

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
2 March 2006 (02.03.2006)

PCT

(10) International Publication Number  
**WO 2006/021590 A1**

(51) International Patent Classification<sup>7</sup>: **A61F 5/453**

(21) International Application Number:  
PCT/EP2005/054241

(22) International Filing Date: 29 August 2005 (29.08.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
04020368.9 27 August 2004 (27.08.2004) EP

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

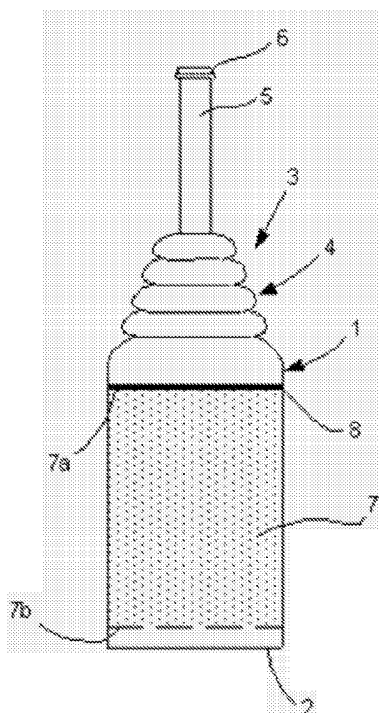
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: AN EXTERNAL URINARY CATHETER



(57) Abstract: The external urinary catheter comprises a sheath portion (1) and a tip portion (3). A layer of adhesive (7) is provided on the inner side of the sheath portion (1) and extends between a first limit (7a) and a second limit (7b). At least one indication (8) indicating at least the first limit (7a) of the layer of adhesive (7) is provided. The indication may be a visual indication, e.g. in the form of a coloured line (8).

The present invention relates to an external urinary catheter comprising a sheath portion and a tip portion, said sheath portion extending between said tip portion and an open end, a layer of adhesive  
5 being provided on an inner side of said sheath portion and extending between a first limit and a second limit.

External urinary catheters, or urisheaths, are conventionally used for aiding male urinary inconti-  
10 nence and for use in hospitals in connection with treatment and surgery of urethral disorders. Such an external urinary catheter normally comprises a sheath or body portion, which in the mounted condition encloses the shaft of the penis, and a tip portion  
15 which via a hose is intended to be connected to a urine collection bag that is e.g. fastened to the bed or the leg of the user.

Traditionally, the external urinary catheter is delivered in a rolled-up condition. In this delivery  
20 condition, the sheath portion is rolled-up in a number of successive windings to such an extent that the layer of adhesive is entirely accommodated in the windings to allow the urisheath to be packaged and handled without the inner side of the sheath portion  
25 adhering to the surroundings. In order to apply the external urinary catheter on a penis, the sheath portion is unrolled slightly until the layer of adhesive on the inner side of the sheath portion is exposed. In this condition, the external urinary  
30 catheter is positioned on the penis such that the layer of adhesive is brought into contact with the skin and the remaining part of the sheath portion is

subsequently unrolled.

When applying the external urinary catheter it is essential that it be positioned correctly before the adhesive contacts the skin. The initial tack of the adhesive is relatively high and it may be difficult to refit an external catheter that has been positioned incorrectly. In some cases the external urinary catheter even has to be replaced by a new one after an unsuccessful attempt has been made.

10        These difficulties are particularly pronounced in the case of disabled users, who most often require help to be able to perform the mounting of the urinary catheter. Such help is costly and since most users consider mounting of urinary catheters to be a private matter, they consider it more or less unpleasant.

With this background it is the object of the present invention to provide an external urinary catheter of the kind mentioned in the introduction, which overcomes or at least alleviates the above-mentioned disadvantages.

This and further objects are met by the provision of an external urinary catheter comprising a sheath portion and a tip portion, said sheath portion extending between said tip portion and an open end, a layer of adhesive being provided on an inner side of said sheath portion and extending between a first limit and a second limit, that the sheath portion is adapted to be rolled-up in a number of successive windings, said external urinary catheter being characterized in that the external urinary catheter comprises at least one indication indicating at least

the first limit of the layer of adhesive.

The invention is based on the recognition that it may be difficult to detect when the adhesive starts to contact the skin, especially when the sheath portion is rolled up. By adding an indication, the beginning of the layer of adhesive, i.e. the first limit, is detectable. This in turn will help the person fitting the external urinary catheter. The sheath portion can safely be unrolled to a point just before the adhesive contacts the skin. With the external urinary catheter positioned correctly, the sheath portion can then be unrolled further for the adhesive to contact the skin.

It should be understood that implicit indication means, such as for example release liners can not be used when the sheath portion is rolled up, since the release liner would wrinkle together and be displaced. Furthermore, such release liners are typically unnecessary since the material of newer urisheath in itself works as release liner, such as for example urisheaths made of silicone. Therefore is it necessary to provide alternative indications for urisheaths where the sheath portion is rolled up.

Furthermore is it often necessary for additional indications since the sheath portion is rolled up and therefore is the adhesive limit often difficult to detect, especially when the sheath portion is transparent, or at least partly transparent, as the overlapping layers will create a diffused view of the adhesive layer.

Thus, it is possible even for disabled users to handle mounting of the external urinary catheter

according to the invention without the need for assistance from a medical staff. As a consequence, users experience a more comfortable mounting of the urinary catheter, and medical personnel may be saved.

5 In an embodiment of the invention, the indication is a visual indication.

The visibility may be provided by means of a colour. This makes the first limit of the layer of adhesive immediately recognizable, and the colour may  
10 be easily applied during the production of the external urinary catheter, thus entailing only low or no additional production costs. In one embodiment, the indication is in the form of a coloured line. As an alternative, the indication is provided by a  
15 colouring of the layer of adhesive.

The choice of the at least one indication as a colour has a further advantage, namely that if different size external urinary catheters have different indication colours, the indication can  
20 additionally be used to identify the size of the external urinary catheter.

Alternatively, or additionally, the at least one indication may be a tactile indication. This entails that even users having impaired eyesight may  
25 perform the mounting. Preferably, such a tactile indication comprises a plurality of circumferential protrusions along said first limit.

In the following the invention will be described in further detail with reference to the  
30 schematic drawings, in which

Fig. 1 shows a side view of a first embodiment of the external urinary catheter according to the

invention in a rolled-up condition;

Fig. 2 shows a side view of the urinary catheter of Fig. 1 in an unrolled condition;

Fig. 3 shows a side view corresponding to Fig. 2 of a second embodiment of the external urinary catheter according to the invention; and

Fig. 4 shows a side view corresponding to Fig. 2 of a third embodiment of the external urinary catheter according to the invention.

10 The structure of the external urinary catheter according to the invention will be described with reference to the first embodiment of Figs. 1 and 2. In the second and third embodiments of Figs. 3 and 4, respectively, elements having the same or analogous  
15 function as in the first embodiment are denoted by the same reference numerals, and only differences in relation to the first embodiment will be described in detail.

The external urinary catheter comprises a soft  
20 thin-walled and flexible sheath portion 1 with an open end 2. At the end opposite the open end 2 the sheath portion 1 is connected to or formed integrally with a tip or end portion 3. The sheath portion 1 is intended for mounting on the penis of a user (not  
25 shown), and the tip portion 3 is intended for connecting the urinary catheter to a urinary bag or the like (not shown) by means of a hose (not shown either).

The sheath portion 1 is made from any suitable  
30 material. Advantageously, the sheath portion is to some extent transparent, the term "transparent" being intended to be understood in such a way that it is

possible to inspect at least some areas of the penis without removing the external urinary catheter.

The tip portion 3 comprises an anti-kinking chamber provided by a flexible bellows portion 4, and  
5 a tip connector 5. The four annular parts of the bellows portion 4 may be arbitrarily compressed, whereby the tip connector 5 may be directed at any angle to the longitudinal axis of the external urinary catheter less than approximately 90°. This  
10 prevents blockage of the hose leading to the urinary bag and allows for movement of the catheter independently from the urinary bag. In the embodiment shown, the tip connector 5 is furthermore provided with a circumferential bead 6.

15 In order to secure the external urinary catheter to the penis of the user, part of the inner side of the sheath portion 1 is provided with a layer of a suitable adhesive. The adhesive layer, which is denoted by 7 in the embodiment of Figs. 1 and 2, may  
20 e.g. be provided as a layer or a coating of a pressure-sensitive adhesive having a relatively high permeability to water vapour. The layer of adhesive extends between a first limit 7a in the vicinity of the tip portion 3 and a second limit 7b, which in the  
25 embodiment shown is situated near the open end 2. However, other extensions of the layer of adhesive 7 are of course conceivable. In the first embodiment, the adhesive layer 7 is virtually transparent and the shading shown in Fig. 2 is for reasons of readability  
30 only, as is the broken line indicating the second limit 7b.

Eventually, the external urinary catheter is

provided with an indication, the function of which will be described in detail further down. In the embodiment of Figs. 1 and 2, the indication is in the form of a coloured line 8. The coloured line 8 is positioned at the beginning of the layer of adhesive 7 such that it substantially coincides with the first limit 7a. It is also possible to position the coloured line 8 slightly offset with respect to the first limit 7a.

10       The urinary catheter is delivered to the user in a rolled-up condition. In this condition the sheath portion 1 is rolled upon itself in successive windings, starting from the open end 2 towards the tip portion 3. In order to prevent successive wind-  
15 ings in the rolled-up sheath portion 1 from sticking together, the outer side is provided with adhesive-rejecting properties in a manner known *per se*. In this rolled-up delivery condition, the layer of adhesive 7 is not exposed, i.e. the coloured line 8  
20 and the first limit 7a are positioned within the windings.

When the external urinary catheter is to be mounted on a user, the sheath portion 1 is unrolled slightly until the indication in the form of the  
25 coloured line 8 appears and is visible to the person performing the mounting, either from the outer side or the inner side of the external urinary catheter. This slightly unrolled condition corresponds in substance to the condition shown in Fig. 1, depending  
30 on the exact position of the coloured line 8 with respect to the first limit 7a. At this point, the external urinary catheter is positioned on the penis



of the user. Further unrolling of the sheath portion 1 entails that the external urinary catheter is held in position by the adhesion provided by the contact between the layer of adhesive 7 and the skin. Subsequently, the remaining part of the sheath portion 1 is unrolled until the sheath portion 1 surrounds the shaft of the penis at least partly.

Referring now to Fig. 3, the layer of adhesive 27 in the second embodiment extends between first and second limits 27a and 27b, corresponding to the first embodiment. However, the indication marking the beginning of the layer of adhesive 27, i.e. at least the first limit 27a, is provided by a colouring of the layer of adhesive 27 itself. This colouring may be accomplished in any suitable manner, e.g. by utilizing an adhesive that is inherently coloured or a separate colouring agent or pigment may be added.

In the third embodiment shown in Fig. 4 the indication marking the beginning of the layer of adhesive 27 extending between first and second limits 27a and 27b is a tactile indication. The indication comprises a plurality of circumferential protrusions 28 along the first limit 27a.

It is of course possible to combine different indications in one external urinary catheter, e.g. an indication that is mainly tactile may also to some extent be visible and vice versa. Indications having an audible element are also conceivable, e.g. a cracking sound that is activated when the beginning of the layer of adhesive on the sheath portion is exposed. It is also possible to have more than one indication.

The invention should not be regarded as being limited to the embodiments described in the above but various combinations and modifications may be carried out without departing from the scope of the following  
5 claims.

For example, although the invention has been described only with respect to external urinary catheters for positioning on the penis, it is of course possible to apply it to other products, in  
10 which adhesive contact between the product and the skin is involved. Evidently, the invention may as well be applied to surgical gloves, contraceptive condoms, fingerstalls etc.

## C L A I M S

1. An external urinary catheter comprising a sheath portion (1) and a tip portion (3), said sheath portion (1) extending between said tip portion (3) and an open end (2), a layer of adhesive (7;17;27) being provided on an inner side of said sheath portion (1) and extending between a first limit (7a;17a;27a) and a second limit (7b;17b;27b), that the sheath portion is adapted to be rolled-up in a number of successive windings, characterized in that the external urinary catheter comprises at least one indication (8;28) indicating at least the first limit (7a;17a;27a) of the layer of adhesive (7;17;27).

15

2. An external urinary catheter according to claim 1, in which said indication (8) is a visual indication.

20 3. An external urinary catheter according to claim 2, in which said indication is in the form of a coloured line (8).

3. An external urinary catheter according to claim 2, in which said indication is provided by a colouring of the layer of adhesive (17).

4. An external urinary catheter according to claim 1, in which said at least one indication (27) is a tactile indication.

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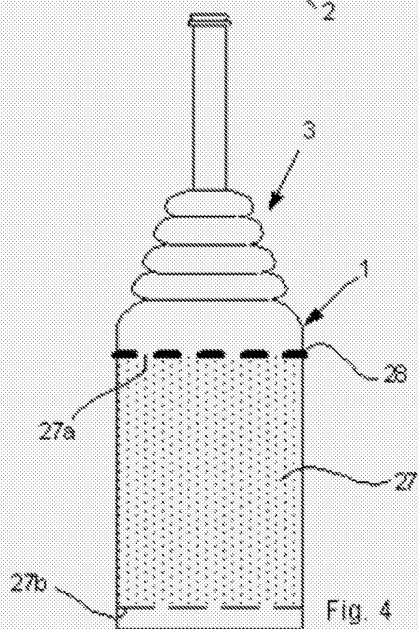
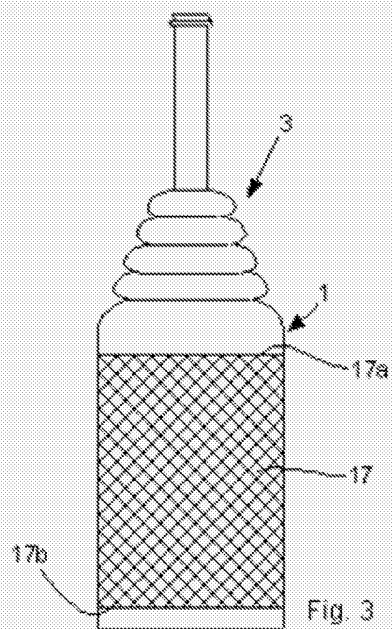
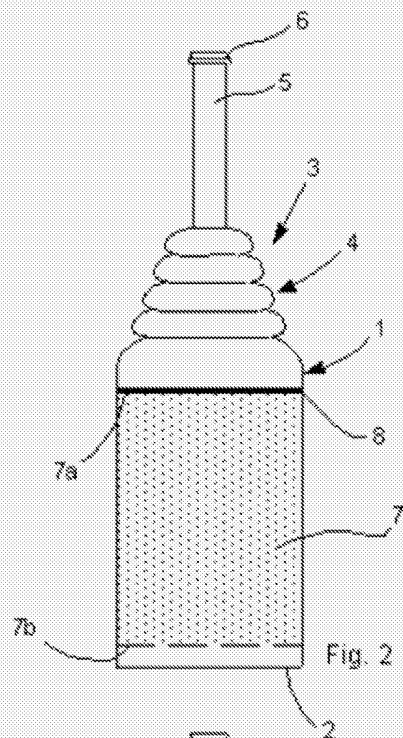
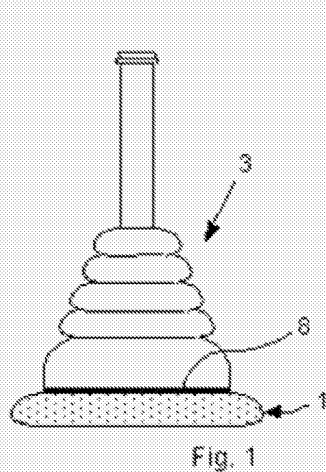
5. An external urinary catheter according to

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claim 4, in which said at least one indication comprises a plurality of circumferential protrusions (28) along said first limit (27a).

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## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/EP2005/054241

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61F5/453

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)

IPC 7 A61F

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 practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                                | Relevant to claim No. |
|------------|-------------------------------------------------------------------------------------------------------------------|-----------------------|
| X          | US 4 586 974 A (NYSTROM ET AL)<br>6 May 1986 (1986-05-06)                                                         | 1,2,5,6               |
| Y          | column 4, line 10 - column 5, line 32;<br>figures 1-7                                                             | 3,4                   |
| Y          | US 5 942 186 A (SANADA ET AL)<br>24 August 1999 (1999-08-24)<br>abstract                                          | 3,4                   |
| X          | EP 0 508 584 A (SMITHS INDUSTRIES PUBLIC<br>LIMITED COMPANY)<br>14 October 1992 (1992-10-14)<br>abstract; figures | 1,2,5,6               |
| X          | US 3 648 700 A (HAROLD W. WARNER)<br>14 March 1972 (1972-03-14)<br>abstract                                       | 1,2,5,6               |
|            | -/--                                                                                                              |                       |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

31 October 2005

Date of mailing of the international search report

09/11/2005

Name and mailing address of the ISA

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International Application No  
PCT/EP2005/054241

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                  | Relevant to claim No. |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| A          | <p>DE 41 30 220 A1 (SCHOLL, THOMAS, 8028<br/> TAUFKIRCHEN, DE; SCHOLL, THOMAS,<br/> STRASSBURG/STRAS)<br/> 17 December 1992 (1992-12-17)<br/> abstract</p> <p style="text-align: center;">-----</p> | 6                     |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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| Patent document<br>cited in search report |    | Publication<br>date | Patent family<br>member(s)     | Publication<br>date      |
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