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(54) **BALLOON CATHETER INFLATION**

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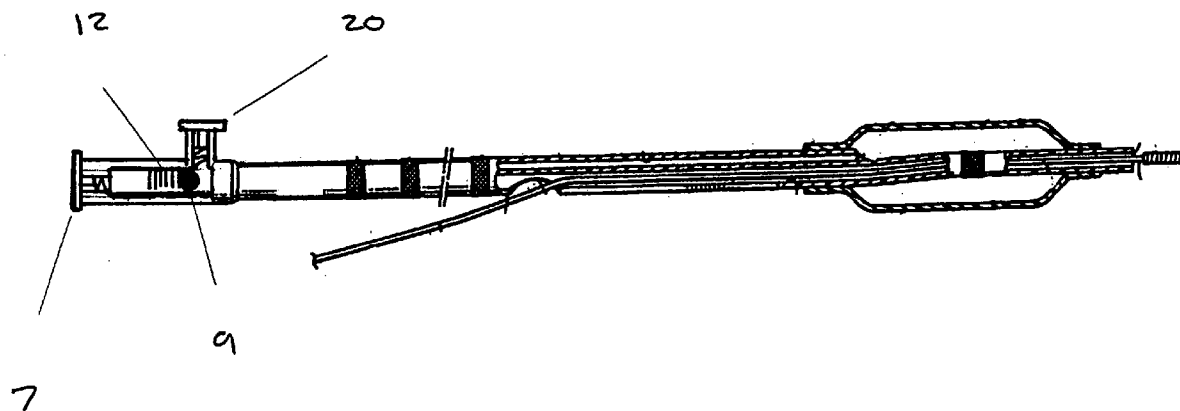
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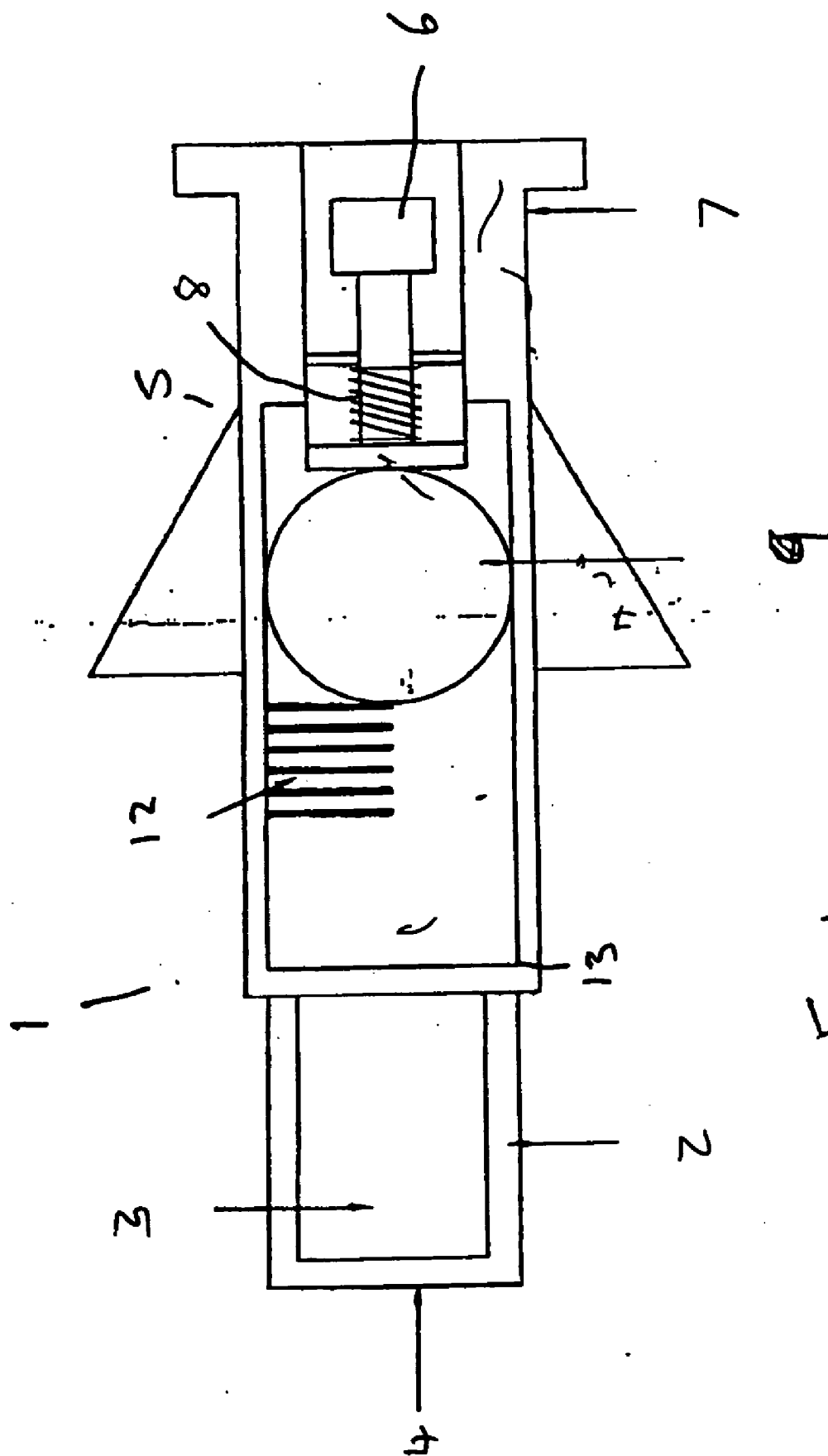
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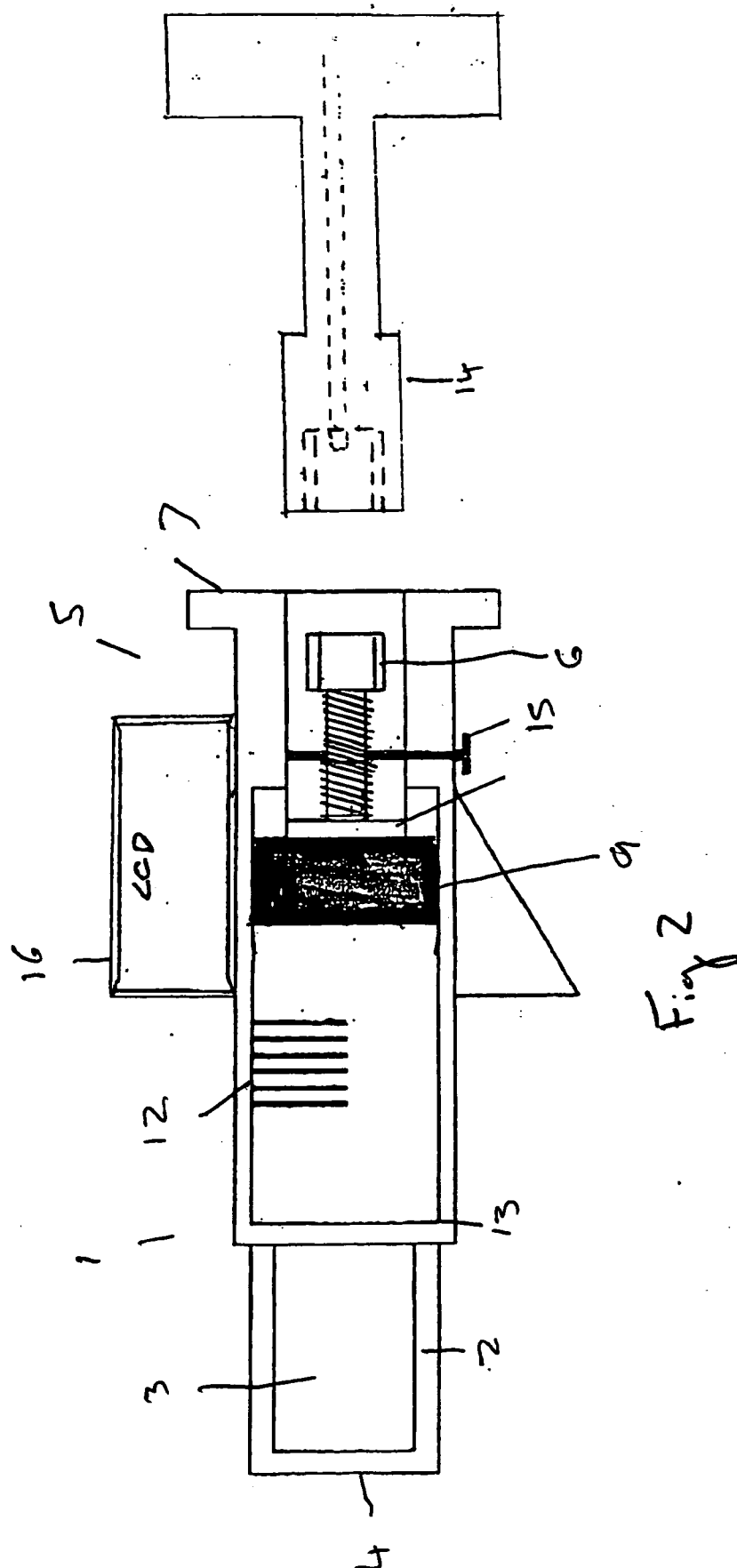
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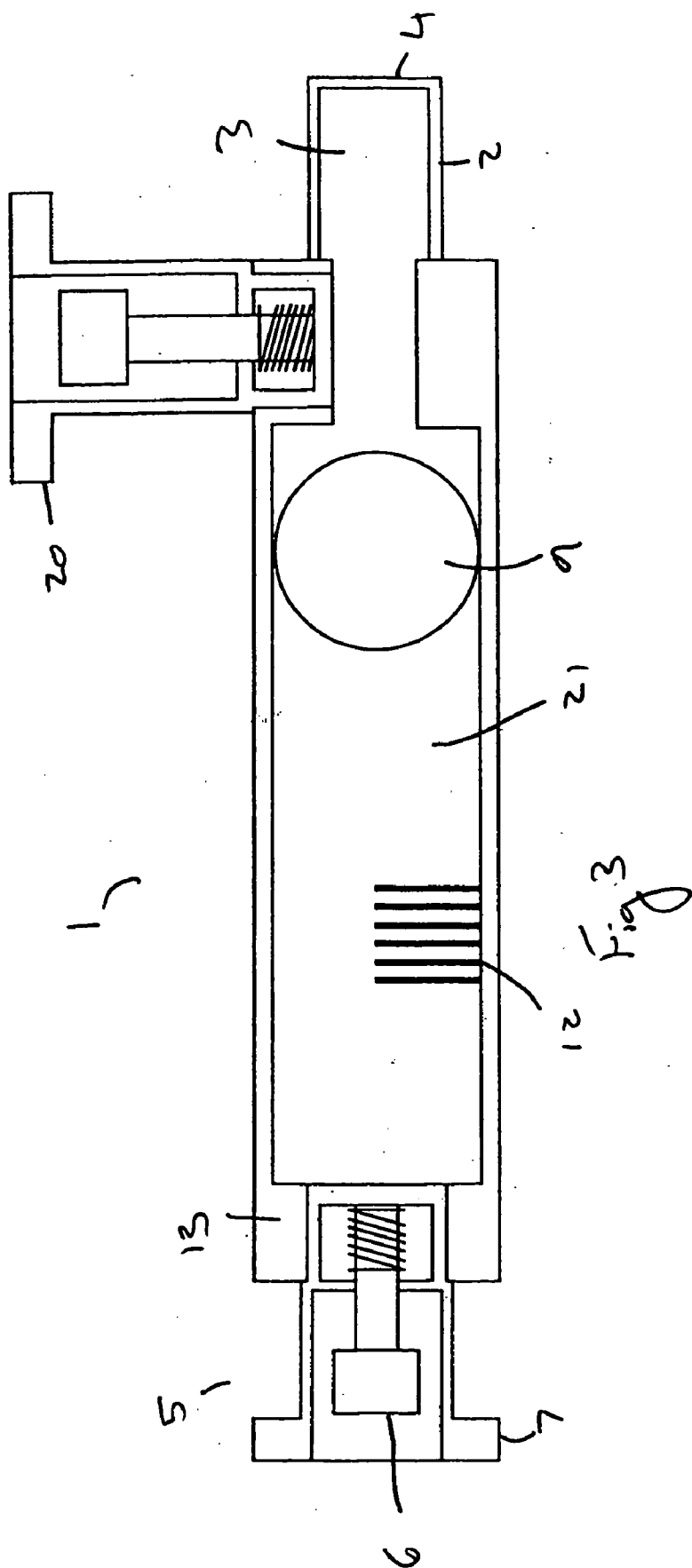
(57) **ABSTRACT**

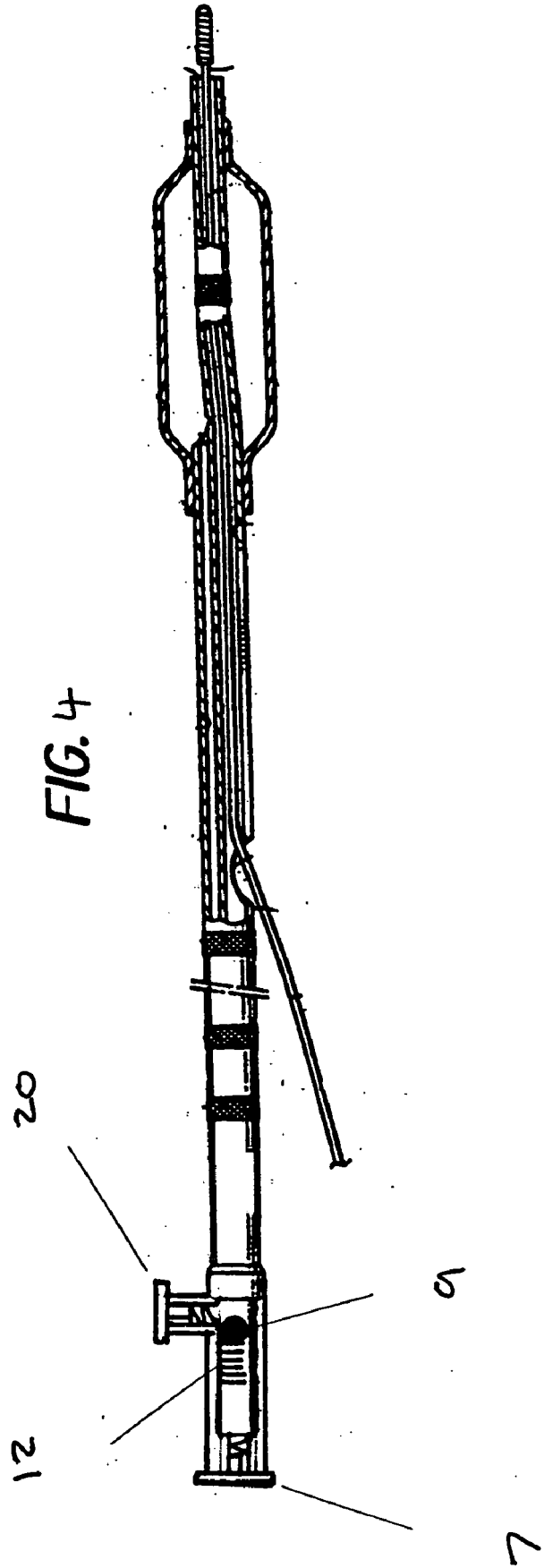
A balloon catheter comprising a fluid dispensing device. The device comprises a housing defining a chamber for retaining, in use, balloon inflation fluid. An outlet attaches, in use, to a catheter inflation lumen, and dispensing means dispenses fluid, in use, from the chamber via the outlet into the catheter lumen. An indicator indicates when a predetermined volume of fluid has been dispensed from the outlet.











BALLOON CATHETER INFLATION

[0001] This invention relates to balloon catheters of the type used for insertion into the lumen of a human or animal body. In particular, it relates to a balloon catheter having a device for controlling the inflation of the balloon catheter.

[0002] Balloon catheters are well known in the art. They are available in various sizes for a variety of medical applications. Generally they comprise an elongate body which has, at its distal end, a balloon which can be inflated when appropriately positioned within a body lumen by delivery of an inflating fluid. The main purpose of their use is to re-open occluded lumens, such as arteries, which may have started to close due to build-up of deposits on the walls of the lumen in question.

[0003] Whilst having become very popular for use in various types of surgery, such balloon catheters have a number of problems associated with them. One such problem is that of inflation of the balloon. Because, by their very nature, the balloons of such catheters are inflated in remote locations in a body which are difficult to monitor, it can be extremely difficult to provide accurate sensing of inflation levels within such balloons. To monitor the inflation of the balloon it is therefore common to monitor the pressure of the fluid applied to the catheter to inflate the balloon and use this as an indication of balloon inflation. Such an approach has problems, however. Firstly, it may be that the catheter has an obstruction which results in an increase in pressure even though an adequate amount of fluid has not been delivered to the balloon to ensure inflation. Secondly, inadequate inflation of the balloon may occur if a particularly rigid obstruction is being opened up and pressure will not indicate that this is the case.

[0004] The above invention seeks to overcome some of the above problems.

[0005] According to the present invention there is provided a balloon catheter comprising a balloon arranged to be inflated, in use, by fluid delivered thereto via a lumen fluid dispensing device attached to the lumen and comprising:

[0006] a housing defining a chamber for retaining, in use, balloon inflation fluid;

[0007] an outlet attached to the lumen;

[0008] dispensing means for dispensing fluid, in use, from the chamber via the outlet into the catheter lumen; and

[0009] an indicator for indicating when a predetermined volume of fluid has been dispensed from the outlet.

[0010] The outlet may comprise a pressure activated seal which opens when a predetermined fluid pressure is exceeded by the fluid contents of the chamber in use.

[0011] The indicator may be a simple graduated window and internal marker configuration, or may comprise an internal sensor attached to an external display such as a liquid crystal display.

[0012] The dispensing means may be a plunger which may be attached to an external removable plunger key to prevent inadvertent dispensing of fluid. The dispensing means may be provided with a lock. The dispensing means, if a plunger is employed, may have biasing means associated therewith.

A portion of the plunger of the dispensing means may act as a component of the indicator.

[0013] The catheter may comprise an inlet valve so that fluid can be inserted into the chamber to prime the device.

[0014] The present invention allows a user to inflate a balloon catheter with reference to a fixed volume accurately calibrated to the balloon and ensures that enough fluid is dispensed to ensure complete expansion of the balloon even if a particularly rigid obstruction is being expanded. The present invention also provides for a sealed dispensable unit to prevent contamination, although with the provision of an additional valve it can enable the provision of a dispenser that is able to dispense fluid with a short shelf life. Furthermore, the provision of the fluid in a discrete component that is integral with the balloon catheter reduces the need to have additional equipment available to a surgeon during operation as well as reducing the overall cost of the equipment.

[0015] Examples of the present invention will now be described with reference to the accompanying drawings, in which:—

[0016] FIG. 1 is a side schematic cross-sectional view of a device forming part of a catheter according to the present invention;

[0017] FIG. 2 is a schematic side cross-sectional view of a second example device forming part of a catheter according to the present invention;

[0018] FIG. 3 is a schematic side cross-sectional view of a third example device forming part of a catheter according to the present invention; and

[0019] FIG. 4 is a side schematic partial cross-sectional view of a catheter according to the present invention.

[0020] FIG. 1 is a side schematic cross-sectional view of a device 1 forming part of a balloon catheter according to the present invention. The device 1 has a housing 2 which defines a fluid-containing chamber 3. An outlet 4 is attached to the lumen 11 of a catheter 10 (FIG. 4). As mentioned above, the outlet 4 may be blocked by a tamper-evident seal that is broken when sufficient pressure is applied to it via fluid in the chamber 3. A dispensing section 5 comprises a plunger 6 disposed within a valve housing 7 in such a manner that it can slide within the housing 7 upon application of external pressure to it in the direction of the outlet 4. In this example the plunger 6 is biased by a spring 8 in the direction of the outlet 4 to reduce the necessary force that needs to be applied by an operator in use, although in many cases this spring may be unnecessary or even undesirable. The plunger 6 drives, in use, a piston, which in this example is provided by a Teflon (RTM) ball. In use, movement of the plunger 6 drives the ball 9 towards the outlet 4 and urges fluid in the chamber 3 to the lumen 11 (FIG. 4) of a catheter 10 (FIG. 4). A portion 12 of the housing is transparent and may be graded, so that an operator can view movement of the ball 9 and hence determine when appropriate volume of fluid has been dispensed by the outlet 4. A final stop 13 may be provided to prevent excess fluid being dispensed from the chamber. FIG. 2 shows a further example of the invention, in which components that correspond to those in FIG. 1 are numbered identically. In this example, the ball 9 is replaced with a piston 9 which is, again, driven by a plunger 6. An actuating key 14 must be applied to the plunger 6 before

operation can be achieved. Furthermore, in this example an optional locking key **15** is provided to prevent accidental actuation of the device **1**. In this example, a display that may be a liquid crystal display **16** is provided to optionally provide a volumetric output to increase the accuracy of the dispense volume reading.

[0021] **FIG. 3** shows a further example device according to the invention in which, again, components which correspond to those in the example of **FIG. 1** are numbered identically. In this example, however, a valve **20** is provided so that fluid can be inserted into the chamber **3**. This provides a device **1** which can be filled on site so that fluid with a limited shelf life can be dispensed from the device. In operation, fluid is input via the valve **20** and fluid in the region **21** of the housing **2** is evacuated via the dispensing region **5** so that the ball piston **9** moves back toward the dispensing region until it engages with the plunger **6**. The valve **20** is configured so that it will not allow outward flow of fluid, and the plunger can then be moved in the direction of the outlet **4** to dispense fluid from the chamber **3**.

[0022] **FIG. 4** shows an example catheter **10** that may be employed with the invention. The catheter has a hub **30** which is attached to the devices of **FIGS. 1** to **3**. In the hub **30** is a fluid inlet which connects with a fluid lumen **11**, which in turn connects with the interior of a balloon **31**. A lumen **32** passes through the lumen **31** so that a guide wire **32** can be inserted therein to guide the catheter **10** to a desired location in use. In operation, the catheter may be placed in position and then the device **1** of the invention attached to the hub **4**, and fluid dispensed by operation of the dispensing region **5** to inflate the balloon **31**. Optimum inflation is ensured because of the ability to measure a

precise volume of fluid. The dispensing device is provided for a specific balloon type so, for improved safety, optimum inflation can be ensured for the device and the likelihood of operator error reduced.

1. A balloon catheter comprising a balloon arranged to be inflated, in use, by fluid delivered thereto via a lumen fluid dispensing device attached to the lumen and comprising:

a housing defining a chamber for retaining, in use, balloon inflation fluid;

an outlet attached to the lumen;

dispensing means for dispensing fluid, in use, from the chamber via the outlet into the catheter lumen; and

an indicator for indicating when a predetermined volume of fluid has been dispensed from the outlet.

2-3. (canceled)

4. A device according to claim 1, wherein the indicator comprises an internal sensor attached to an external display.

5. A device according to claim 1, wherein the dispensing means is a plunger which is attached, in use, to an external removable plunger key to prevent inadvertent dispensing of fluid.

6. A device according to claim 1, wherein the plunger has biasing means associated therewith.

7. (canceled)

8. A device according to claim 1, wherein the dispensing means is provided with a lock.

9. A device according to claim 1, further comprising an inlet valve so that fluid can be inserted into the chamber, in use, to prime the device.

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