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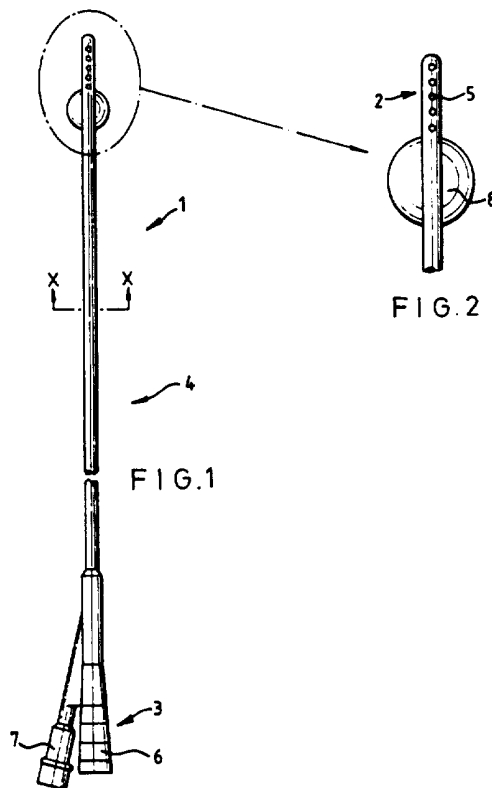
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(56) Documents Cited
GB 2235384 A GB 2043457 A GB 2037393 A
GB 1230552 A EP 0299622 A2 EP 0284365 A2
WO 89/02290 A1 WO 85/00526 A1 US 5098413 A
US 4391276 A US 4349029 A

(58) Field of Search
UK CL (Edition O) **A5R RCEX RGAA RGH RGV**
INT CL⁶ **A61M 25/00**

(54) **Body fluid drainage apparatus**

(57) The apparatus comprises a catheter having entry means 2 and exit means 3 for fluid connected by a lumen 10, the entry means comprising a plurality (particularly 5 - 40) of apertures of diameter less than 50% of the diameter of the lumen so that blockage of the entry means and lumen is prevented while maintaining an acceptable flow rate. The apertures may be disposed over 1/10 to 2/3 of the length of the catheter and may vary in size. An inflatable balloon 8 may be provided to retain the entry means inside e.g. the bladder.



At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1995

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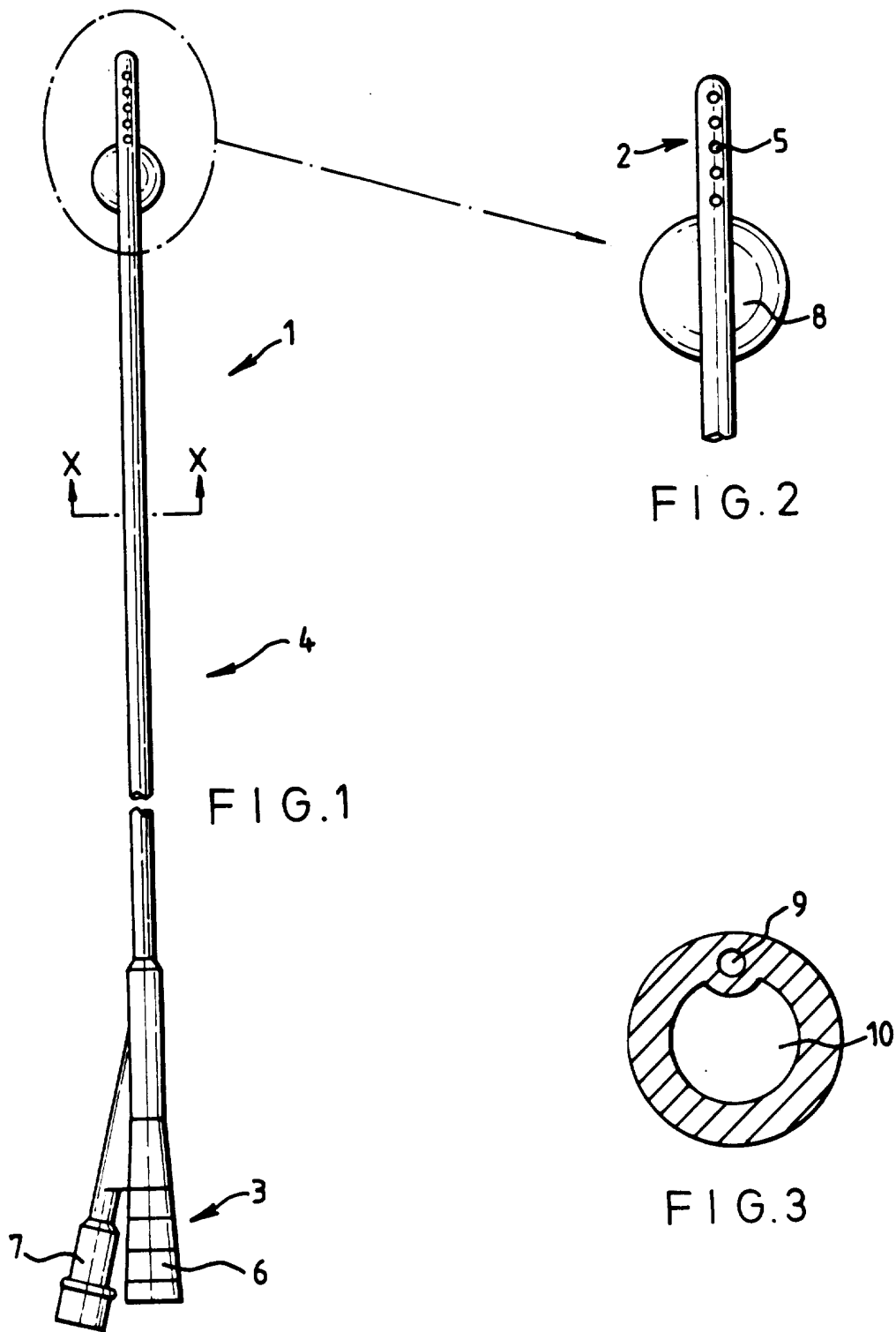


FIG. 2

FIG. 1

FIG. 3

FLUID DRAINAGE APPARATUS

The present invention relates to fluid drainage apparatus, and to a method of using the apparatus. More particularly, the invention relates to apparatus which may be used to drain bodily fluids, such as a catheter.

Apparatus for draining fluids usually comprises a conduit having at least one lumen for fluid conduction, and an entry thereto and exit therefrom. It is often the case that the entry comprises two apertures known as eyes. Such apparatus is used for fluid drainage in many areas of medicine, one example being to prevent build up of fluids such as urine in the bladder. The apparatus may be used post-operatively, on a short term basis, as for example when surgery has been performed on the bladder or associated structures, or it may be used on a long term basis, where patients are unable to pass or control the flow of urine.

One common problem associated with existing apparatus is that of blockage. This can occur when the apparatus is used on a long term or short, post-operative basis, for a variety of reasons. In short term use, blockage can occur through surgical debris entering the drainage lumen and becoming lodged in the lumen itself. Such debris can also become lodged in the entry to the lumen. In longer term use, blockages can occur through the deposition and encrustation of fluid dissolved substances such as waste products, around the entry and lumen walls. In such cases, it may be necessary to replace the apparatus, which takes time, is expensive, and can cause added discomfort to the patient.

Further, it has often been found on removal of the apparatus from the patient that the cause of the blockage cannot be identified, there being no

apparent blockage present in the lumen or entry, even though the performance of the apparatus is obviously being impaired in some way. It has been found that with existing apparatus, blockage can occur by elements such as membranes being sucked into the eyes of the entry. In the case of apparatus for urinary drainage, it has been found that the bladder mucosa can be sucked into the eyes, resulting, in addition to blockage, in damage to the bladder mucosa.

It is an object of this invention to seek to mitigate problems such as these.

According to the invention there is provided apparatus for fluid drainage from a body, the apparatus comprising entry means and exit means for fluid, operatively connected by fluid conducting means, wherein the entry means is adapted to prevent blockage of the entry and conducting means, and to provide a medically acceptable fluid flow rate.

The term "medically acceptable flow rate" as used herein means any flow rate which provides sufficient fluid drainage as is required by the condition of the patient.

It is preferred that the size of each aperture is such that entry of particles similar in size to the bore of the fluid conducting means is substantially prevented, whilst a medically acceptable flow rate is maintained. As is known in the art, apertures may be of different shapes, and it is preferred that the size of the major diameter of each aperture is less than 50% of the size of the major diameter of the fluid conducting means.

In order to maintain a said medically acceptable flow rate, the entry may comprise a plurality of apertures disposed adjacent an end of the fluid

conducting means intended in use to be positioned within the patient. There are preferably from five to forty, more preferably, from ten to thirty apertures. It is most preferred that the entry comprises about twenty apertures. The apertures are preferably disposed in pairs, each member of each pair being substantially opposite each other member. The apertures are preferably disposed at intervals along the fluid conducting means. The apertures may be disposed over from one tenth to two thirds of the length of the fluid conducting means.

The size of each individual aperture may vary.

The apparatus may have retention means in order to retain it in place in the patient in use. The retention means may be remotely operable, and preferably comprises an inflatable member, such as a balloon.

There may be a plurality of separate bores in the fluid conducting means.

The apparatus preferably includes attachment means adjacent the exit to allow it to be attached to receiving means such as a fluid collection bag to provide a sealed system.

According to a second aspect of the invention there is provided a method of treatment comprising the use of apparatus as hereinabove described.

According to a third aspect of the invention there is provided a catheter for use in fluid drainage from a body, comprising apparatus as hereinabove described.

According to a fourth aspect of the invention there is provided a kit for use in the treatment of humans or animals including apparatus as hereinabove described.

The invention will hereinafter be described by way of example, with reference to the accompanying drawings in which;

Figure 1 is a side view of apparatus according to an embodiment of the invention;

Figure 2 is an enlarged view of a part of the apparatus of Figure 1; and

Figure 3 is a transverse sectional view along the line X-X in Figure 1.

Referring to the drawings there is illustrated apparatus 1 for fluid drainage comprising entry means 2 and exit means 3 for fluid, operatively connected by fluid conducting means 4, wherein the entry means 2 is adapted to prevent blockage of the entry means 2 and conducting means 4, and to provide a medically acceptable fluid flow rate.

As illustrated, the fluid conducting means 4 comprises an elongate tube. Entry means 2 is provided at one end of the tube in the form of a series of apertures 5, in this example twenty, arranged in four rows of five spaced equally around the end. It will be appreciated that the precise arrangement of apertures 5 is not crucial however, and rather than being opposite one another, the eyes of opposing rows may be offset from one another, i.e. in a staggered configuration.

Within the tube is a lumen 10 through which fluid drains from the entry means 2 to the exit means 3. The exit means 3 is provided with attachment means 6 as is well known in the art, for connection of the apparatus 1 to a fluid collection bag (not shown) to form a sealed system to prevent escape of fluid, and ingress of dirt or microorganisms. Branching off from the attachment means 6 is a valve 7, for inflating a balloon 8.

The apparatus may be constructed from any suitable material for catheter construction, such as for example silicone.

In use, the end of the apparatus 1 bearing the entry means 2 is inserted into the bladder of a patient, the tube running from the bladder through its connection with the urethra and thence to the collection bag outside of the patient. Where an inflatable retention means is present, fluid such as sterile water is passed up a second, separate lumen 9 to the fluid conducting lumen, into a balloon 8, which when sufficiently inflated, prevents the apparatus 1 from being removed inadvertently.

CLAIMS

1. Apparatus for fluid drainage from a body, the apparatus comprising entry means and exit means for fluid, operatively connected by fluid conducting means, wherein the entry means is adapted to prevent blockage of the entry and conducting means, and to provide a medically acceptable fluid flow rate.
2. Apparatus according to Claim 1, wherein the entry means comprises a plurality of apertures disposed adjacent an end of the fluid conducting means intended, in use, to be positioned within the patient.
3. Apparatus according to Claim 2, wherein each aperture is adapted such that entry of particles similar in size to the bore of the fluid conducting means is substantially prevented, whilst a medically acceptable flow rate is maintained.
4. Apparatus according to Claim 2 or Claim 3, wherein the size of the major diameter of each aperture is less than 50% of the size of the major diameter of the fluid conducting means.
5. Apparatus according to any of Claims 2 to 4, comprising from five to forty apertures.
6. Apparatus according to any of Claims 2 to 4, comprising from ten to thirty apertures.
7. Apparatus according to any of Claims 2 to 4, comprising about twenty apertures.

8. Apparatus according to any of Claims 2 to 7, wherein the apertures are disposed in pairs, each member of each pair being substantially opposite each other member.
9. Apparatus according to any preceding claim, wherein the apertures are disposed at intervals along the fluid conducting means.
10. Apparatus according to any preceding claim, wherein the apertures are disposed over from about one tenth to about two thirds of the length of the fluid conducting means.
11. Apparatus according to any of Claims 2 to 10, wherein the size of each aperture varies.
12. Apparatus according to any of Claims 2 to 11, including retention means to retain it in place in a patient, in use.
13. Apparatus according to Claim 12, wherein the retention means is remotely operable.
14. Apparatus according to Claim 13, wherein the retention means comprises an inflatable member.
15. Apparatus according to Claim 14, wherein the inflatable member comprises a balloon.
16. Apparatus according to any preceding claim, including a plurality of separate bores in the fluid conducting means.

17. Apparatus according to any preceding claim, including attachment means adjacent the exit to allow it to be attached to receiving means such as a fluid collection bag.

18. Apparatus for fluid drainage from a body, substantially as hereinbefore described, with reference to the accompanying drawings.

19. A catheter for use in fluid drainage from a body, comprising apparatus as claimed in any preceding claim.

20. A catheter, substantially as hereinbefore described, with reference to the accompanying drawings.



Application No: GB 9423207.1
Claims searched: 1-20

Examiner: L.V.Thomas
Date of search: 8 February 1996

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:
UK CI (Ed.O): A5R (RCEX, RGAA, RGH, RGV)
Int CI (Ed.6): A61M 25/00
Other:

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	GB 2235384 A (Thermedics) see p.5 ll.4-12 and p.8 l.28 - p.9 l.22	1-5,9,16
X	GB 2043457 A (Gerhard Hug) see Fig.2 and p.1 ll.32-64 and ll.115-129	1-6,8,9
X	GB 2037393 A (Zahorsky) see p.1 ll.36-85 and 105-125 and p.2 ll.35-65	1-7,9,10,16
X	GB 1230552 (Hakim) see p.1 ll.20-64 and p.2 ll.24-32	1-3
X	EP 0299622 A2 (3M) see col.2 l.26 - col.3 l.22 and col.5 ll.16-32	1-6,11
X	EP 0284365 A2 (Yarger) see col.2 ll.15-62	1-6,8-10
X	WO 89/02290 A1 (Neurodynamics) see p.4 l.15 - p.5 l.5, p.10 l.30 - p.12 l.33 and Figs.1,10 and 11	1-6,9,10
X	WO 85/00526 A1 (Sterimed) see abstract and Figs. 1 and 2	1-6,9,10
X	US 5098413 (Trudell et al.) see col.2 ll.29-40 and 57-63	1-6,8-11
X	US 4391276 (Lazarus et al.) see col.1 l.66 - col.2 l.35 and col.2 ll.50-55	1-6,9

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.



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Application No: GB 9423207.1
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Date of search: 8 February 1996

Category	Identity of document and relevant passage	Relevant to claims
X	US 4349029 (Mott) see col.3 ll.9-41 and col.4 l.41 - col.5 l.31	1-4,12-15, 17

X Document indicating lack of novelty or inventive step	A Document indicating technological background and/or state of the art.
Y Document indicating lack of inventive step if combined with one or more other documents of same category.	P Document published on or after the declared priority date but before the filing date of this invention.
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