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(54) Title of the Invention: **The orange catheter**
Abstract Title: **Drainage catheter**

(57) This invention relates to a catheter 220, and in particular to a urinary catheter. A catheter 220 comprises an elongate shaft 222 having a longitudinal drainage bore 224 for conveying fluid along the shaft 222; an elongate, tapered tip portion 228 extending from an end of the shaft 222, the tip portion 228 having a distal end furthest from the shaft 222; a drainage aperture 232 provided in the tip portion 228, said aperture 232 being in fluid communication with said bore, 224 and an inflatable balloon element 236 attached to said tip portion 228, the balloon element 236 being configured such that, when fully inflated, the balloon element 236 fully surrounds the distal end of the tip portion 228 and extends along the tip portion 228 to a point on an opposite side of the drainage aperture 232 to said distal end, a surface of the balloon element 236 including a depression 242 providing a passageway in fluid communication with the drainage aperture 232.

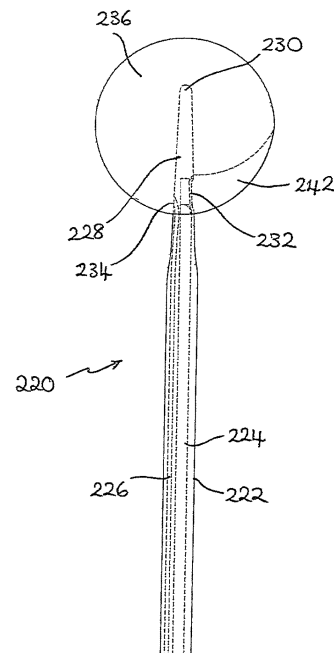


Fig. 5

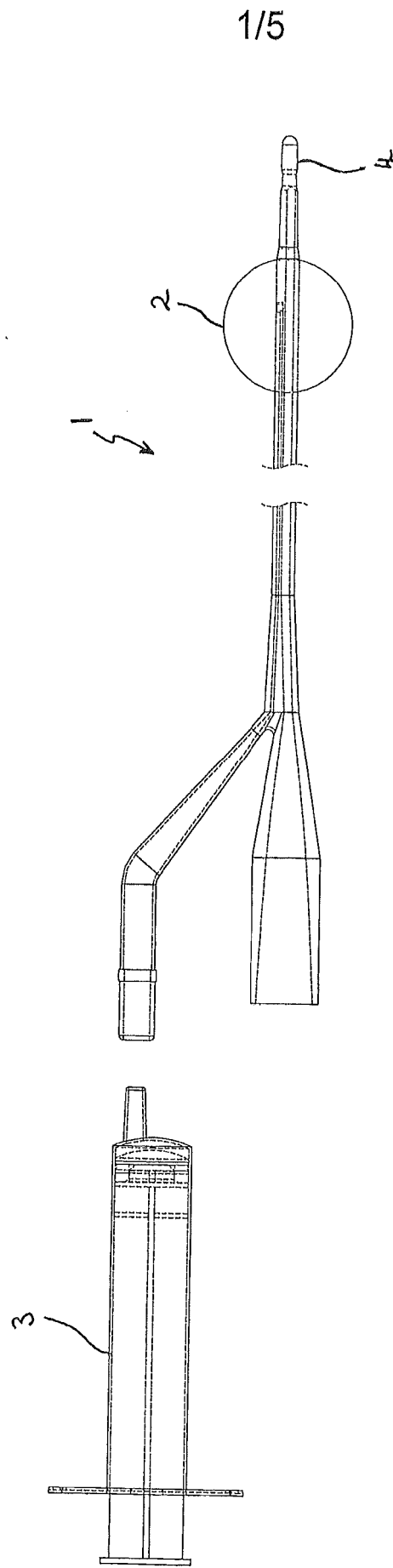


Fig. 1

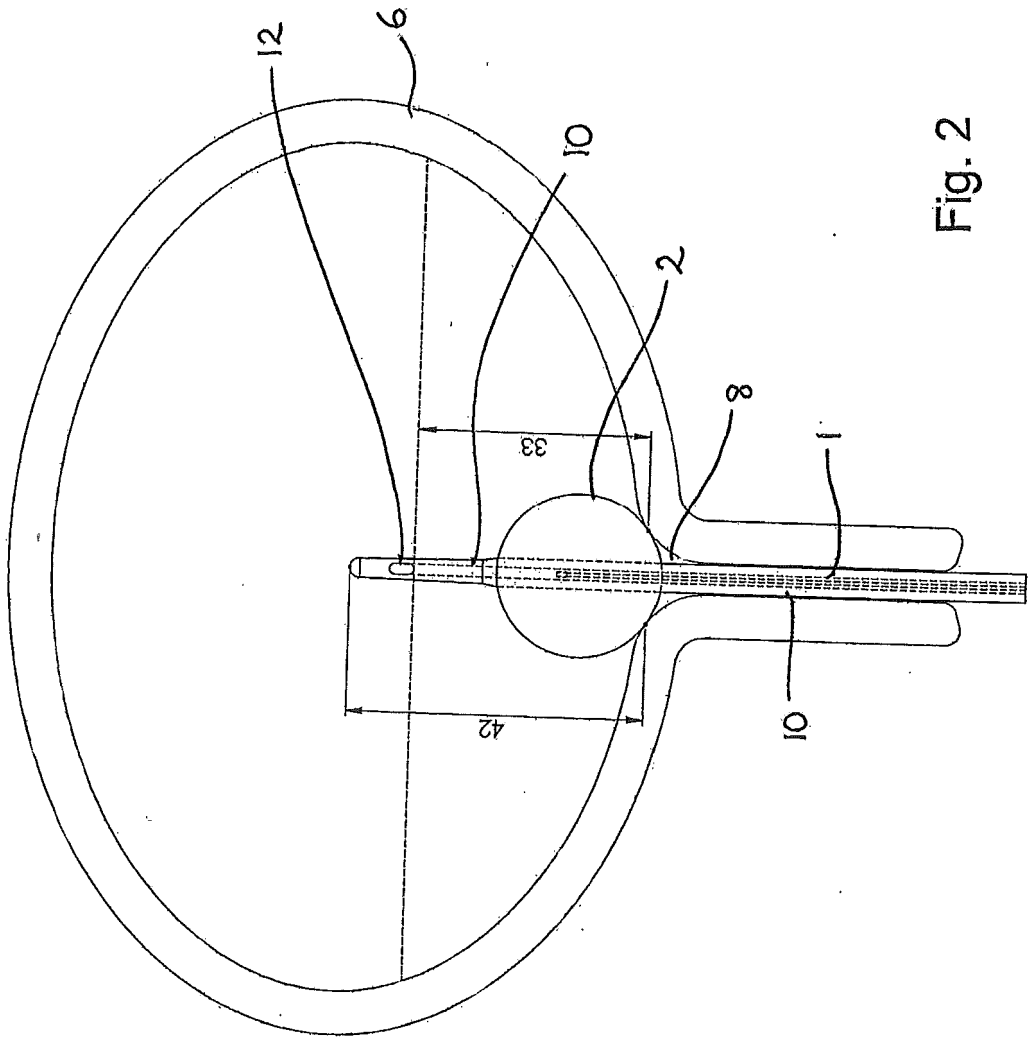


Fig. 2

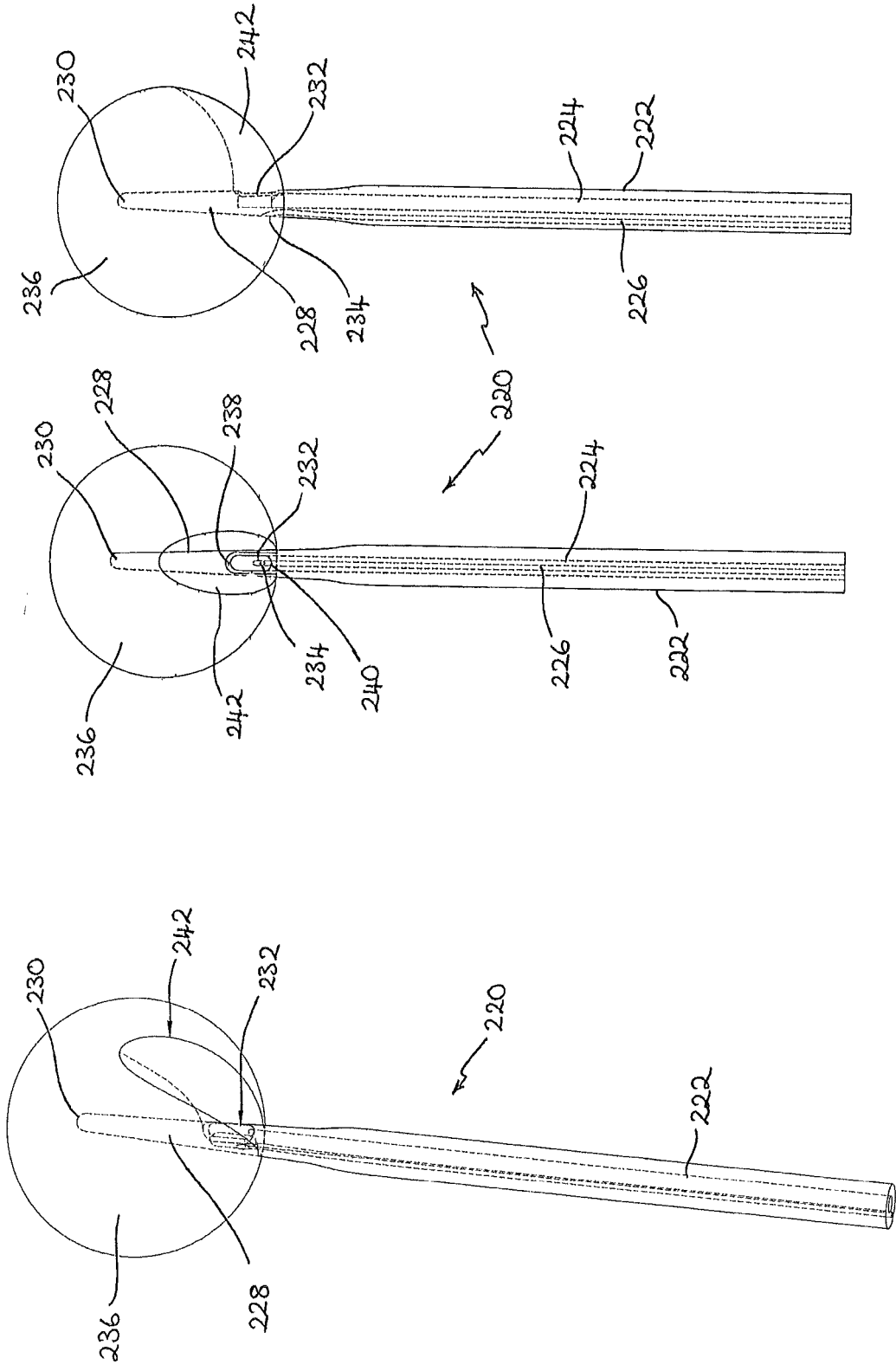


Fig. 3

Fig. 4

Fig. 5

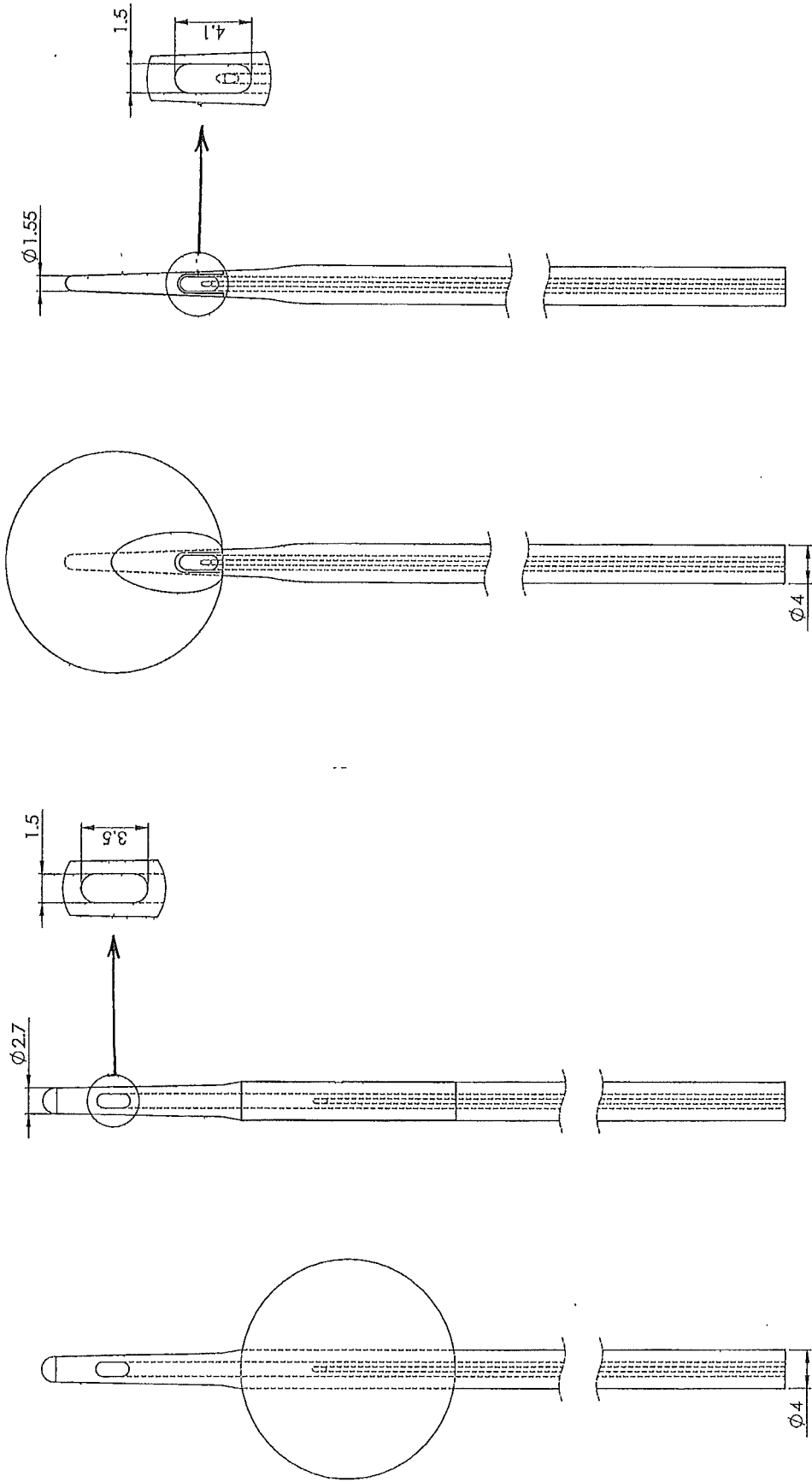


Fig. 7

Fig. 6

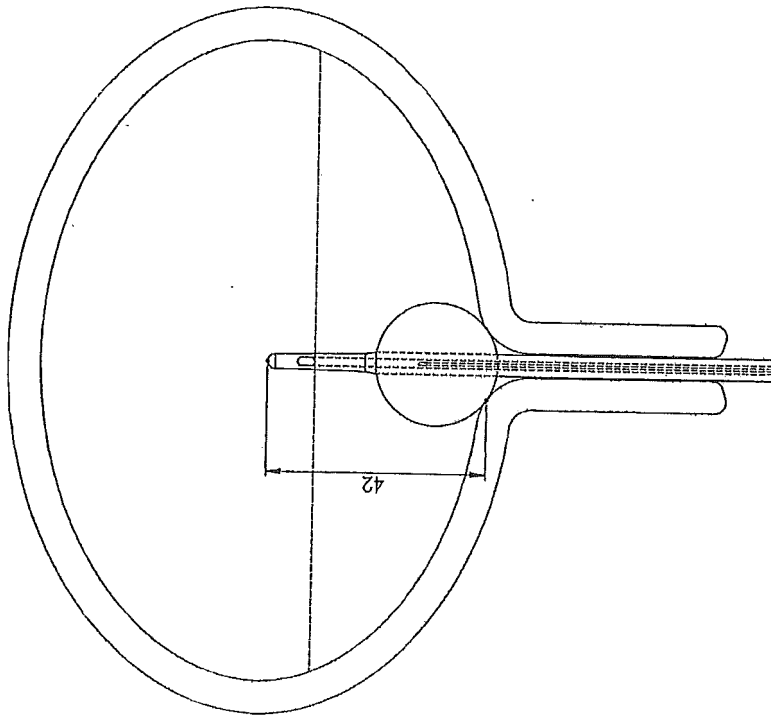


Fig. 8

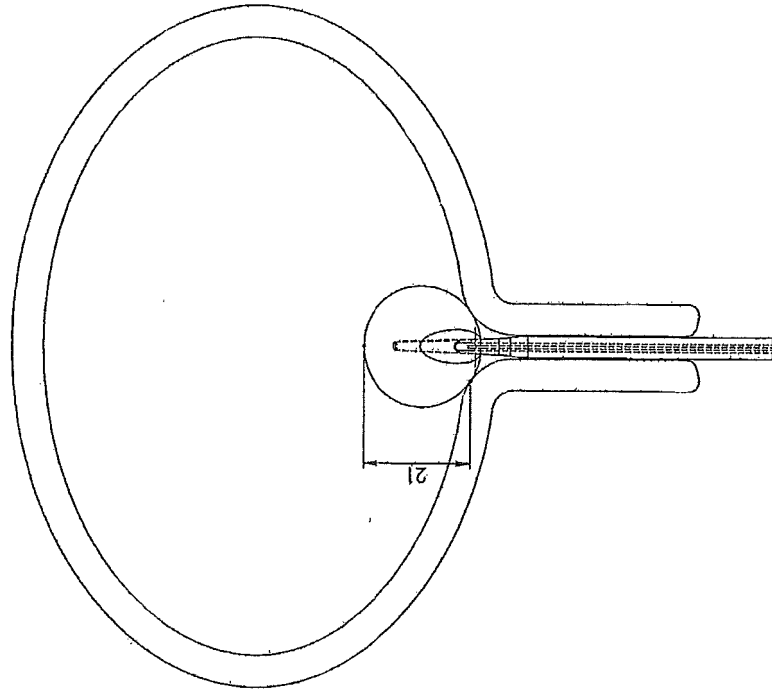


Fig. 9

Catheter

BACKGROUND

5 a. Field of the Invention

This invention relates to a catheter, and in particular to a urinary catheter.

10 b. Related Art

Current catheters have an inflatable balloon to keep the catheter in situ in the bladder and urine drainage apertures above the balloon and below the tip of the catheter.

15 This means there remains residual urine in the bladder below the level of the drainage holes. This urine tends to become infected and, through well understood processes, cause encrustations and catheter blockage. This in turn leads to patient discomfort and bypassing of urine that then demands an urgent change of catheter when the whole process only starts again. Some patients with chronic
20 conditions have catheters that may only last a couple of weeks so over the years these individuals have to sustain a lot of discomfort with recurrent blockages and changes. The National Health Service (NHS) in the United Kingdom or funding authorities over the world have to fund catheter changes that often occur as emergencies when the costs are high. The clinical and financial problem is
25 massive since there are currently 100 million catheters in use.

Another disadvantages of current catheter designs include damage or trauma to the bladder wall by the catheter tip, and damage to the bladder wall due to the bladder wall being sucked into the drainage hole, caused by the dome of the
30 bladder collapsing over the drainage hole.

It is, therefore, an object of the present invention to provide an improved catheter that overcomes at least some of the problems associated with prior art catheters.

SUMMARY OF THE INVENTION

According to the present invention, there is provided a catheter comprising:

- 5 - an elongate shaft having a longitudinal drainage bore for conveying fluid along the shaft;
- an elongate, tapered tip portion extending from an end of the shaft, the tip portion having a distal end furthest from the shaft;
- a drainage aperture provided in the tip portion, said aperture being in fluid communication with said bore; and
- 10 - an inflatable balloon element attached to said tip portion, the balloon element being configured such that, when fully inflated, the balloon element fully surrounds the distal end of the tip portion and extends along the tip portion to a point on an opposite side of the drainage aperture to said distal end, a surface of the balloon element including a depression providing a passageway in fluid
- 15 communication with the drainage aperture.

The catheter will typically be a urethral catheter.

Preferably the catheter further comprises:

- 20 - an inflation bore provided in the shaft; and
 - an inflation aperture provided in the tip portion, the inflation aperture being in fluid communication with the inflation bore and with an internal volume of the balloon element.
- 25 Preferably the inflation aperture is provided on an opposite side of the tip portion to the drainage aperture.

Preferably, when the balloon element is inflated, the depression in the surface of the balloon element does not extend beyond the distal end of the tip portion.

30

Preferably the balloon element is substantially spherical when fully inflated.

Preferably a dimension of the balloon element, when fully inflated, in a longitudinal

direction is at least three times the dimension of the drainage aperture in the longitudinal direction.

5 Preferably a length of the tip portion between the drainage aperture and the distal end is at least two times the length of the drainage aperture in the longitudinal direction.

10 The catheter design of the present invention, therefore, allows complete emptying of the bladder which will tackle the main factor influencing blockage. The balloon will retain the catheter in the bladder and the design has a missing half segment at the bottom where the drainage aperture is located. This allows complete bladder drainage while ensuring the aperture remains positioned at the base of the bladder. Since the hole is at the level of the balloon and not above it this means the length of catheter above the balloon can be shortened. This fact, combined
15 with the inflatable tip, will both reduce trauma from the catheter tip to the bladder and also eliminate bladder wall damage from being sucked into the drainage hole. Catheter life, damage to the bladder wall and insertion difficulties will all be greatly improved with the catheter of the present invention.

20

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be further described, by way of example only and with reference to the accompanying drawings, in which:

25

Figure 1 shows an example of a known, prior art catheter;

Figure 2 shows an example of a know, prior art catheter in position within a bladder;

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Figure 3 shows a catheter according to a preferred embodiment of the present invention;

Figure 4 is a plan view from the front of the catheter of Figure 3;

Figure 5 is a plan view from the side of the catheter of Figure 3;

5 Figure 6 illustrates an example of a known, prior art catheter;

Figure 7 illustrates an embodiment of a catheter of the present invention;

10 Figure 8 shows an example of a know, prior art catheter in position within a bladder; and

Figure 9 shows an embodiment of a catheter according to the present invention in position within a bladder.

15

DETAILED DESCRIPTION

As shown in Figure 1, it is known to provide catheters 1 with retention balloons 2 that function to retain the distal end 4 of the catheter 1 within a bladder during use.

20 The catheters 1 may be supplied with a pre-filled water balloon or may use a syringe 3 to inflate the distal retention balloon. They are also made of differing materials but the spherical retention balloon 2 is a common feature to them all.

25 Figure 2 illustrates a prior art catheter 1 inserted and functioning within a bladder 6. The balloon 2 sits over the urethral exit 8 from the bladder 6 and seals it along with the catheter tubing 10 itself. The drawing demonstrates that the bladder 6 can never empty because the drainage hole 12 sits approximately 33 mm into the bladder 6. This is the fundamental design flaw of current catheters, because stagnant urine remaining in the bladder encourages infection, commonly by
30 Proteus Mirabilis. This then leads to the sequence of biofilm formation followed by crystal deposition in the urine carrying tubing 10 called encrustation, which then causes catheter blockage. The other feature of this drawing is that it clearly shows 42 mm of tubing 10 inside the bladder 6. The tip 14 of the catheter 1 has been

shown to cause bladder damage but also the bladder wall can be sucked into the drainage hole 12. The bladder 6 tends to collapse from the top hence it is possible for the walls to get damaged in this way.

5 Figures 3 to 5 illustrate a preferred embodiment of a catheter 220 according to the present invention. The catheter 220 comprises an elongate shaft 222 having two bores 224, 226 extending axially along its length. The bores 224, 226 allow fluids, in particular water and urine, to travel through the shaft 222. In particular, a first bore 224 is a drainage bore 224 and a second bore 226 is an inflation bore. At an
10 end of the shaft 222 is a tapered tip portion 228. The tip portion 228 is elongate and extends coaxially from the end of the shaft 222, terminating at a distal end 230 of the catheter 220.

This is the only urethral catheter design that has a graduated or tapered profile of
15 the tip 228 to allow gentle urethral dilatation during insertion which should therefore be easier to execute. The distal end 230 of the catheter 220 has a smaller bore that opens out proximally along the shaft of the catheter to the full cross section of the particular size being used. The smaller cross section of the tip may mean that a larger catheter can be used without insertion difficulties.

20

The tip portion 228 includes a drainage aperture 232 which is in fluid communication with the drainage bore 224 and an inflation aperture 234 which is in fluid communication with the inflation bore 226. In this embodiment the inflation aperture 234 is on an opposite side of the tip portion 228 from the drainage
25 aperture 232. In this example the drainage aperture 232 is elongate having a first end 238 nearer the distal end 230 of the catheter 220 and a second end 240 furthest from the distal end 230.

An inflatable retention balloon 236 is attached to the tip portion 228 of the catheter
30 220. In a fully inflated state, as shown in Figures 3 to 5, the balloon 236 is substantially spherical, however, in other embodiments the balloon 236 may be of any suitable shape. The dimensions of the balloon 236 are such that the balloon fully surrounds the distal end 230 of the catheter 220. The balloon 236 extends

along the tip portion 228 to a point on an opposite side of the drainage aperture 232 to the distal end 230. Preferably the balloon 236 extends just beyond the second end 240 of the drainage aperture 232, such that the drainage aperture 232 is located close to the surface of the balloon 236.

5

The inflatable balloon 236 around the catheter tip means that there is a soft fluid-filled membrane against the bladder wall when it collapses.

10 A surface of the balloon 236 includes a depression 242 that provides a passageway or recess in fluid communication with the drainage aperture 232. In preferred embodiments, the depression 242 in the surface of the balloon 236 does not extend beyond the distal end 230 of the tip portion 228. The depression 242 may be substantially in the shape of a spherical wedge or segment, and in preferred embodiments is substantially in the shape of half a spherical wedge.

15

The retention balloon 236, therefore, inflates to cover not only the tip but also all the circumference of the catheter 220 save the drainage aperture 232. This design resembles an orange with half a segment missing at the bottom where the drainage hole 232 is located. This ensures the bladder mucosa is kept away from the aperture 232 so it cannot get drawn in and damaged. The mucosa cannot collapse in on the aperture 232 like in a traditional catheter and so the risk of bladder damage is therefore minimised.

25 The location of the drainage aperture 232 nearer the tip or distal end 230 of the catheter 220 and surrounded by the balloon 236 makes the device less susceptible to kinking around the aperture 232 and therefore blocking. This means that the length of the aperture 232 can be increased compared with the traditional catheter which will allow for freer drainage of urine and less likelihood of blockage due to bladder debris or encrustation.

30

In preferred embodiments there is half the length of catheter 220 in the bladder (about 21mm compared with about 42mm) so less interference with normal biological bladder function.

As the drainage hole 232 is at the very base of the bladder it will not be able to collapse onto the hole. In any event the base of the bladder does not collapse down like the dome does.

5

Figure 3 shows a 3D impression that illustrates both the shortened tip as well as the inflated balloon covering the tip. Just like in current catheters the inflated balloon will retain the catheter in the bladder but, as the drainage aperture is in the lower half of a segment without the balloon, it will allow complete bladder emptying. Figure 4 (a front elevation) and Figure 5 (a side elevation) show how the inflation tube links to the balloon and opens out into the balloon behind the urine drainage tube. The drawing also shows how the drainage aperture links to the drainage tube down the body of the catheter.

15 Figures 6 and 7 illustrate the cross sections of both an existing catheter design (Figure 6) and the catheter of the present invention (Figure 7). Catheters are supplied according to their external diameters and the narrower tip of the catheter of the present invention makes insertion of a particular sized catheter easier. Furthermore the length of the urine drainage aperture is longer in the catheter of the present invention (Figure 7) compared to a traditional catheter (Figure 6) which makes blockage less likely. As the drainage aperture of the catheter of the present invention is both nearer the distal end and surrounded by the balloon, it can safely be lengthened without risk of kinking. The traditional catheter balloon is well below the urine aperture leaving a significant length of soft tubing that is susceptible to kinking if the length of the aperture is too long.

A larger drainage hole will facilitate the efficient and complete emptying of the bladder and the graduated/tapered design allows easier insertion for a particular catheter size because of the graduated increase in cross-sectional area.

30

Figures 8 and 9 show the traditional catheter and catheter of the present invention for a side by side comparison in the bladder so all the differences can be appreciated. The analogy with a bath or sink helps to make the changes

understandable. The traditional catheter (Figure 8) always allows a significant volume of urine to be retained in the bladder which is the major contributor to the consequence of frequent blockage. Excess urine drains via the 'overflow' so the bladder cannot fill above the drainage hole unless the outflow tubing blocks but
5 crucially neither can it empty. The catheter of the present invention (Figure 9) allows complete drainage down the 'plughole' so urine cannot fester in the bladder and cause these well recognised problems. The retention balloon is perfectly adequate for retaining the catheter in the bladder and looks like an orange with half a segment missing at the bottom where the drainage aperture is located. The
10 catheter of the present invention allows both for a soft fluid membrane to be the catheter tip and also for a shorter length of catheter to be within the bladder which should both dramatically reduce the risk of bladder wall damage.

CLAIMS

1. A catheter comprising:
 - an elongate shaft having a longitudinal drainage bore for conveying fluid
5 along the shaft;
 - an elongate, tapered tip portion extending from an end of the shaft, the tip portion having a distal end furthest from the shaft;
 - a drainage aperture provided in the tip portion, said aperture being in fluid communication with said bore; and
 - 10 - an inflatable balloon element attached to said tip portion, the balloon element being configured such that, when fully inflated, the balloon element fully surrounds the distal end of the tip portion and extends along the tip portion to a point on an opposite side of the drainage aperture to said distal end, a surface of the balloon element including a depression providing a passageway in fluid
15 communication with the drainage aperture.

2. A catheter as claimed in Claim 1 further comprising:
 - an inflation bore provided in the shaft; and
 - an inflation aperture provided in the tip portion, the inflation aperture being
20 in fluid communication with the inflation bore and with an internal volume of the balloon element.

3. A catheter as claimed in Claim 2, wherein the inflation aperture is provided on an opposite side of the tip portion to the drainage aperture.
25

4. A catheter as claimed in any preceding claim, wherein, when the balloon element is inflated, the depression in the surface of the balloon element does not extend beyond the distal end of the tip portion.

- 30 5. A catheter as claimed in any preceding claim, wherein the balloon element, when fully inflated, is substantially spherical.

6. A catheter as claimed in any preceding claim, wherein a dimension of the

balloon element, when fully inflated, in a longitudinal direction is at least three times the dimension of the drainage aperture in the longitudinal direction.

7. A catheter as claimed in any preceding claim, wherein a length of the tip
5 portion between the drainage aperture and the distal end is at least two times the length of the drainage aperture in the longitudinal direction.

8. A catheter substantially as herein described with reference to or as shown
in Figures 3, 4, 5, 7 and 9.

Amendments to the claims have been filed as follows

CLAIMS

1. A catheter comprising:

- an elongate shaft having a longitudinal drainage bore for conveying fluid
5 along the shaft;

- an elongate, tapered tip portion extending from an end of the shaft, the tip
portion having a distal end furthest from the shaft;

- a drainage aperture provided in the tip portion, said aperture being in fluid
communication with said bore, and a length of the tip portion between the drainage
10 aperture and the distal end being at least two times the length of the drainage
aperture in the longitudinal direction; and

- an inflatable balloon element attached to said tip portion, the balloon
element being configured such that, when fully inflated, the balloon element is
substantially spherical and fully surrounds the distal end of the tip portion and
15 extends along the tip portion to a point on an opposite side of the drainage
aperture to said distal end, a surface of the balloon element including a depression
providing a passageway in fluid communication with the drainage aperture,

wherein, when the balloon element is inflated, the depression in the surface
of the balloon element does not extend beyond the distal end of the tip portion.

20

2. A catheter as claimed in Claim 1 further comprising:

- an inflation bore provided in the shaft; and

- an inflation aperture provided in the tip portion, the inflation aperture being
in fluid communication with the inflation bore and with an internal volume of the
25 balloon element.

3. A catheter as claimed in Claim 2, wherein the inflation aperture is provided
on an opposite side of the tip portion to the drainage aperture.

30 4. A catheter as claimed in any preceding claim, wherein a dimension of the
balloon element, when fully inflated, in a longitudinal direction is at least three
times the dimension of the drainage aperture in the longitudinal direction.

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5. A catheter substantially as herein described with reference to or as shown in Figures 3, 4, 5, 7 and 9.

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08 05 14



Application No: GB1401538.2

Examiner: Dr Matthew Parker

Claims searched: 1-8

Date of search: 10 February 2014

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-7	US4351342 A (WIITA), see Figure 2
X	1-7	US3954110 A (HUTCHISON), see Figures 3 and 4
X	1-3,5	US5250029 A (LIN EDWARD), see Figure 10
X	1-3	WO2010/090671 A1 (HOLLISTER), see Figure 1A

Categories:

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.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^X:

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Worldwide search of patent documents classified in the following areas of the IPC

A61M

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI

International Classification:

Subclass	Subgroup	Valid From
A61M	0025/00	01/01/2006
A61M	0025/10	01/01/2013