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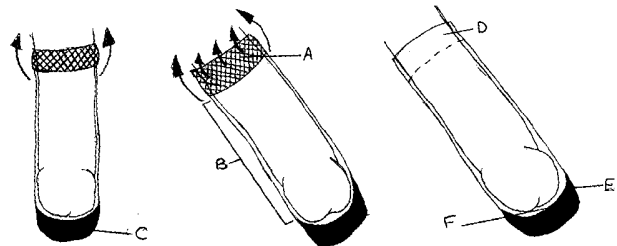
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(56) Documents Cited:  
GB 2016929 A FR 002822057 A  
US 5643235 A US 4790835 A  
US 20060229576 A US 20010031933 A

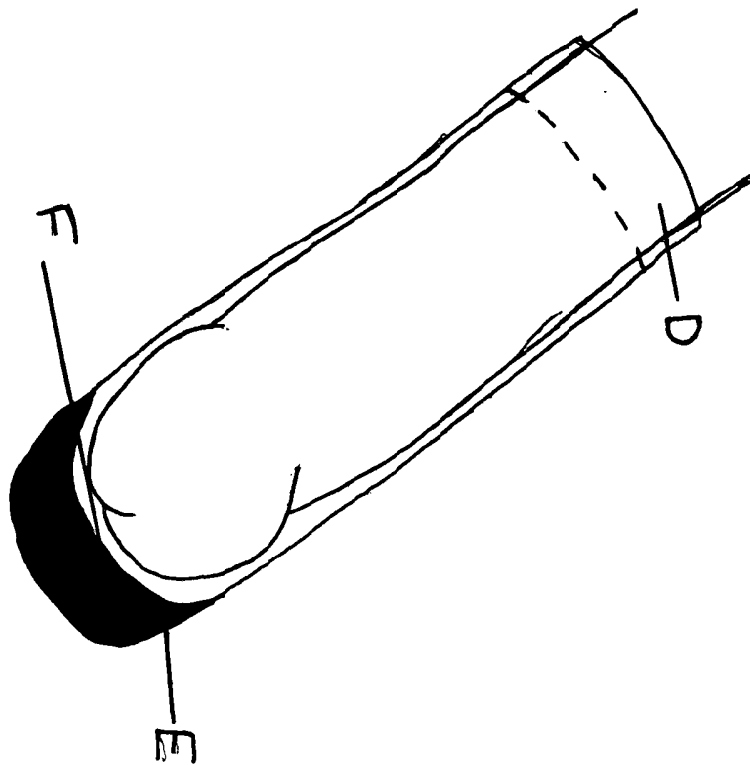
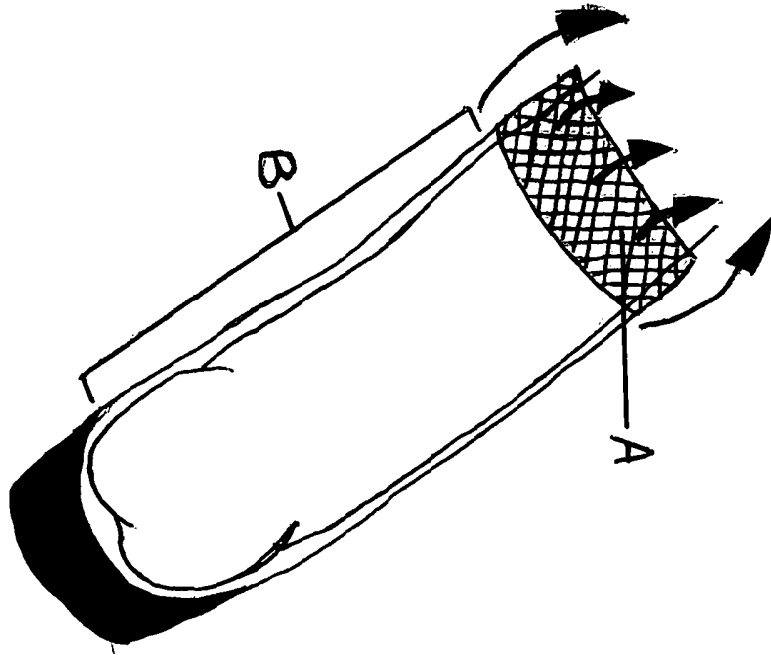
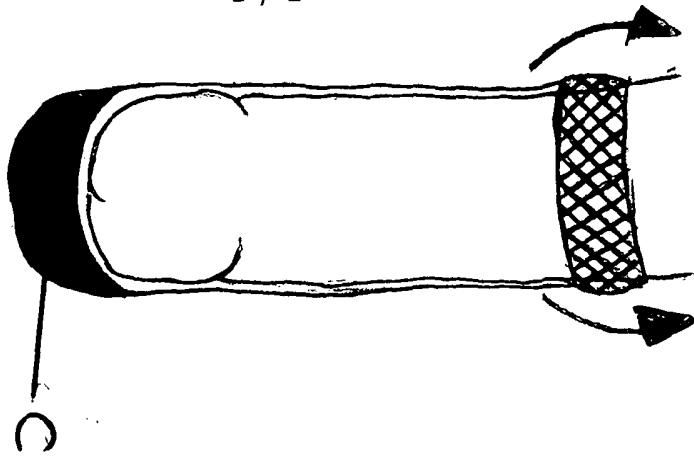
(58) Field of Search:  
INT CL A61F  
Other: WPI & EPODOC

(54) Abstract Title: **Male incontinence sheath**

(57) A male incontinence sheath B comprises an elongate tubular member having a distal end and proximal end. The distal end contains an absorbent material C overlaid by a liquid permeable layer. The whole of the sheath B has microscopic air inlets to allow the sheath B to be breathable. This air permeable material may stretch to allow for the increased volume of the saturated absorbent. The proximal end of the sheath B has an adhesive area D to allow the sheath B to be secured to a penis. The absorbent material may be cellulose fibres and may contain microcrystalline silver having anti-bacterial and anti-odour properties. The sheath B may be degradable and flushable.



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### Description.

The present invention relates to male urinary incontinence devices.

Incontinence affects approximately 6.6% of the male population living at home<sup>1</sup>.

Management methods available include incontinence pads and catheters, both of which can prove problematic in their application, removal and side effects.

Internal catheters carry with them the difficulties of insertion, which can often not be achieved without aid. The insertion itself can also be painful and damage the urethra, causing further problems relating to infection.

Condom catheters, although no insertion is required, are nevertheless complicated to apply and remove. Many designs also leave open the possibility of back-flow of urine from the drainage bag, causing both irritation and increased chance of infection of the skin and urinary tract.

Both internal and external catheters also require the presence of a storage bag, and however discreet the manufacturers claim this bag to be, it can still be cumbersome and many people would be uncomfortable wearing one of these catheters in public. Any design of drainage bag is also susceptible to damage, and any puncture or weakening of the bag could cause a large spillage. A study into the experience of catheterisation found that almost a quarter of the patients surveyed felt wearing a drainage bag proved to be a major impact on their daily life.<sup>2</sup>

Incontinence pads, although the easiest product to use, are awkward to dispose of due to their size and leave the patient in constant contact with the urine, again causing irritation to the skin and consequently discomfort.

One of the main disadvantages of the incontinence products available today is the issue of disposal - either the drainage bag must be emptied or the pads thrown away. Whilst at home both of these methods are adequate (if a little awkward), in a public there is the problem of discreetly emptying an amount of urine into the toilet or throwing away large pads where there is possibly no bin.

There currently exists no incontinence device styled on a condom catheter but without the need for a drainage bag. This invention addresses the disadvantages of current products and provides patients with a discreet and effective way to manage their incontinence.

Furthermore, this invention proposes to be flushable and fully degradable, adding to its convenience and advantage over other, non-disposable product

The invention comprises an air-permeable degradable sheath (b) applied in the manner of a condom – no additional applicator is required as the method should already be familiar to most men. The permeability of the sheath (achieved through microscopic air inlets) allows the skin to ‘breathe’ and prevent sweat rash and discomfort from excess moisture. The materials used to construct the sheath will all be degradable. This will mean the sheath can simply be disposed of in a toilet rather than having to find a bin.

The end of the sheath is filled with absorbent cellulose fibres (or similar absorbent material) (c) impregnated with microcrystalline silver as an antibacterial, reducing the chances of infection of the skin and unpleasant odours forming. The device would also be available without the silver, in respect of those with sensitivities to this element. The cellulose (or similar) fibres may be similar to tampon material, of approximately 2cm depth. This would provide sufficient absorption for several hours’ wear without discomfort to the patient.

There will be a layer of permeable material between the absorbent pad and the end of the penis (f) to allow absorption of the urine into the wadding but, importantly, protect the skin from prolonged contact with the urine. There will be sufficient space inside the end of the sheath for the absorbent material to expand with the absorption of urine and not stretch or dislodge the adhesive. The material surrounding the absorbent pad will not include air inlets and will be completely impermeable (e).

The sheath is fixed in place using non-allergenic adhesive (a). The adhesive is backed with a strip of plastic and/or a non adherent material, which is removed on application of the sheath. The nature of the adhesive would have to be such that the sheath will remain in place on the penis despite movement, temperature and moisture, yet be easy to remove and suitable to dispose of in a toilet.

The sheath will be entirely collapsible and as such can be packaged in an approximately 2cm x 2cm container (made of either hard or soft material). This leaves the device easily portable and very discreet to carry.

The size and composition of this device means that it is entirely flushable and eventually degradable – much like tampons and other flushable sanitary products. The ease of disposal also lends itself to better hygiene as the sheath can be changed regularly (e.g. every 4-6 hours).

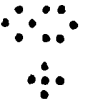
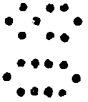
The specifications stated above are meant for illustrative purposes only, and should not be considered limiting. Various modifications, if viewed necessary, would be welcomed providing they do not stray from the original scope of the invention, for example the design of the sheath can be of a different size and shape with regard to comfort and or functional properties. Those skilled in the art may be in a position to provide suitable material suggestions, for example, and an efficient adhesive preparation. The product is limited by the claims below.

#### References:

1. Fraczyk, L, Godfrey, H and Feneley, R. (2003). A pilot study of users' experiences of urinary catheter drainage bags. *British Journal of Community Nursing* (8) 104 – 111.
2. Brocklehurst, JC. (1993). Urinary incontinence in the community – analysis of a MORI poll. *British Medical Journal* (306) 832 – 834.

Key to Drawings.

1. The adhesive lining (A) is folded backwards (away from the penis, when applied) and is backed with plastic and/or a non adherent material, which is removed on application of the sheath. The top of the sheath is then unfolded and effectively adhered to the penis.
2. Microscopic air inlets cover the surface of the degradable (e.g. degradable plastic) sheath (B). These allow the air/moisture to permeate the device and increase the comfort of the wearer. The air inlets cease where the sides of the device meet the material encasing the absorbent pad, which is impermeable.
3. The tip of the sheath (C) is filled with cellulose, or similar absorbent fibres, which will absorb approximately 4-6 hours of leaked urine. The absorbent material may/may not be impregnated with micro-crystalline silver depending on the sensitivity of the wearer.
4. Once the top of the sheath is folded into place (D) the adhesive should remain secure and comfortable for the wearer even despite temperature, moisture and movement.
5. The material surrounding the absorbent wadding (E) does not contain air-inlets, and is completely liquid impermeable.
6. A layer of permeable material protects the end of the penis from the absorbent pad (F), preventing prolonged contact between the skin and urine.



Claims.

1. A flushable male incontinence sheath comprising: absorbent cellulose (or similar absorbent material) padding embedded with/without antibacterial microcrystalline silver; a liquid permeable barrier to prevent prolonged exposure of the skin with urine but to allow the urine to be absorbed; an effective, non-allergenic adhesive device allowing for universal fitting and usage without an applicator; and microscopic holes allowing permeation of air to the skin, all discreetly packaged.
2. A flushable male incontinence sheath of Claim 1 wherein the absorbent component of the device may/may not be impregnated with microcrystalline silver, having anti-bacterial and –odour properties, depending on the sensitivity of the wearer.
3. A flushable male incontinence sheath of Claim 1, wherein a permeable lining separating said cellulose (or similar absorbent material) and the skin will allow leaked urine to be absorbed and simultaneously form a barrier between the damp material and the skin.
4. A flushable male incontinence sheath of Claim 1, comprising of a non-allergenic adhesive inner lining around the top section of the sheath to fold back and affix the device to the penis.
5. A flushable male incontinence sheath of Claim 4 wherein a non-adherent backing on the adhesive lining is removed on application of the sheath allowing for adhesion to the penis.
6. A flushable male incontinence sheath of Claim 1 consists of a material containing microscopic air inlets to allow air to permeate the length of the sheath and keep the penis in comfortable condition.
7. A flushable male incontinence sheath of Claim 6, wherein the said air-permeable material will also allow for stretch from both a larger penis and the increased volume of a saturated absorbent pad, leading to the universal fit of the device.
8. A flushable male incontinence sheath of Claim 7, wherein the air-permeable material covers the length of the sheath and a completely impermeable material surrounds the absorbent material at the base of the device.
9. A flushable male incontinence sheath of Claim 1 being entirely flushable and degradable alongside other sanitary products (e.g. tampons) due to the composition of the device and its components.
10. A flushable male incontinence sheath of Claim 1 being collapsible to an approximate 2cm x 2cm package, leaving the product discreet and portable.

**Application No:** GB0813892.7

**Examiner:** Hayley Yates

**Claims searched:** 1-10

**Date of search:** 26 November 2008

**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, 2, 4, 5, 9, 10	US 2006/0229576 A Conway et al; see figures 2-5 and 14
X	1, 2, 3, 6-10	US 2001/0031933 A Cannon; see paragraphs [0022 and 0023]
X	1, 2, 6, 7, 9, 10	US 4790835 A Elias; see figures and whole document
X	1, 2, 3, 6-10	US 5643235 A Figuerido; see figures and whole document
X	1, 2, 3, 6 and 10	GB 2016929 A Edet AB; see figures 1 -3 and whole document
X	1, 2, 3 and 10	FR 2822057 A Young; see figures and abstract translation

**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<sup>X</sup> :

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

A61F
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The following online and other databases have been used in the preparation of this search report

WPI & EPODOC
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**International Classification:**

<b>Subclass</b>	<b>Subgroup</b>	<b>Valid From</b>
A61F	0005/453	01/01/2006