous medium is attached to the end of the applicator by a cord or thread, whereby a first end of the cord or thread is secured to the porous medium and a second end of the cord or thread is secured to the applicator at a position spaced from the porous medium, such that the cord or thread extends at least partway along the length of the applicator.

37. The kit of parts of any of Claims 34 to 36, further comprising a tube arranged to fit over the applicator so as to provide a fluid conduit.

38. The kit of parts of any of Claims 34 to 37, further comprising an adaptor for coupling the tube to a vacuum apparatus, the adaptor arranged to allow the applicator to pass therethrough.

39. The kit of parts of any of Claims 34 to 38, further comprising a guidewire and a means for inserting the guidewire into a body, wherein the catheter is arranged to be deployed along the guidewire.

40. A substrate for delivering bio-active material into an internal wound in a human or animal body, the substrate carrying a bio-active material, wherein the substrate is

configured at least partially to shed the bio-active material into a wound, for example wherein the substrate is arranged to be extensible.

41. The substrate of Claim 40, wherein the substrate is more flexible than the bio-active material such that flexure of the substrate causes shedding of the bio-active material.

42. The substrate of Claim 40 or 41, wherein the substrate is elongate and configured to form a mesh when not restrained and/or under tension.

43. The substrate of Claim 42, wherein the substrate is arranged to form a resilient mesh when not restrained and/or under tension.

44. The substrate of any of Claims 40 to 43, wherein the substrate comprises a wire or tape.

45. The substrate of any of Claims 40 to 44, wherein the substrate comprises a memory metal, such as nitinol.

46. The substrate of any of Claims 40 to 45, wherein the bio-active material comprises collagen.

47. The substrate of any of Claims 40 to 46, wherein the bio-active material is water soluble.

48. The substrate of any of Claims 40 to 47, wherein the bio-active material is adhered to the substrate by a water-soluble adhesive.

49. A method of delivering bio-active material into an internal wound in a human or animal body, comprising:

positioning a catheter at the wound; and

deploying an extensible substrate from the catheter into the wound;

wherein said substrate carries the bio-active material and is configured to at least partially shed the bio-active material into the wound.

50. The method of Claim 49, wherein the substrate is flexible.

51. The method of Claim 50, wherein the substrate is more flexible than the bio-active material such that flexure of the substrate causes shedding of the bio-active material.

52. The method of any of Claims 49 to 51, wherein the bio-active material is water soluble.

53. The method of any of Claims 49 to 52, wherein the bio-active material is adhered to the substrate by a water-soluble adhesive.

54. The method of any of Claims 49 to 53, wherein the substrate is deployed from a distal end of the catheter positioned at the wound.

55. The method of Claim 54, wherein deployment of the substrate is controlled from a proximal end of the catheter.

56. The method of any of Claims 49 to 55, wherein the substrate sheds bio-active material while extended from the catheter, for example during deployment or during retraction.

57. The method of Claim 56, wherein the distal end of the catheter is configured to cause at least some of the bio-active material to shed from the substrate into the wound as the wire is retracted back into the catheter.

58. The method of any of Claims 49 to 57, wherein the substrate is elongate and configured to form a mesh when not restrained by the catheter and/or under tension.

59. The method of any of Claims 49 to 58, wherein the elongate substrate is arranged to form a resilient mesh when not restrained by the catheter and/or under tension.

60. The method of any of Claims 49 to 59, wherein the substrate comprises a wire or tape.

61. The method of any of Claims 49 to 60, wherein the substrate comprises a memory metal, such as nitinol.

62. The method of any of Claims 49 to 61, wherein the bio-active material comprises collagen.

63. A catheter for treatment of a defect internal of a human or animal body substantially as described herein with reference to the accompanying drawings.

64. A method for treatment of a defect internal of a human or animal body substantially as described herein with reference to the accompanying drawings.

65. A system for treatment of a defect internal of a human or animal body substantially as described herein with reference to the accompanying drawings.

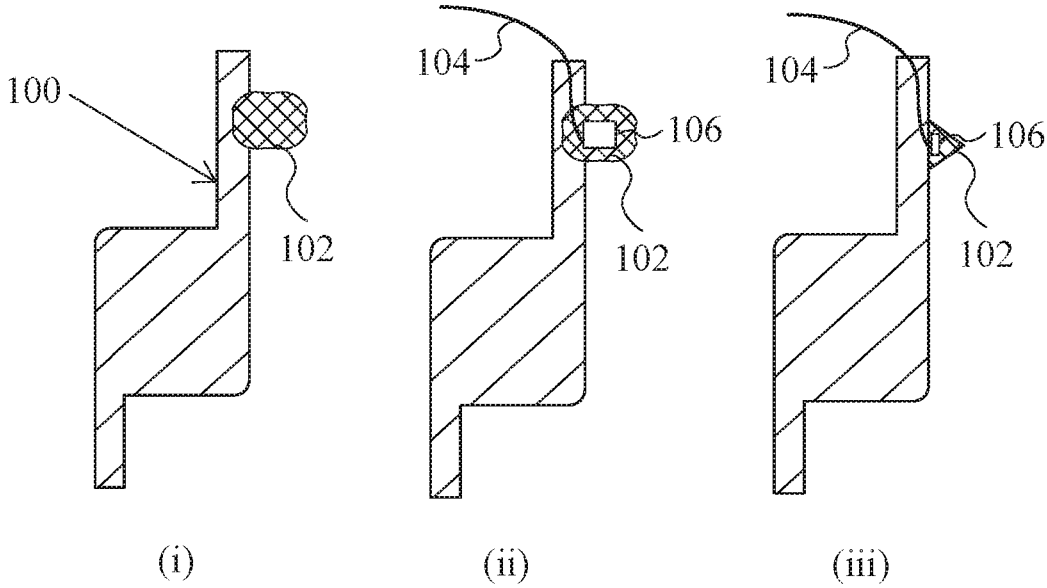

Fig. 1

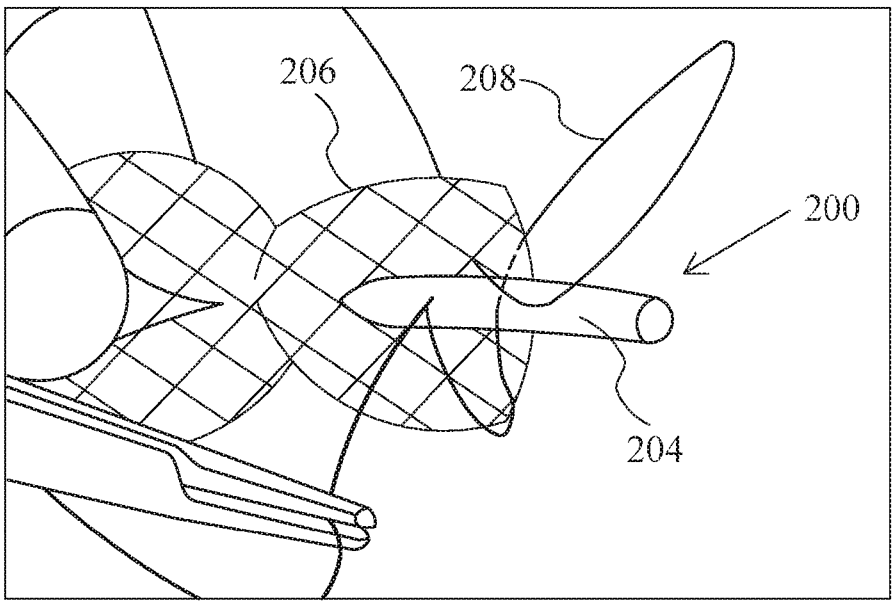

Fig. 2

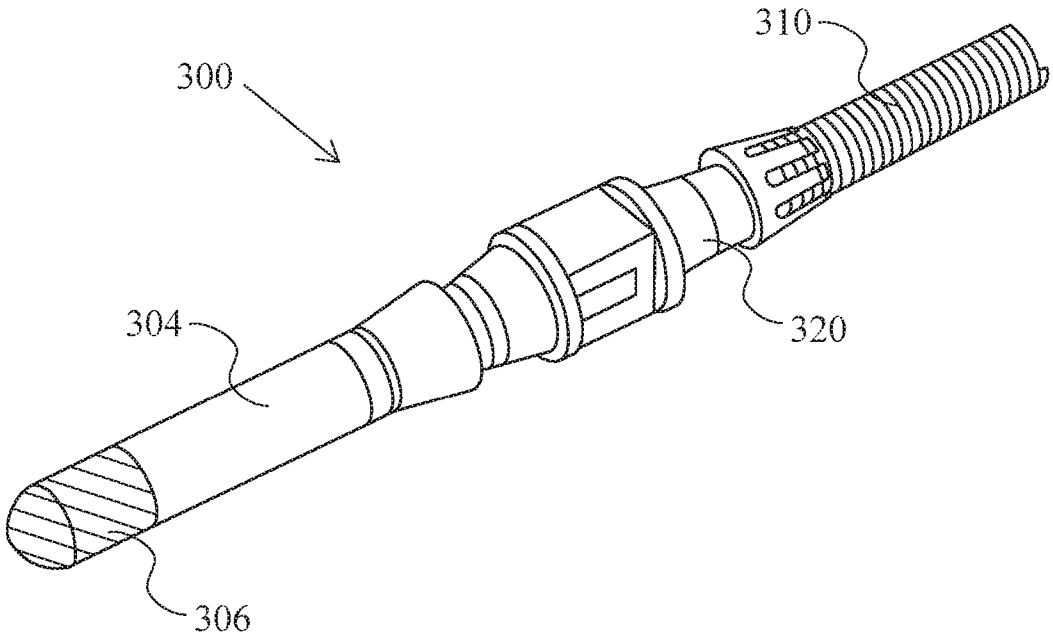

Fig. 3

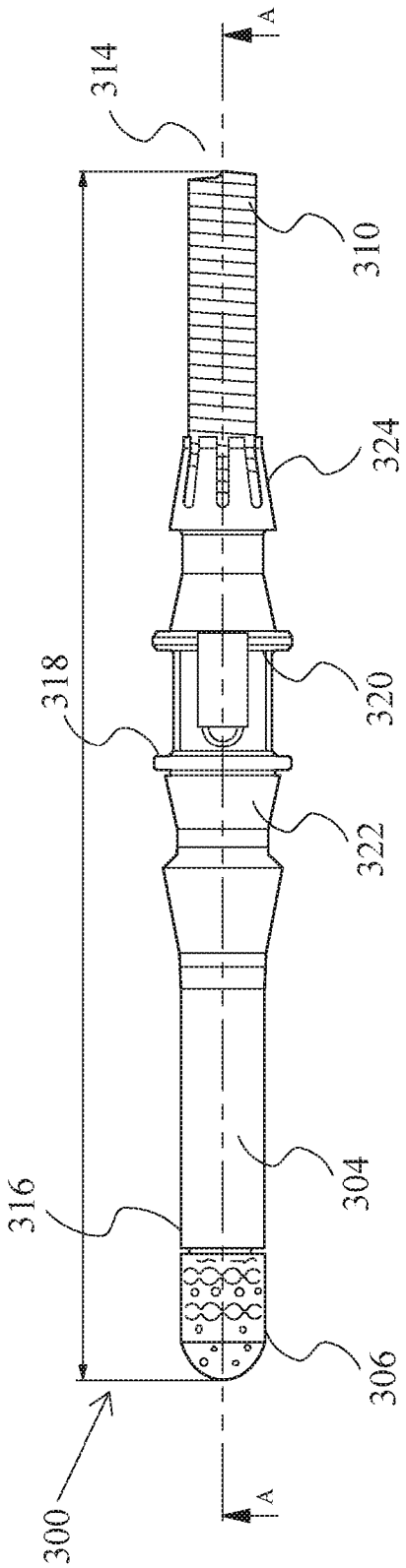
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Fig. 4A

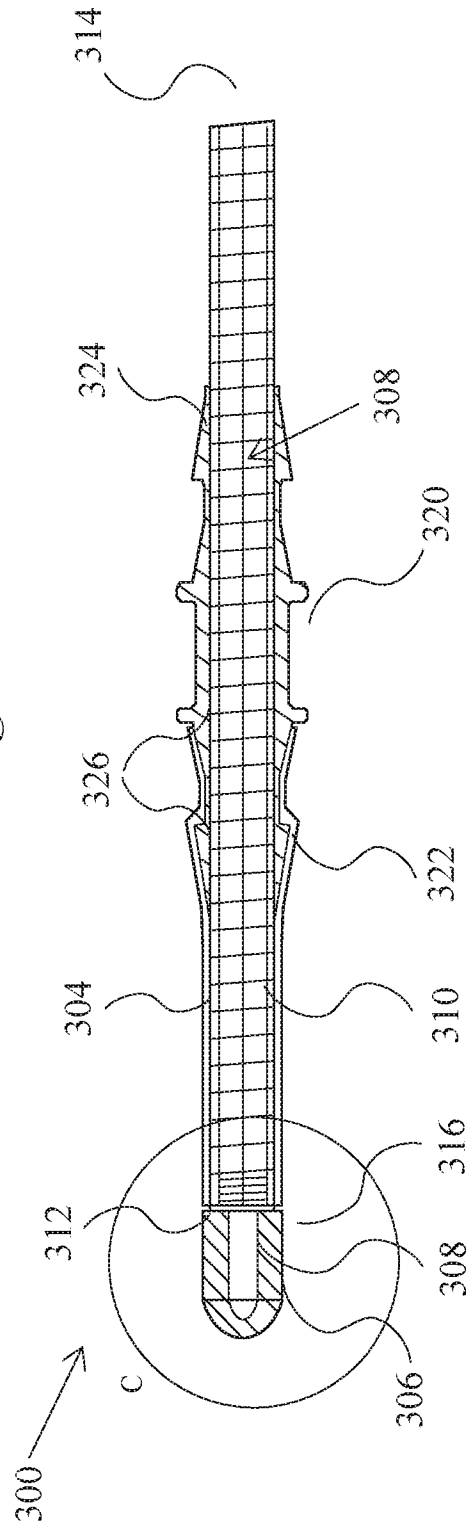
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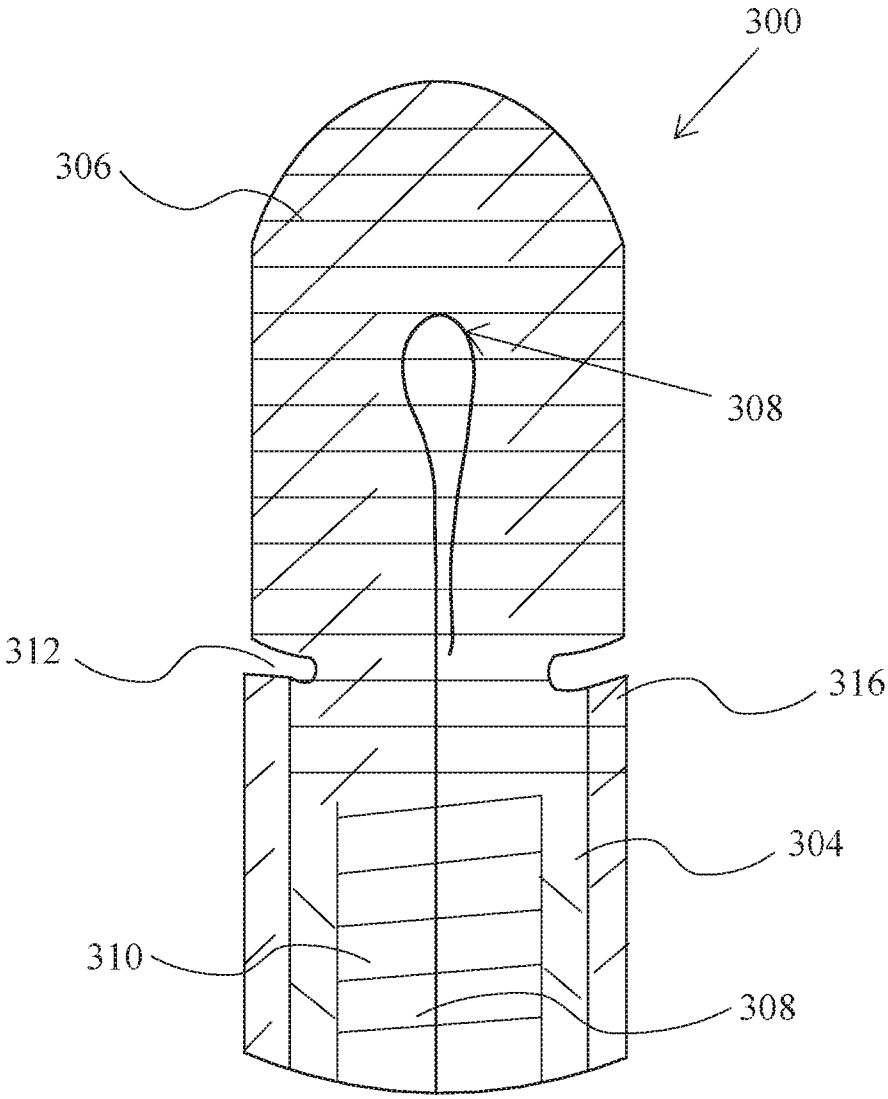
Fig. 4B



Detail C

Fig. 5

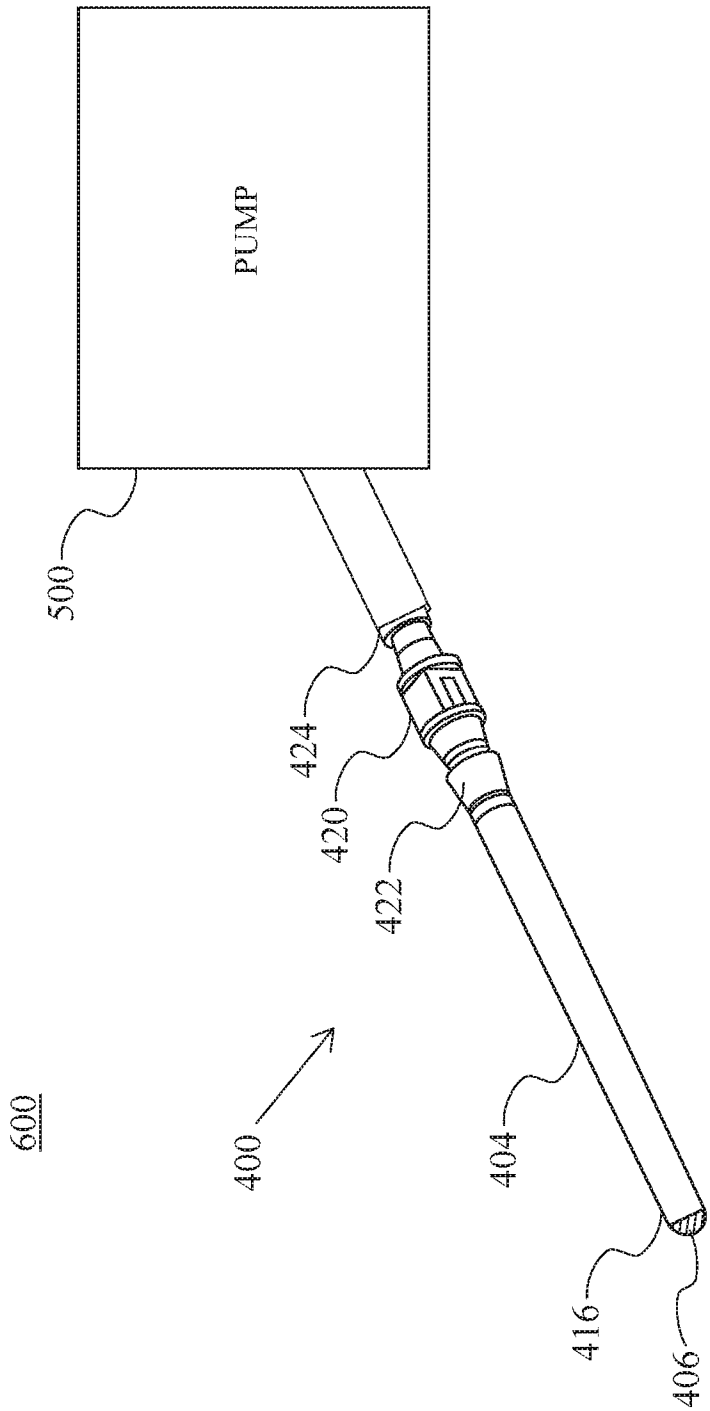


Fig. 6

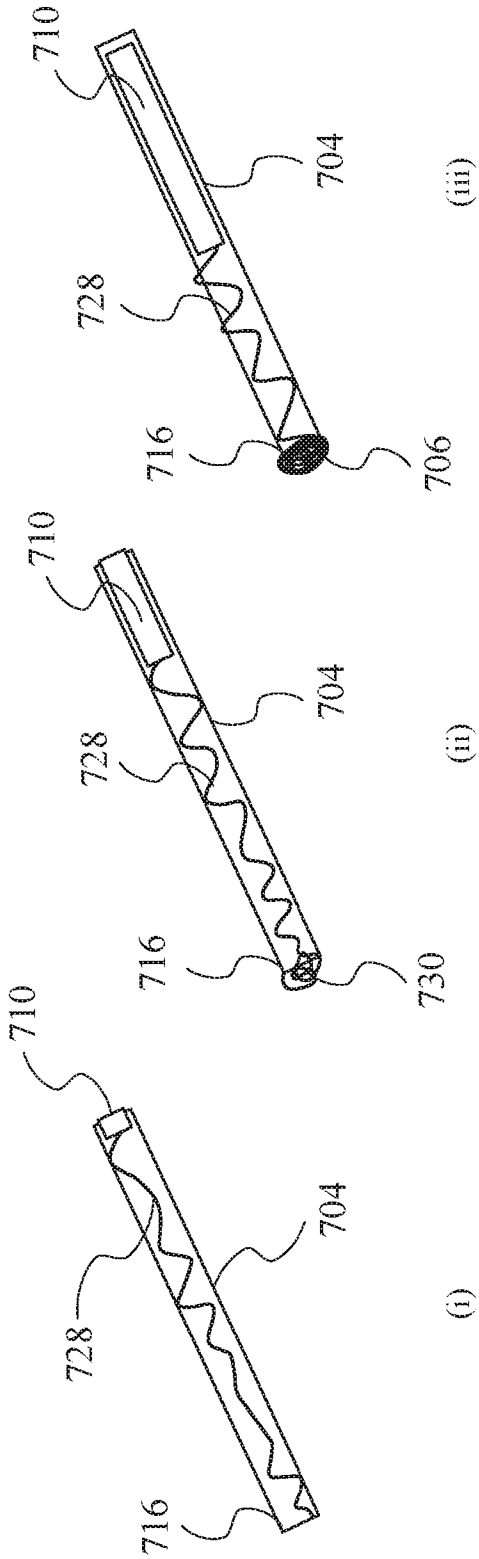


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2017/051123

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M27/00 A61M1/00 A61M25/09
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 572 286 A1 (WEIDENHAGEN ROLF [DE]; GRUETZNER KLAUS UWE [DE]) 14 September 2005 (2005-09-14)	1-6, 8-11, 14-21, 29-39
Y	paragraphs [0052] - [0056]; figures 1,3a-3e	7,12,13, 35
Y	EP 1 960 030 A1 (BOSTON SCIENT LTD AN IRISH CO [BB]) 27 August 2008 (2008-08-27) paragraphs [0015], [0016]; figures 1,2	7,35
Y	JP 2001 252349 A (YANAGIDA SACHIKO) 18 September 2001 (2001-09-18) abstract; figures 3,5,6	12,13
A	US 2015/250979 A1 (LOSKE GUNNAR [DE]) 10 September 2015 (2015-09-10) paragraph [0091]; figure 1	1-20, 29-39

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

☒ See patent family annex.

* Special categories of cited documents :

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

"E" earlier 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
4 August 2017	10/10/2017

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2017/051123

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

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

1. [X] Claims Nos.: 22-28, 49-65
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-21, 29-39

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-21, 29-39

A catheter with a tube adapted for insertion into the body; an applicator disposed within and moveable relative to the tube; and a porous medium attached to the applicator wherein the porous medium is capable of fitting inside the tube.

---

2. claims: 40-48

A substrate for delivering bio-active material into an internal wound in a human or animal body, the substrate carrying a bio-active material, wherein the substrate is configured at least partially to shed the bio-active material into a wound, for example wherein the substrate is arranged to be extensible.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 22-28, 49-65

Claims 22-28; 49-62 relate to methods for treatment of the human or animal body by surgery, because they all comprise at least the steps of introducing a catheter or guidewire into the body which are considered surgical procedures. This Authority is not required to search the present application with respect to the aforementioned claims (Article 17(2)(b) PCT and Rule 39.1(iv) PCT). Consequently, no International Search Report and no Written Opinion (Rule 67.1 PTC in combination with Rule 43bis.1(b) PCT) have been established with respect to them. Claims 63-65 solely rely, in respect of technical features of the invention, on references to the description or drawings. Such claims are not acceptable according to Rule 6.2(a) PCT.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2017/051123

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1572286 A1	14-09-2005	AT 431170 T	15-05-2009
		AU 2002347516 A1	07-06-2004
		CN 1720077 A	11-01-2006
		EP 1572286 A1	14-09-2005
		ES 2328908 T3	19-11-2009
		JP 4418756 B2	24-02-2010
		JP 2006505316 A	16-02-2006
		US 2004093026 A1	13-05-2004
		WO 2004041346 A1	21-05-2004
EP 1960030 A1	27-08-2008	AT 470471 T	15-06-2010
		CA 2631648 A1	07-06-2007
		EP 1960030 A1	27-08-2008
		JP 2009518065 A	07-05-2009
		US 2007129682 A1	07-06-2007
		WO 2007064832 A1	07-06-2007
JP 2001252349 A	18-09-2001	NONE	
US 2015250979 A1	10-09-2015	AU 2013320589 A1	16-04-2015
		CA 2885594 A1	27-03-2014
		CN 104870029 A	26-08-2015
		EP 2897662 A1	29-07-2015
		JP 2015529117 A	05-10-2015
		KR 20150058444 A	28-05-2015
		RU 2015114583 A	10-11-2016
		US 2015250979 A1	10-09-2015
		WO 2014044400 A1	27-03-2014