

CLAIMS:

1. A system for delivering a medicament to a target tissue site in a patient over a period of time, the system comprising:
 - 5 a catheter configured for implantation in a target tissue site, the catheter extending from a proximal end to a distal end and having a sidewall which defines an internal lumen, said distal end having one or more apertures either in the sidewall or at the distal end for the release of the medicament into the target tissue site;
a medicament reservoir fluidly communicable with the internal lumen of the
10 catheter;
an adhesive member configured to adhere to the skin of the patient around the exit wound and having an opening therein to allow the catheter to pass through the adhesive member; and
a retaining member configured to be overlaid on the adhesive member and
15 comprising a guide surface configured to receive a length of the catheter and a plurality of retaining portions to retain the catheters against the guide surface.
2. The system of claim 1 wherein the catheter comprises two or more catheters.
- 20 3. The system of claim 2, wherein the two or more catheters have a trocar receiving opening in the sidewall at the distal end, the proximal end or both the distal and proximal ends.
4. The system of any one of the preceding claims, further comprising a trocar,
25 said trocar having an elongate solid body which extends from a proximal end to a distal end, the trocar having a hook feature at or adjacent to either the proximal or distal end.
5. The system of 3, further comprising a nerve stimulating trocar.

6. The system of claim 5, wherein the nerve stimulating trocar comprises an elongate body having a proximal region, a distal region having a distal tip and an intermediate region between the proximal and distal regions.
- 5 7. The system of claim 6, wherein the nerve stimulating trocar comprises one or more electrodes.
8. The system of claim 7, wherein the one or more electrodes are at the distal tip of the nerve stimulating trocar.
- 10 9. The system of any one of claims 6 to 8, wherein the intermediate region of the nerve stimulating trocar forms a bend such that a main axis of the proximal region is offset and substantially parallel to a main axis of the distal region.
- 15 10. The system of claim 9, wherein the proximal region of the nerve stimulating catheter is configured to extend along an outer surface of the two or more catheters and the intermediate region passes through the trocar receiving opening such that the distal region is housed within the internal lumen of the two or more catheters and the distal tip extends from the distal end of the two or more catheters.
- 20 11. The system of any one of the preceding claims, wherein the retaining member is a partially circular structure having a relatively planar base surface and wherein the guide surface is opposed to the planar base and is a curved surface which terminates in an outer rim.
- 25 12. The system of claim 11, wherein the retaining member includes one or more clips to retain the catheter against the guide surface.
13. The system of claim 12, wherein the clips comprise a pair of opposed jaw members which together form a tunnel therethrough.

14. The system of claim 13, wherein the jaw members are made from a resiliently flexible material and are biased in a closed configuration such as to form the tunnel therethrough.

15. The system of any one of the preceding claims further comprising a retainer housing comprising a substantially circular base having an outer facing surface and a substantially flat inner surface and an outer rim which extends peripherally from circular base and terminates in a lip.

16. The system of claim 15, wherein the retainer housing further comprises a plurality of arms which extend centrally from an inner edge of the circular base and which terminate in a central body.

17. The system of any one of the preceding claims wherein the catheter includes a balloon having an internal passage to thread over an end of the catheter such that the balloon slides over the catheter to a desired location.

18. The system of any one of the preceding claims, further comprising a pump, wherein the pump comprises two separate pumping members each connected to the medicament reservoir and to respective catheters.

19. The system of claim 18, further comprising a power source to power the pump and a control unit to control the rate of flow of the medicament from the medicament reservoir to the two or more catheters.

20. The system of claim 19, wherein the control unit is pre-programmed to deliver a pre-determined regimen of medicament over a period of time.

21. The system of claim 20, wherein the pre-determined regimen includes different pre-programmed intervals.

22. The system of claim 21 including a bolus interval wherein during the bolus interval, an increased amount of medicament is delivered to the patient compared to one or more of the other pre-programmed intervals.

23. A method for implanting a catheter to deliver medicament to a patient after
5 haemorrhoid surgery, the method including:

providing a catheter which extends from a proximal end to a distal end and has a sidewall which defines an internal lumen, said distal end having one or more apertures either in the sidewall or at the distal end for the release of the medicament into a target tissue site;

10 connecting a distal end of the catheter to a stimulator trocar, the stimulator trocar comprising an elongate body which is made from a material having a greater rigidity than the catheter, the stimulator trocar comprising a nerve stimulator configured to stimulate nerves in a target tissue site;

15 advancing the stimulator trocar and the catheter through the tissue of the patient;

actuating the nerve stimulator at a determined frequency and adjusting the positioning of the stimulator trocar and the distal end of the catheter until a physical contraction of the external anal sphincter is observed at a frequency that correlates with the determined frequency of the nerve stimulator;

20 identifying the location of the nerve stimulator and the distal end of the catheter where physical contraction of the external anal sphincter is achieved;

disconnecting the nerve stimulator from the catheter and withdrawing the nerve stimulator through the first incision leaving the distal end of the catheter implanted in the target tissue site.

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24. A method for positioning a catheter in a target tissue site to deliver a medicament to a patient after haemorrhoid surgery, the method including:

providing a catheter which extends from a proximal end to a distal end and has a sidewall which defines an internal lumen, the distal end of the catheter having one or
30 more apertures either in the sidewall or at a distal end for the release of the medicament to the target tissue site;

making a lateral incision in the skin of the thigh of the patient and a first incision on one side of the anus;

tunnelling a trocar from the lateral incision through the tissue and towards the first incision;

5 at the first incision, connecting a tip of the trocar to the proximal end of the catheter and withdrawing the trocar towards the lateral incision until a desired length of the catheter is pulled through, and extends from, the lateral incision and the distal end of the catheter extends from the first incision;

 connecting the distal end of the catheter to a stimulator trocar, the stimulator
10 trocar comprising an elongate body which is made from a material having a greater rigidity than the catheter, the stimulator trocar comprising a nerve stimulator configured to stimulate nerves in the target tissue site;

 advancing the stimulator trocar and the catheter through the tissue of the patient;

15 actuating the nerve stimulator at a determined frequency and adjusting the positioning of the stimulator trocar and the distal end of the catheter until a physical contraction of the external anal sphincter is observed at a frequency that correlates with the determined frequency of the nerve stimulator;

 identifying the location of the nerve stimulator and the distal end of the
20 catheter where physical contraction of the external anal sphincter is achieved;

 disconnecting the nerve stimulator from the catheter and withdrawing the nerve stimulator through the first incision leaving the distal end of the catheter implanted in the first target tissue site;

 connecting the proximal end of the catheter to a reservoir of medicament and
25 infusing the medicament through the internal lumen of the catheter to deliver the medicament to the target tissue site.

25. The method of claim 23 or claim 24 wherein a second catheter is inserted
into a different target tissue site, the second catheter extending from a proximal end to a
30 distal end and has a sidewall which defines an internal lumen, the distal end of the

second catheter having one or more apertures in the sidewall for the release of the medicament to the target tissue site.

26. The method of claim 25, wherein a second incision is made on the opposite
5 side of the anus to the first incision and a trocar is tunnelled through the tissue from the lateral incision and across the midline of the patient towards the second incision;
at the second incision, connecting the tip of the trocar to the proximal end of the second catheter and withdrawing the trocar until a desired length of the second catheter is pulled through, and extends from, the lateral incision and the distal end of
10 the second catheter extends from the second incision;
connecting the distal end of the second catheter to a stimulator trocar;
advancing the stimulator trocar and the second catheter through the tissue of the patient;
actuating the nerve stimulator at a determined frequency and adjusting the
15 positioning of the stimulator trocar and the distal end of the second catheter until a physical contraction of the external anal sphincter is observed at a frequency that correlates with the determined frequency of the nerve stimulator;
identifying the location of the nerve stimulator and the distal end of the second catheter where physical contraction of the external anal sphincter is achieved;
20 disconnecting the nerve stimulator from the second catheter and withdrawing the nerve stimulator through the first incision leaving the distal end of the second catheter implanted in the first target tissue site;
connecting the proximal end of the second catheter to a reservoir of medicament and infusing the medicament through the internal lumen of the second
25 catheter to deliver the medicament to the target tissue site.

27. A method for positioning a catheter in a target tissue site to deliver a medicament to a patient after haemorrhoid surgery, the method including:
providing a catheter which extends from a proximal end to a distal end and
30 has a sidewall which defines an internal lumen, the distal end of the catheter having one

or more apertures either in the sidewall or at a distal end for the release of the medicament to the target tissue site;

making a lateral incision in the skin of the thigh of the patient and a first incision on one side of the anus;

5 tunnelling a trocar from the first incision through the tissue and towards the lateral incision;

 at the lateral incision, connecting a tip of the trocar to the distal end of the catheter and pulling the trocar towards the first incision until a desired length of the catheter is pulled through, and extends from, the first incision and the proximal end of
10 the catheter extends from the lateral incision;

 connecting the distal end of the catheter to a stimulator trocar, the stimulator trocar comprising an elongate body which is made from a material having a greater rigidity than the catheter, the stimulator trocar comprising a nerve stimulator configured to stimulate nerves in the target tissue site;

15 advancing the stimulator trocar and the catheter through the tissue of the patient;

 actuating the nerve stimulator at a determined frequency and adjusting the positioning of the stimulator trocar and the distal end of the catheter until a physical contraction of the external anal sphincter is observed at a frequency that correlates with
20 the determined frequency of the nerve stimulator;

 identifying the location of the nerve stimulator and the distal end of the catheter where physical contraction of the external anal sphincter is achieved;

 disconnecting the nerve stimulator from the catheter and withdrawing the nerve stimulator through the first incision leaving the distal end of the catheter
25 implanted in the target tissue site;

 connecting the proximal end of the catheter to a reservoir of medicament and infusing the medicament through the internal lumen of the catheter to deliver the medicament to the target tissue site.

30 28. The method of claim 27, wherein a second catheter is inserted into a different target tissue site, the second catheter extending from a proximal end to a distal end and

having a sidewall which defines an internal lumen, the distal end of the second catheter having one or more apertures in the sidewall for the release of the medicament to the target tissue site.

5 29. The method of claims 28, wherein a second incision in the skin is made on the opposite side of the anus to the first incision and a trocar is tunnelled through the tissue from the second incision and across the midline of the patient towards the lateral incision;

10 tunnelling a trocar from the second incision through the tissue, across the midline of the patient and towards the lateral incision;

at the lateral incision, connecting a tip of the trocar to the distal end of the second catheter and pulling the trocar towards the second incision until a desired length of the catheter is pulled through, and extends from, the second incision and the proximal end of the second catheter extends from the lateral incision;

15 connecting the distal end of the catheter to a stimulator trocar, the stimulator trocar comprising an elongate body which is made from a material having a greater rigidity than the second catheter, the stimulator trocar comprising a nerve stimulator configured to stimulate nerves in the target tissue site; advancing the stimulator trocar and the catheter through the tissue of the patient;

20 actuating the nerve stimulator at a determined frequency and adjusting the positioning of the stimulator trocar and the distal end of the second catheter until a physical contraction of the external anal sphincter is observed at a frequency that correlates with the determined frequency of the nerve stimulator;

25 identifying the location of the nerve stimulator and the distal end of the second catheter where physical contraction of the external anal sphincter is achieved;

disconnecting the nerve stimulator from the distal end of second catheter and withdrawing the nerve stimulator through the second incision leaving the distal end of the second catheter implanted in the target tissue site;

30 connecting the proximal end of the second catheter to a reservoir of medicament and infusing the medicament through the internal lumen of the second catheter to deliver the medicament to the target tissue site.

30. The method of any one of claims 23 to 29, wherein the target tissue site comprises tissue adjacent to the anal and/or rectal branches of the pudendal nerves.

5 31. The method of any one of claims 23 to 30, wherein the medicament is selected from any one of bupivacaine, lidocaine, ropivacaine, buprenorphine, hydromorphone, ketobemidone, levomethadyl, levorphanol, mepiridine, methadone, morphine, nalbuphine, opium, oxycodone, pentazocine, phenoperi- dine, butorphanol, dextromoramide, dezocine, dextropropoxyphene, diamorphine, fentanyl, alfentanil,
10 sufentanil, hydrocodone, piritramide, dextropropoxyphene, remifentanyl, sufentanil, tilidine, tramadol, codeine, dihydrocodeine, meptazinol, dezocine, eptazocine, flupirtine, or a combination thereof

32. The method of any one of claims 23 to 31, wherein the medicament is
15 delivered in solution with a concentration between 0.25%, and 0.75%.

33. The method of any one of claims 23 to 32, wherein the medicament is delivered at a dose of between 1ml and 40mls per day.

20 34. The method of claims 33 wherein the medicament is delivered at a dose of 20ml per day.

35. A surgical kit comprising:
two or more catheters configured for implantation in a target tissue site of a
25 patient, each catheter extending from a proximal end to a distal end and having a sidewall which defines an internal lumen, said distal end having one or more apertures either in the sidewall or at a distal end;
an adhesive member configured to adhere to the skin of the patient around
the exit wound and having an aperture therein to allow the catheters to pass through the
30 adhesive member;

an open ring-shaped retaining member configured to be overlaid on the adhesive member and comprising a substantially flat base, a guide surface configured to receive a length of the two or more catheters and a plurality of retaining portions to retain the catheters against the guide surface;

5 a tunnelling trocar configured for attachment to the proximal ends of the catheters;

 a stimulator trocar comprising an elongate body which is made from a material having a greater rigidity than the two or more catheters, the stimulator trocar comprising a nerve stimulator configured to stimulate nerves in a target tissue site;

10 a pump and a medicament reservoir;

 a sheet for application to the patient's skin around the surgical site, the sheet having an adhesive surface for adhering to the skin of the patient and a series of frangible regions for removal of parts of the sheet.

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