FEMALE URINARY AID

An urinary aid able to be positioned by a female user to allow that female user to urinate with control, the device comprising a tube-like engagement head having a urine receivable end for engaging the mouth of the urethra and a urine discharge end, tube-like engagement head comprising a locator element, located at the urine receivable end of the engagement head that allows urine from the female to access the urine discharge end of the engagement head, the locator element extending substantially transverse to the walls of the tube-like engagement head to define (a) an inner locator element region that extends from about the wall of the tube-like engagement head towards the centre of the tube-like engagement head, and (b) an outer locator element region, that extends radially outwards from the wall of the tube-like engagement head, and a conformable material attached to, or formed unitarily with, the locator element, such that positioning of the locator element by the user against the urethral opening actuates the locator element to move into a substantially sealing configuration about the users urethral opening.
"FEMALE URINARY AID"

FIELD OF THE INVENTION

The present invention relates to a urinary aid for woman. More particularly but not exclusively it relates to a urinary aid that operatively fits within the folds of the labia minora.

BACKGROUND OF INVENTION

The use of public toilets can be an unwelcome experience for females, both in terms of hygiene and their requirement to squat over the toilet. Some contactable infections and venal diseases can be transmitted through contact with a toilet seat.

Additionally, urinating outside (i.e. when hiking, camping or travelling) can also be inconvenient.

Various urinary aids are known. For example, US patent application 20080262448 of Padmanabhan Mahalingam describes a device consisting of a cup that fits about the urethra for collecting urine, a shield, and an outlet tube. US patent application 20050097662 of Brett Leimkuhler describes a device having a funnel and a flexible tube, the funnel contoured to conform to the labia region. US patent 5,893,176 of Rainbow Medical describes a device that has two sealing rings, the interior ring comprising a circumferential wall that engages the exterior of the labia minor and an exterior ring that engages the exterior of the labia majora. US patent application 20090089919 of Cynthia Rudolph describes a biodegradable funnel-shaped female urination device.

Problems with such devices include

- a propensity to leak,
- uncomfortable to use,
- not convenient (in terms of carrying by a female), and
- not easily disposable.

In this specification, where reference has been made to external sources of information, including patent specifications and other documents, this is generally for the purpose of providing a context for discussing the features of the present invention. Unless stated otherwise, reference to such sources of information is not to be construed, in any jurisdiction, as an admission that such sources of information are prior art or form part of the common general knowledge in the art.
OBJECT OF THE INVENTION

It is an object of the present invention to provide an urinary aid for woman that overcomes or at least ameliorates some of the abovementioned disadvantages or which at least provides the public with a useful choice.

Other objects of the invention may become apparent from the following description which is given by way of example only.

SUMMARY OF THE INVENTION

Broadly stated, the invention relates to a tube-like device for sealing against a fluid opening, the device comprising a locator element that extends substantially transverse to the walls of the tube-like device, with an aperture therein to allow fluid flow, having (a) an inner region that extends from about the wall of the tube-like device head towards the centre of the tube-like device and (b) an outer region, that extends radially outwards from the wall of the tube-like device, such that positioning of the locator element by the user against a fluid opening actuates the locator element through deflection of the inner region away from the user and simultaneous deflection of the outer region towards the fluid opening to form a seal.

Another aspect of the invention relates to an urinary aid able to be positioned by a female user to allow that female user to urinate with control, the device comprising:

(A) a tube-like engagement head having a urine receivable end for engaging the mouth of the urethra and a urine discharge end, the tube-like engagement head comprising
   (i) a locator element, located at the urine receivable end of the engagement head that allows urine from the female to access the urine discharge end of the engagement head, the locator element extending substantially transverse to the walls of the tube-like engagement head to define (a) an inner locator element region that extends from about the wall of the tube-like engagement head towards the centre of the tube-like engagement head, and (b) an outer locator element region, that extends radially outwards from the wall of the tube-like engagement head, and
   (ii) a conformable material attached to, or formed unitarily with, the locator element,

such that positioning of the locator element by the user against the urethral opening actuates the locator element to move into a substantially sealing configuration about the users urethral opening.
In some embodiments the positioning of the locator element against the urethral opening by the user actuates the inner locator element such that the outer locator element moves towards a substantially urethral opening sealing configuration.

In some embodiments the inner locator element is deflected inward of the tube-like engagement head such that the outer locator element is simultaneously deflected or moved towards or about the urethral opening of the user or into a substantially sealing configuration.

In some embodiments, when in use, positioning of the locator element against the urethral opening causes the locator element to act as a fulcrum as the urethral opening pushes against the inner region causing the outer region to move towards the female user, resulting in a seal being formed between the user and the urinary aid.

Another aspect of the invention relates to an urinary aid able to be positioned by a female user to assist that female to urinate with control, the device comprising an engagement head that engages the urine receivable end of the ducting apparatus, wherein the engagement head includes an annular seal member about an entrance of the engagement head, which entrance can allow urine to the ducting apparatus, and wherein variation of the disposition of the ducting apparatus to at least part of the engagement head or to the annular seal, or both, can create a couple on the annular section thereby to vary conformation of the annular seal member to that female.

Another aspect of the invention relates to an urinary aid able to be positioned by a female user to assist that female to urinate with control, the device comprising a first annular seal located about the urine receivable end of the duct, the first annular seal adapted to seal against the urethra and be contained within the labia minora, a second annular seal located radially outwards of the first annular shield, the second annular shield adapted to seal against the user, and be contained within the labia minora.

The following embodiments may relate to any of the above aspects.

In some embodiments the urinary device is formed with a duct, or the duct is applied to the device just prior to use.

In some embodiments the ducting is attached to the urinary aid just prior to use.

Another aspect of the invention relates to a pack of urinary aids of the present invention, with or without the ducting.
In some embodiments the duct is a flexible hose. Preferably the duct includes an expanding concertina arrangement, or bellows that provide for its bendability.

In some embodiments the duct is telescopic.

In some embodiments the locator element is a contoured circular seal adapted to form a seal when pressed around the mouth of urethra opening.

In some embodiments the locator element self aligns to the mouth of the urethra to form the seal. Preferably the locator element is moveable to facilitate the sealing of the locator element to the mouth of the urethra.

In some embodiments the conformable material is present as a layer of soft absorbent material on at least part of the locator element. Preferably the conformable material is present on that part of the locator element that forms a seal against the user.

In an alternate embodiment the conformable material is present about the locator element.

In some embodiments the locator element and the conformable material are formed from a single material. Preferably the material for the conformable material remains soft while the material for the locator element is compressed so as to have an increased rigidity compared to the conformable material.

In an alternate embodiment the locator element and the conformable material are formed from two or more different materials, joined to each other by gluing, heat adhering, stitching, or any other method for attaching a soft and absorbable material to a more rigid material.

In some embodiment the seal between the user and the urinary aid is facilitated by hydration of one or both of the locator element or the conformable material.

In some embodiments the urinary device comprises one or more sealing rings radially outwards of the locator element.

In some embodiments the urinary device comprises an exterior shell. Preferably the shell is formed from a plastic or a rigid paperboard material. Preferably the shell is biodegradable.

In some embodiments the locator element and/or conformable material are coated or imbibed with a lubricant, an anti-bacterial or a perfume, scent or antifungal or a combination thereof.
In some embodiments at least part thereof of the urinary aid is biodegradable. Preferably the locator element is biodegradable. Preferably the locator element and the conformable material are both biodegradable. Preferably the locator element, the conformable material and the duct are all biodegradable. Preferably the conformable material is biodegradable. Preferably the conformable material and the duct are both biodegradable. More preferably the entire urinary device is biodegradable.

In some embodiments the locator element is formed, at least in part by, wood pulp, tissue, polyacrylate polymers, absorbing fabric, absorbing paper, gelatine, starch, cellulose, alginate or carageenan, or a combination thereof.

In some embodiments the absorbable material is formed, at least in part by, wood pulp, tissue, polyacrylate polymers, absorbing fabric, absorbing paper, gelatine, starch, cellulose, alginate or carageenan, or a combination thereof.

In some embodiments the duct comprises a one way valve. Preferably the valve opens in response to the collection of a small amount of urine. More preferably the valve only opens when about 0.1, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, or 50 ml of urine is accumulated.

In some embodiments the engagement head is 10, 15, 20, 25, 30, 35, 40, 45 and 50 millimetres in diameter. More preferably the engagement head is about 25 millimetres in diameter.

In some embodiments the urinary aid comprises an air excluder, aperture or inlet to allow air flow between the environment and the internal ducting of the urinary aid so that when in use (and the aid is sealed against the user) air can pass out/in of the device (without needing to pass through the distal opening of the duct) to avoid a vacuum forming.

In some embodiments the urinary aid 1 is positioned against the urethral opening and more preferably against the urethral meatus.

Another aspect of the invention relates to a method of making an urinary aid of the present invention comprising the steps (in no particular order) of:

forming the locator element, wherein the locator element is adapted to seal about the mouth of the urethra,

forming the absorbable material on or about the locator element,

attaching a duct to the locator element and absorbable material pair,
such that when in use the urine passes from the urethra past the locator element and into the duct.

In some embodiments the locator element is formed unitarily with the absorbable material. Preferably the locator element material is compressed to form it as a rigid material. More preferably the locator element and absorbable material are compression moulded, with the locator element material having greater compression (and thus increased density) compared to the absorbable material.

In an alternate embodiment the locator element and the absorbable material are formed from separate materials. Preferably the locator element and the absorbable material are bonded to each other. In one embodiment the locator element and the absorbable material are heat moulded together, the heat moulding bonding the two materials together.

In one embodiment the method of forming the urinary aid comprises the step of forming the device into a lie flat blank, wherein the lie flat blank can be inflated 01 pulled into its 3-dimensional operational state.

In one embodiment the urinary aid is packaged in a compressed condition. Preferably the compressed urinary aid is biased to form to its 3-dimensional condition.

Another aspect of the invention relates to a method of using an urinary aid comprising the steps of

1. obtaining an urinary aid that comprises
   (a) a duct having a urine receivable end and a urine discharging end,
   (b) a locator element, located at the urine receivable end of the duct that allows urine from the female to access the duct, that effectively extends substantially transverse to the duct to define (a) an inner locator element region that extends from about the wall of the duct towards the notional centre of the duct, and
   (b) an outer locator element region, that extends away radially outwards from the wall of the duct, and
   (c) a conformable and absorbable material ("conformable material") attached or formed unitarily with the locator element,

2. wherein the female user applies the device to the mouth of her urethra so that the locator element forms a seal substantially about the urethral mouth, such that the locator element is positioned within the confines of the labia minora.
In some embodiments the use of the device includes the step of pressing the urinary aid against the mouth of the urethra so that the conformable material, located about the locator element, pushes forward in a fulcrum motion so that the conformable material forms a seal against the female user. Preferably the seal is formed within the confines of the labia minora.

In one embodiment after use, the urinary aid is rotated slightly such that the conformable material can absorb any urine that has escaped the seal between the locator element and the user. This also aids as a wipe.

Another aspect of the invention relates to the use of an urinary aid of the present invention.

Another aspect of the invention relates to an urinary aid substantially described, with or without reference to any one or more of the accompanying drawings.

Other aspects of the invention may become apparent from the following description which is given by way of example only and with reference to the accompanying drawings.

As used herein the term "conformable" includes the ability to adopt a shape complementary to the object to which it is being applied.

As used herein the term "biodegradable" means that the material will decompose or break down when exposed to the environment. In some embodiments, the biodegradation occurs within two weeks, three weeks, one month, one, two, three, four, five, six, seven, eight, nine, ten, eleven or twelve months. More preferably, the biodegradation does not require any active steps on behalf of the user, the device fully breaking down when or after being disposed.

As used herein the term "and/or" means "and" or "or", or both.

As used herein "(s)" following a noun means the plural and/or singular forms of the noun.

The term "comprising" as used in this specification and claims means "consisting at least in part of. When interpreting statements in this specification and claims which include that term, the features, prefaced by that term in each statement, all need to be present but other features can also be present. Related terms such as "comprise" and "comprised" are to be interpreted in the same manner.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without
departing from the scope of the invention as defined in the appended claims. The disclosures and
the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

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

Figure 1 is a section view through AA of Figure 3C of an urinary aid of the present
invention having the locator element adapted to seal against the mouth of the urethra,

Figure 2 is a section view through AA of Figure 3C showing the fulcrum like movement of
the locator element of an urinary aid of Figure 1,

Figure 3A is a section view through AA of Figure 3C showing the locator element adapted
to seal against the mouth of the urethra,

Figure 3B is a section view through AA of Figure 3C showing the locator element adapted
to seal against the mouth of the urethra with a layer of conformable material that forms a layer
between the locator element and the female user,

Figure 3C is an end view of the locator element and conformable material of an
embodiment of the invention whereby the conformable material surrounds the locator element,

Figure 4 shows a side view of a duct,

Figure 5 shows a perspective view of an alternate embodiment of the invention, showing an
urinary device with multiple annular seals,

Figure 6 shows a cross-section view of an urinary aid of Figure 5 with the duct attached,

Figure 7 shows a cross-section view of an urinary aid of Figure 5 without the duct attached,

Figure 8A shows an end view of an urinary aid of Figure 5,

Figure 8B shows an end view of an urinary aid of Figure 5,

Figure 9 shows a cross-section view through BB of Figure 12B,

Figures 10A and 10B show a end and side view of an urinary aid of Figure 8,

Figure 11A shows a locator element of an urinary aid of Figure 8,

Figure 11B shows an end view of a locator element of Figure 8,

Figure 12 shows the use of an urinary device of Figure 1,

Figure 13 shows the use of an urinary device of Figure 9,

Figure 14 shows how an urinary aid of the present invention fits to the female anatomy,

Figure 15 shows urinary devices of the present invention in the form of a pen clip,

Figures 16 and 17 show how multiple urinary aids can be stored in an indexed manner when
present without the duct,
Figure 18 shows how urinary device of the present invention without the duct can be stored in a container, and

Figure 19 shows how urinary device of the present invention without the duct can be stored in a container for ease of use.

DETAIL DESCRIPTION OF THE INVENTION

The invention can broadly be stated to relate to a small portable urinary aid that can be held by a female against their urethral opening, to permit them to urinate with control. For example, such an urinary aid will allow the female to urinate while crouched, standing, sitting or leaning against a support.

The urinary aid comprises:

- an engagement head 2 formed of a locator element 3 and an conformable material attached or formed unitarily with the locator element 3,
- a duct 4 (that may be supplied with the urinary aid or supplied separately and attached to the urinary aid just prior to use), and
- optionally a shell 11.

The urinary device 1 is formed from an engagement head 2 that is attached to a duct 5 whereby the engagement head is placed against the mouth of the urethral opening to form a seal. Preferably there is located on or about the locator element 3 conformable material 4. The conformable material 4 can form a layer on top of the locator element 3 so that when placed against the female user it forms a soft layer between the user and the locator element 3. In addition, or alternatively, the conformable material 4 can be located radially outwards and around the locator element 3.

Preferably the conformable material 4 is of a lower density than the locator element 3. In these embodiments the locator element 3 is more rigid than the conformable material 4 and may also have a higher density. The conformable material 4 is preferably soft and absorbable so as to be comfortable for the user and to prevent seepage of any urine that escapes during use.

In some embodiments, the duct includes a one-way valve. The valve is preferably designed to open in response to the accumulation of a certain amount of urine. The purpose of such a valve is to prevent dribbles emanating from the urine discharge end of the duct which may mark the user's clothing. The valve collects that small amount of dribble and prevents it from dribbling out of the end of the duct. Preferably the valve only opens when about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13,
14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45 or 50 ml of urine is accumulated, and useful ranges may be selected between any of these values (these values for example, about 1 to about 50, about 1 to about 40, about 7 to about 47, about 12 to about 50, about 17 to about 24, about 21 to about 49, about 26 to about 43, about 31 to about 50, about 38 to about 46, about 41 to about 48).

When sealed against the user and the duct 5 having been filled with urine, a vacuum may form. In some embodiments, the urinary aid also comprises an air-excluder, aperture or inlet that allows air flow between the environment and the internal ducting of the urinary aid 1 so that when in use, and the aid is sealed against the user, air can pass in or out of the urinary aid, without needing to pass through the urine outlet end of the duct, to avoid a vacuum forming.

In one embodiment, the urinary aid is comprised of engagement head 2 that comprises at the urine receivable end 6 a number of concentric seals concentrically disposed from each other. Preferably the first seal is disposed concentrically around the urine receivable end 6 of the engaging head 2 and is adapted to fit conformably about the mouth of the urethral opening. As seen in Figure 5, a device may include multiple seals including an inner seal 13 and an outer seal 14. As further seen in Figure 5, the outer seal may be raised in relation to the inner seal.

In some embodiments the device may comprise multiple seals, each seal being disposed concentrically and radially outwards of the inner seal. Each seal helps reduce the potential for urine leakage to occur.

An advantage of the urinary aid 1 of the present invention is that it is of a very small size.

In some embodiments the size of the engagement head is 10, 15, 20, 25, 30, 35, 40, 45 and 50 millimetres, and useful ranges may be selected from any of these values (for example, about 1 to about 40, about 7 to about 47, about 12 to about 50, about 17 to about 24, about 21 to about 49, about 26 to about 43, about 28 to about 43, about 31 to about 50, about 35 to about 41, about 38 to about 46, about 41 to about 48).

Preferably the thickness of the engagement head is approximately 5, 10, 15, 20, 25, 30, 35, 40, 45 and 50 millimetres, and useful ranges may be selected between any of these values (for example, about 1 to about 40, about 7 to about 47, about 12 to about 50, about 17 to about 24, about 21 to about 49, about 26 to about 43, about 28 to about 43, about 31 to about 50, about 35 to about 41, about 38 to about 46, about 41 to about 48).
1. Engagement head

The engagement head 2 engages to the mouth of the urethral opening to form a seal. The engagement head 2 has an essentially tube-like arrangement to allow the passage the urine from the urine receivable end 6 to the urine discharge end 7 of the engagement head 2.

In some embodiments the engagement head 2 can be sold separately to a duct 5, the urinary aid 1 being capable of assembly by attaching the duct 5 to the urine dischargeable end 7 of the engagement head 2.

At the urine receivable end 6 of the engagement head 2 there is present a locator element 3 that extends transversally to the walls of the engagement head 2. The locator element 3 comprises an aperture to allow flow of urine through the engagement head 2 to the urine discharge end 7 of the engagement head 2.

The engagement head 2 also includes the conformable material 4, that can be formed either as a layer on top of the locater element 3 or formed radially about the locator element.

The engagement head 2 may also include a liquid impermeable shell 11.

2. Locator Element

Figure 1 shows an urinary aid 1 with the locator element 2 shown in greater detail in the cross-section in Figures 2 and 3. The locator element 3 helps to locate the urinary aid 1 to the mouth of the urethral opening to form a seal between the urinary aid 1 and the user.

A feature of the locator element 3 is its ability to "self align" to the mouth of the urethral opening which helps form a seal and prevent leakage of the urine. More preferably the locator element 3 of the urinal aid 1 aligns against the urethral meatus.

It should be appreciated that the locator element 3 and the conformable material 4 of the engagement head 2 may be manufactured as one piece, for example, through plastic moulding. Alternatively the locator element 3 and the conformable material 4 of the engagement head 2 could be formed as separate pieces which are then bonded to each other.

As seen in detail in the cross-section shown in Figures 2 and 3, the locator element 3 is positioned substantially transverse to the walls of locator element 3. The locator element 3 has an inner region 8 and an outer region 9. The inner region 8 of the locator element 3 is located radially
inwards of the walls of the engagement head 2 and the outer region 9 of locator element 3 is located radially outwards of the walls of the engagement head 2.

The operation of the locator element 3 is shown in Figure 2 by the arrows. Force applied to the inner region 8 of the locator element 3 causes the inner region 8 to be deflected inwardly to the engagement head 2 causing a simultaneous deflection of the outer region 9 of the locator element 3 towards the user. This actuation of the locator element 3 is similar to a fulcrum action with the axis of rotation being about where the wall of the engagement head 2 meets the locator element 3.

As mentioned above, in some embodiments the locator element 3 is a rigid material, as a too soft material would merely deflect without leading to a simultaneous deflection of the outer region 9.

In some embodiments the locator element 3 locates solely on the mouth of the urethral opening. The mouth of the urethra is surrounded by a raised circular portion (like the mouth of a volcano). The vaginal opening is located below the urethral opening and both openings are surrounded by the labia minora. The whole region is surrounded by the labia majora. The urinary device 1, when in use, is centred upon the mouth of the urethra opening and the raised surrounding portion of the urethra and placed such that the engagement head 2 lies within the folds of the labia minora.

One advantage of the locator element is that it helps locate the device onto the mouth of the urethral opening.

The locator element may have a projection 10 as seen in Figures 9 and 10. The projection 10 inserts into the urethra, the projection 10 having smooth round edges and is small enough to centre on the urethral opening. For example, the projection 10 may be a bulging elliptical section or a cylindrical tube. Typically the entry is only a few millimetres into the mouth of the urethra, thus causes minimal or no discomfort to the user.

As described above, in other embodiments the locator element is a soft seal that presses around the mouth of the urethra avoiding the need to insert it into the urethral opening.

3. Conformable material

The engagement head 2 includes conformable material 4, for enhancing the comfort of the device in use and helping prevent leakage of any urine.

In some embodiments the conformable material 4 is compressible. Preferably the conformable material is also absorbable.
In some embodiments the conformable material 4 is made of a fibrous material such as used in nappies. It should be appreciated that other material could be used such as wood pulp (that is highly absorbent), polyacrylate polymers (a highly absorbent material in powdered form) that may be packed inside a layer of wood pulp an absorbing fabric, an absorbing paper, gelatin, starch, cellulose, alginate or carageenan, or a combination thereof.

As seen in Figures 1 and 2 the conformable material 4 may be formed radially outwards of the locator element 3 so that when in use, the conformable material 4 is displaced forwards and forms a seal against the user.

As further shown in Figures 1 and 2 the conformable material 4 can be manufactured to surround the entirety of the engagement head 2.

In some embodiments the locator element 3 and conformable material 4 are formed from two different materials, the locator element 3 being formed from a material with a higher rigidity than the conformable material 4. In some embodiments, or additionally, the conformable material 4 has bonded to the locator element 3. This bonding can be in the form of gluing, heat compression, or any other method known in the art.

As shown in Figure 3B the conformable material 4 may be formed as a layer on top of the locator element 3. In such embodiments, when the engagement head 2 is placed against the urethral opening the conformable material 4 is pressed against the user. The locator element 3 still actuates since the mouth of the urethral opening presses against the inner region 8 of the locator element 3 pushing the outer region 9 of the locator element 3 against the user.

The conformable material may be formed as a layer along the outer region of the locator element 3. In this form the locator element will position against the urethral opening and the conformable material 4 will also form a seal adjacent the locator element 3.

In some embodiments the locator element 3 and the conformable material 4 are formed from a single material. For example, the locator element 3 and the conformable material 4 may be formed from a plastic such as polystyrene or polyurethane. The increased rigidity of the locator element 3 compared to the conformable material 4 can be provided for through differential compression of the locator element 3 and the conformable material. For example, to obtain a locator element 3 that has a higher rigidity than the conformable material 4 the material that is to form the locator element 3 can be subjected to a higher compression than the material that is to
form the conformable material 4. Such manufacturing will result in a locator element 3 having a greater density and rigidity in comparison to the conformable material 4.

In some embodiments the surface of the locator element 3, conformable material 4 or the entire engagement head 2 is coated or imbibed with an antibacterial or antiseptic film for hygiene and comfort. It should be appreciated that other additives such as scent could be coated to or imbibed into the locator element 3, and/or the conformable material 4 of the engagement head 2.

4. Shell

In some embodiments the urinary aid 1 comprises a shell 11 that encapsulates the lower portion of the engagement head 2. The function of the shell 11 is to hold and contain the engagement head 2 (that comprises the locator element 3 and the conformable material 4). Preferably the shell 11 is impervious to liquid and thus provides an impenetrable membrane that liquid cannot pass through. This will prevent any leakage of urine outside of the urinary aid 1.

It should be appreciated that the shape of the shell 11 conforms to the engagement head 2 of the urinary aid 1. For example, in those embodiments where the conformable material 4 is located about the locator element 3 the shell 11 will be formed about the conformable material 4.

In those embodiments where the conformable material 4 is formed as a layer on top of the locator element 3 then the shell 11 may form a layer about the engagement head 2 up to the edge of the locator element 3.

The shell 11 can be formed from any impermeable material such as a plastic or coated fibreboard. For example, some fibreboard has a coating that makes it impervious and/or less impervious to liquid. In some instances this may be a plastic coating.

5. Duct

The urinary aid 1 comprises a duct 5 that attaches to, or within, the urine discharge end 7 of the engagement head 2.

The purpose of the duct 5 is to direct urine away from the engagement head 2.

It should be appreciated that the length of the duct 5 can be at any length and can include any number of the different modifications such as a flexible bellow 12 (as seen in Figure 4) or it could be formed telescopically. The advantage of a telescopic duct is that it makes the urinary aid 1 more compact.
In some embodiments the engagement head 2 and the duct 5 could be sold separately or assembled separately. For example, prior to use a female user may insert the duct 5 into the urine discharge end 7 of the engagement head 2 to complete the assembly of the urinary aid 1. At this point the urinary aid 1 is ready for use.

In other embodiments, owing to the compact size of the engagement head 2 it could form part of a panty or a device that is worn by a female, so that when the female wishes to urinate they merely need to either lower their zip or undo their buttons of the pants and insert the duct 5 into the urine receiving end 6 into the engagement head 2.

In some embodiments the duct 5 may be connected to the engagement head 2, but stored in a compact arrangement.

The length of the duct 5 may be straight or curved or made of flexible or stiff material.

In some embodiments the tube has an expanding concertina arrangement that allows the tube to be bent so as to direct the urine flow.

In some embodiments the tube comprises a number of valves that assists in the collection of particular amounts of urine. For example, the urinary aid 1 could be used to sample urine. The use of multiple valves could assist in this by collecting the initial urine flow, which is the disposed of, so as to sample the mid-stream urine flow for analysis. A number of different valves could be used that are responsive to a collection of a certain amount of urine or that can be manually opening or closed or are of a squeezable valve sort, squeezing of the valve cause deformation of the valve allowing urine to flow through.

The tube may also incorporate bellows or a pump. The pump or bellows could be useful for developing a positive pressure to suck liquid from the liquid-expelling opening.

6. Use of an urinary aid

As stated above, prior to use the device the urinary aid 1 can either be formed as a complete device or can be assembled prior to use.

For use, the female user parts the lips of her labia minora applying the locater element 3 against the mouth of the urethral opening. In those embodiments where the conformable material 4 is formed as a layer on the locater element 3 it will be the conformable material 4 that actually engages to the user.
Alternatively, in some embodiments the conformable material 4 forms a layer merely over the outer region 9 of the locator element 3. In such an arrangement, the locator element 3 will contact the mouth of the urethral opening and be displaced inwards thereby causing a corresponding outward displacement of the outer region 9 of the locator element 3 bringing the conformable material 4 that is present as a layer over the outer region 9 of the locator element 3 against the user to form a seal.

In a further embodiment the conformable material 3 may both be formed (1) on the locator element 3 and (2) radially about the locator element 3.

Shown in Figure 12 is an example of an urinary aid 1 wherein the urinary aid 1 comprises an engagement head 2 with the conformable material 4 located radially about the locator element 3.

It is seen in Figure 12 that upon engagement of the locator element 3 with the mouth of the urethral opening the outer region of the locator element 3 is displaced forwards causing a seal to be formed by the conformable material 4 against the user. Therefore, should any urine escape between the seal formed between the locator element 3 and the mouth of the urethral opening, the urine will be caught by the conformable material 4 which will prevent leakage.

Once the female user begins to urinate, the urine flows through the engagement head 2 and into the duct 5.

It should be appreciated that as females may have different anatomy the urinary aid can be manufactured in variety of sizes to suit. It should also be appreciated that the locator elements 3 seen in Figures 12 and 13 would not normally be visible, except with a tube, as it would be covered by the folds of the labia minora.

In those embodiments comprising a projection 10 as seen in Figure 13, the projection is inserted into the urethral opening and the seal is formed about the projection.

7. Portability

An advantage of the urinary aid 1 of the present invention is its small size and thus greater portability. As shown in Figure 16 and 17 are examples of how an urinary aid 1 could be index stacked for ease of portability. Such index stacking could also be used in a dispenser unit that may be present in a urinal.

In some embodiments the index stacking of the urinary aid 1 could be in a device as shown in Figure 15. Figure 15 shows a cylindrical pen-type carrying arrangement that can be clipped to the
top of a trouser pocket or carried in a purse or handbag or other such thing. The outer body is a cylindrical body that can house the duct. The upper part of the cylindrical pen-type arrangement shown in Figure 15 may include a top cover that is removed from prior to use. The pressure of the pen may be used to push a carriage passed through a raised ridge to bring the engagement head 2 to the top of the cylindrical pen.

The stack arrangement of the engagement head 2 could be used with a tube arrangement as shown in Figure 18. Here the ducts 5 are arranged radially which can be used with the pen like arrangement to prepare an urinary aid 1.

For example, pushing down on a portion on the top of a pen (i.e. a ring) can engage an engagement head 2 through the insertion of a duct 5 within to the engagement head 2. The assembled urinary aid 1 can then be removed from the pen like device and utilised. The urinary aid 1 can then be thrown away. Second and subsequent urinary aids can be prepared in the same manner through pushing down on the ring that engages each subsequent engagement head 2 with a duct 5.

As seen in Figure 19 is a pack that could be used to transport a number of engagement heads and/or tubes 5. The engagement heads can be mated with a duct at a later point prior to use.

8. **Method of manufacture**

Another aspect of the invention relates to a method of making an urinary **aid** of the present invention comprising the steps (in no particular order) of:

- forming die locator element, wherein the locator element is adapted to seal about the mouth of the urethra,
- forming the absorbable material on or about the locator element,
- attaching a duct to the locator element and absorbable material pair,
- such that when in use the urine passes from the urethra past the locator element and into the duct.

In some embodiments the locator element is formed unitarily with the absorbable material. Preferably the locator element material is compressed to form it as a rigid material. More preferably the locator element and absorbable material are compression moulded, with the locator element material having greater compression (and thus increased density) compared to the absorbable material.
In an alternate embodiment the locator element and the absorbable material are formed from separate materials. Preferable the locator element and the absorbable material are bonded to each other. In one embodiment the locator element and the absorbable material are heat moulded together, the heat moulding bonding the two materials together.

In some embodiments, the urinary aid 1 is formed as an expandable blank that can be expanded to the use condition through inflation or expansion of the lie-flat blank. The advantage of such a lie-flat blank is that it will be easy to store and transport. For example, the engagement head 2 that defines the locater element 3 and the conformable material 4 may be made from material that is compressible. This compressible material would have a memory so that when flattened and released from that flattened state, to which it is biased, it will form the three-dimensional state that is the condition for use. The duct may yet form part of the device or be inserted into the bias following its transition from the flat state to the fully 3-dimensional in use state.

In one embodiment the urinary aid 1 is packaged in a compressed condition. Preferable the compressed urinary aid is biased to reform to its 3-dimensional condition.

It should be appreciated that may different methods could be used to manufacture the device the urinary aid 1 of the present invention. Such methods may use compression moulding or heat moulding if the conformable material 4 and the locater element 3 of the engagement head 2 are formed from either the same material or differing materials.

9. Biodegradability

In some embodiments, part or all of the urinary aid 1 is biodegradable. For example, in some embodiments the engagement head 3 is biodegradable. In alternate embodiments, the engagement head 2 and the duct 5 are both biodegradable.

In alternate embodiments, the conformable material 4 may be biodegradable as may also be the duct 5 or the locater element 3 or the shell 11.

In some embodiments at least part thereof of the urinary aid 1 is biodegradable. Preferably the locater element 3 is biodegradable. Preferably the locater element 3 and the conformable material 4 are both biodegradable. Preferably the locater element 3, the conformable material 4 and the duct 5 are all biodegradable. Preferably the conformable material 4 is biodegradable. Preferably the conformable material 4 and the duct 5 are both biodegradable. More preferably the entire urinary device 1 is biodegradable.
In summary, some features of the urinary aid 1 of the present invention include:

- The entire urinary aid 1 is placed within the folds of labia minora, and seals against the raised circular portion of the urethra opening. Therefore, the urinary aid 1 does not need to take its location from any other feature of the females anatomy, such as the clitoris or vagina. Nor does the urinary aid 1 cover any part of a female's anatomy outside the folds or lips of the labia minora.

- The urinary aid 1 uses a conformable material 4, that preferably is absorbent, that forms a seal around the urethra opening as it compresses to the shape of an individual's anatomy. This removes any need to press a cup shape item over the urethra opening using a shield or a covering.

- The urinary aid 1 uses a locator element 3 that locates over the raised portion surrounding the urethra opening. The locator element 3 is moveable allowing it to "self-align" with the urethral opening, helping to form a seal.

- As the urinary aid 1 does not allow leakage of urine, it substantially reduces the risk of infections incurring in the vaginal passage from cross-contamination with urine.

- The urinary aid 1 can be disposed off after a single use.

- The urinary aid 1 covers only the region around the urethra opening, resulting in a small compact size. For example, in one embodiment the overall size is about 20 mm in diameter and about 60 mm in length. This makes it very portable and discreet.

EXAMPLE

The urinary aid 1 of this example is compact and portable. It enables women to urinate like a male. The urinary aid 1 is held against the female's urethra opening, within the folds of labia minora, without covering the vaginal passage opening or the pubic area. The urinary aid is made available in standard sizes, without the need to be personalised.

The urinary aid consists of a locator element 3 that locates the urinary aid 1 to the urethral opening to direct the flow of urine away from the urethral opening with minimal or no leakage to the surrounding area. Two types of urinary aids are available. The first urinary aid is a modified nozzle that forms a contoured face circular seal when pressed around the mouth of urethra. The forward end sits away from the urethra and has a circular opening of comparatively generous section through which the urine flows. The second aid has a smooth rounded edge hollow nozzle that is
small enough to be inserted into the urethral opening. The forward end sits away from the urethra and has a circular opening of comparatively generous section through which the urine flows.

The urinary aid also includes an absorbing seal element that is made of a highly absorbent material. This absorbing seal element is about 5 mm in thickness and forms a tight surface contact seal with the wall of labia minora so as to absorb any leakage that may escape past the locator element. The locator element, whether the smooth rounded edge nozzle or the profiled circular seal, has a circular passage that is in line with the axis of the locator element that is coated to make it liquid resistant. This ensures the urine cannot leak to the surrounding regions. The outer edge of the contoured face has a profile to suit the region surrounding the urethra opening within the labia minora. This is a bottom semicircular with a triangular top with a rounded apex to suit the triangular region of a female's anatomy within the labia minora around the urethra opening.

The part of the urinary aid that does not come into contact with the urethra is covered by a thin plastic part referred to as the shell element. The shell element is shaped to cover the surface of the absorbing seal element. The shell element has a hollow saucer-like shape, or cylindrical shallow dish-like shape, with the hollow portion facing the urethra. The shell element closely conforms to the shape of the absorbing seal element, with a circular opening located at the end opposite to the urethra through which a thin wall tube ("tube element") is inserted.

The tube element is inserted in the absorbent seal element to direct the urine away from the user and is made of thin plastic material, or material that is coated to make the passage temporary impervious to urine. The tube may be straight or curved, with slight flexibility to direct the flow, or with a bellow-type portion that permits bending of the tube up to about 45 degrees.

Urinary aids are produced with locator elements, absorbing seal elements, shell elements and tube elements of particular sizes and profiles to account for the varying sizes and shapes of women anatomy in the urethra region. The urinary aid is also made of particular material (biologically degradable or recyclable), and with particular surface coatings to account for personal preferences regarding hygiene and comfort.

In one type of urinary aid the locator element is a smooth rounded edge short nozzle made of plastic material. For example, polycarbonate, medical grade thermo-sensitive PVC material that is a non-irritant to the delicate mucous membranes of the urethra, LDPE or plastic material that is elastic and easy to mould in thin sections, or coated paper/fabric. This type of locator element has an inserting end that is small enough to be inserted into the urethra, a slightly bulging section along
the axis in the middle of the nozzle that may be circular or elliptical so as to make good contact with
the walls of urethra, yet is of thin elastic section so as not to cause discomfort to the user.

Attached is a washer like rigid ring that snugly fits into a groove in the absorbing seal
element that permits small movements to facilitate alignment with the urethra passage. It is
generally of circular section having a comparatively larger sectional area to permit easy flow of urine.

For the locator element of a type that is inserted into the urethra, it is coated with a fine
filament of lubricant to ease insertion. The lubricant is like a moisturizing body lotion an includes
an anti-bacterial and perfume.

For the locator element of a type that forms a contoured face circular seal when pressed
around the mouth of the urethra opening, it is connected to a washer like rigid-ring. This
connection is by way of a circular passage, that is a thin tube like structure. The washer-like rigid
ring fits into a groove in the absorbing seal element to permit small movements of the contoured
circular face seal so that it can self align with the mouth of the urethra and also permit the flow of
urine. The contoured face of the circular seal is a concave inner annular ring and convex outer
annular ring, for example, somewhat like a saucer with a central hole, blended to form an effective
seal with the region around urethra opening. The contoured face circular seal connected by the
thin tube to the rigid ring is moulded in one piece.

In another form the contoured face circular seal is formed by having a raised annular
projection on the face of the absorbing seal element to form an effective seal with the region around
urethra opening. It has a central circular passage in the absorbing seal element that is coated to
make the passage temporary impervious to urine.

The absorbing seal element is made of highly absorbent material such as wood pulp, or
contain polyacrylate polymers (an absorbent material in powder form packed inside layer of wood
pulp), and/ or absorbing fabric/paper and may be coated with an anti-bacterial/ antiseptic film to
provide hygiene and comfort.

The shell element is formed by moulding from plastic material or chemically treated
compressed fabric/paper. Another form of the shell is produced by coating the surface of the
absorbing seal insert element, that is not in contact with the labia minora region, with a plastic film
or lacquer or chemical treatment to form a fairly firm, impervious liquid resistant surface.
The urinary device can be assembled as one piece or in two or more sub assemblies. The subparts can easily be assembled with each other by mere insertion into one another. Such an arrangement facilitates the use of an "easy-carry" and discreet urinary aid such as, for example, a thick clip-on pen, or a compact box. These can be carried in a purse or kept in a pouch of the undergarments to provide for a female's urinary requirements for a day or so.

Where in the foregoing description reference has been made to elements or integers having known equivalents, then such equivalents are included as if they were individually set forth.

Although the invention has been described by way of example and with reference to particular embodiments, it is to be understood that modifications and/or improvements may be made without departing from the scope or spirit of the invention.
WE CLAIM

1. An urinary aid able to be positioned by a female user to allow that female user to urinate with control, the device comprising:
   (i) a tube-like engagement head having a urine receivable end for engaging the mouth of the urethra and a urine discharge end, tube-like engagement head comprising
      (a) a locator element, located at the urine receivable end of the engagement head that allows urine from the female to access the urine discharge end of the engagement head, the locator element extending substantially transverse to the walls of the tube-like engagement head to define (a) an inner locator element region that extends from about the wall of the tube-like engagement head towards the centre of the tube-like engagement head, and (b) an outer locator element region, that extends radially outwards from the wall of the tube-like engagement head, and
   (b) a conformance material attached to, or formed unitarily with, the locator element,
      such that positioning of the locator element by the user against the urethral opening actuates the locator element to move into a substantially sealing configuration about the users urethral opening.

2. An urinary aid of claim 1 comprising a duct, wherein the duct is formed with the urinary device, or attached prior to use.

3. An urinary aid of claim 1 or 2 wherein positioning the locator element against the urethral opening by the user actuates the inner locator element such that the outer locator element moves towards a substantially urethral opening sealing configuration.

4. An urinary aid of any one of claims 1 to 3 wherein the inner locator element is deflected inward of the tube-like engagement head such that the outer locator element is simultaneously deflected or moved towards or about the urethral opening of the user or into a substantially sealing configuration.

5. An urinary aid of any one of claims 1 to 4 wherein, in use, positioning of the locator element against the urethral opening causes the locator element to act as a fulcrum as the urethral opening pushes against the central locator element region causing the proximal locator element region to move towards the female user, resulting in a seal being formed between the user and the urinary aid.
6. An urinary aid of any one of claims 1 to 5 wherein the locator element is a contoured circular seal adapted to form a seal when pressed around the mouth of urethra opening.

7. An urinary aid of any one of claims 1 to 6 wherein the locator element self aligns to the mouth of the urethra to form the seal.

8. An urinary aid of claim 7 wherein the locator element is moveable to facilitate the sealing of the locator element to the mouth of the urethra.

9. An urinary aid of any one of claims 1 to 8 wherein the conformable material is present as a layer of soft absorbent material on at least part of the locator element.

10. An urinary aid of claim 9 wherein the conformable material is present on that part of the locator element that forms a seal against the user.

11. An urinary aid of any one of claims 1 to 8 wherein the conformable material is present about the locator element.

12. An urinary aid of any one of claims 1 to 11 wherein the locater element material has a greater density and rigidity than the conformable material.

13. An urinary aid of any one of claims 1 to 12 wherein the locator element and the conformable material are formed from a single material.

14. An urinary aid of any one of claims 1 to 12 wherein the locator element and the conformable material are formed from different materials.

15. An urinary aid of any one of claims 1 to 14 wherein the urinary aid comprises one or more sealing rings exterior to said locator element.

16. An urinary aid of any one of claims 1 to 15 wherein the seal between the user and the urinary aid is facilitated by hydration of one or both of the locator element or the conformable material.

17. An urinary aid of any one of claims 1 to 16 wherein at least part of the urinary aid is biodegradable.

18. An urinary aid of any one of claims 1 to 16 wherein the locator element is biodegradable.

19. An urinary aid of any one of claims 1 to 16 wherein the locator element and the conformable material are both biodegradable.
20. An urinary aid of any one of claims 1 to 16 wherein the locator element, the conformable material and the duct are all biodegradable.

21. An urinary aid of any one of claims 1 to 16 wherein the conformable material is biodegradable.

22. An urinary aid of any one of claims 1 to 16 wherein the conformable material and the duct are both biodegradable.

23. An urinary aid of any one of claims 1 to 16 wherein the entire urinary device is biodegradable.

24. An urinary aid of any one of claims 1 to 23 wherein the locator element and/or conformable material are coated or imbibed with a lubricant, an anti-bacterial or a perfume, or a combination thereof.

25. An urinary aid of any one of claims 1 to 24 wherein the locator element is formed, at least in part by, wood pulp, tissue, polyacrylate polymers, absorbing fabric, absorbing paper, gelatine, starch, cellulose, alginate or carageenan.

26. An urinary aid of any one of claims 1 to 25 wherein the absorbable material is formed, at least in part by, wood pulp, tissue, polyacrylate polymers, absorbing fabric, absorbing paper, gelatine, starch, cellulose, alginate or carageenan.

27. An urinary aid able to be positioned by a female user to assist that female to urinate with control, the device comprising or including
   a duct (formed with the device or applied prior to use) to proximately receive urine and to distally discharge urine,
   a first annular seal located about the proximal inlet of the duct, the first annular seal adapted to seal against the urethra and be contained within the labia minora,
   a second annular seal located exterior to the first annular shield, the second annular shield adapted to seal against the user, and be contained within the labia minora.

28. An urinary aid of claim 26 wherein the seal between the first annular seal or the second annular seal and the user is facilitated by hydration.

29. An urinary aid of either claim 26 or 27 wherein the first annular seal has increased rigidity and density compared to the second annular seal.
30. An urinary aid of any one of claims 27 to 29 wherein the second annular seal is raised in relation to the first annular seal

31. An urinary aid of any one of claims 27 to 30 wherein the urinary aid is biodegradable.

32. An urinary aid of any one of claims 27 to 31 wherein urinary aid is coated or imbibed with a lubricant, an anti-bacterial or a perfume, or a combination thereof.

33. An urinary aid of any one of claims 27 to 32 wherein the annular seals are formed, at least in part by, wood pulp, tissue, polyacrylate polymers, absorbing fabric, absorbing paper, gelatine, starch, cellulose, alginate or carageenan.

34. An urinary aid of any one of claims 1 to 33 wherein the urinary aid comprises a shell.

35. An urinary aid of any one of claims 1 to 34 wherein the duct comprises a one way valve.

36. An urinary aid of claim 35 wherein the valve only opens when about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, or 50 ml of urine is collected.

37. An urinary aid of any one of claims 1 to 36 comprising an air excluder, aperture or inlet separate to the duct inlet or outlet.

38. An urinary aid of any one of claims 1 to 37 wherein the duct is a flexible hose.

39. An urinary aid of any one of claims 1 to 38 wherein the duct is telescopic.

40. A **method of making an** urinary **aid** of the present invention comprising the steps (in no particular order) of:

   forming the locator element, wherein the locator element is a fulcrum and is adapted to seal about the mouth of the urethra,

   forming the absorbable material on or about the locator element,

   attaching a duct to the locator element and absorbable material pair,

   such that when in use the urine passes from the urethra past the locator element and into the duct.

41. A method of claim 40 wherein the locator element is formed unitarily with the absorbable material.
42. A method of claim 40 or 41 wherein the locator element and/or absorbable material are compression moulded.

43. A method of any one of claims 40 to 42 wherein the locator element has a density and rigidity greater than that of the absorbable material.

44. A method of claim 43 wherein the locator element and the absorbable material are formed from separate materials.

45. A method of claim 44 wherein the locator element and the absorbable material are bonded to each other.

46. A method of claim 44 or 45 wherein the locator element and the absorbable material are heat moulded together, the heat moulding bonding the two materials together.

47. A method of any one of claims 40 or 46 wherein the urinary aid comprises the step of forming the device into a lie flat blank, wherein the lie flat blank can be inflated or pulled into its 3-dimensional operational state.


49. The use of an urinary aid comprising the steps of

(i) obtaining an urinary aid that comprises

(a) a duct to proximately receive urine and to distally discharge urine,

(b) a locator element, located at die proximal inlet end region of the duct that allows urine from the female to access the duct, that effectively extends substantially transverse to the duct to define

(a) a central locator element region that extends from about the wall of the duct towards the notional centre of the duct, and

(b) a proximal locator element region, that extends away from the wall of the duct,

(c) a conformable and absorbable material ("conformable material") attached or formed unitarily with the locator element,

(ii) wherein the female user applies the device to the mouth of her urethra so that the locator element forms a seal substantially about the urethral mouth, such that the locator element is positioned within the confines of the labia minora.

50. The use of an urinary aid of claim 49 including the step whereby the female user presses the urinary aid against the mouth of the urethra so that the conformable material, located about the
locator element, pushes forward in a fulcrum motion so that the conformable material forms a seal against the female user.

51. The use of an urinary aid of claim 49 or 50 wherein the seal is formed within the confounds of the labia minora.

52. The use of an urinary aid of any one of claims 1 to 39.

53. A pack of urinary aids of any one or more of claims 1 to 39, without or without the duct.

54. An urinary aid substantially as described herein, with ot without reference to any one or more of the accompanying drawings.
**INTERNATIONAL SEARCH REPORT**

A. **CLASSIFICATION OF SUBJECT MATTER**

   Int. Cl.
   A61F 5/455(2006.01)

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)

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 practicable, search terms used)

   EPDOC, WPI: IPC and ECLA 'A61F 5/' and keywords: urinary, female, aid, seal, plug, duct, conduit, hose, locator, align, retain, dock, deflect, resilient, annular, concentric, portable; and similar terms

C. **DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
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<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<td>X</td>
<td>U S 4690677 A (ERB) 1 September 1987 See figures 2, 2a, 3, 3a; column 4, line 24-column 5, line 18; column 6, line 32-column 7, line 2; column 7, lines 22-25</td>
<td>1-3, 6-26, 34, 36, 37, 39-53</td>
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<td>Y</td>
<td>See figures 2, 2a, 3, 3a; column 4, line 24-column 5, line 18; column 6, line 32-column 7, line 2; column 7, lines 22-25</td>
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<td>X</td>
<td>K R 2001-0091 188 A (LEE) 23 October 2001 See figures 1-3</td>
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<td>X</td>
<td>U S 6123691 A (KARAVANI et al.) 26 September 2000 Column 3, line 30-column 4, line 35; figures 1-3</td>
<td>27-33 and 38</td>
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</table>

[X] Further documents are listed in the continuation of Box C  [X] See patent family annex

- \* Special categories of cited documents:
  - "A" document defining the general state of the art which is not considered to be of particular relevance
  - "E" earlier application or patent but published on or after the international filing date
  - "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  - "O" document referring to an oral disclosure, use, exhibition or other means
  - "P" document published prior to the international filing date but later than the priority date claimed
  - "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  - "X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
  - "Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
  - "&" document member of the same patent family

Date of the actual completion of the international search: 7 December 2009

Date of mailing of the international search report: 10 DEC 2009

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<td>US 2001/0041882 A1 (BRINK) 15 November 2001</td>
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<td>Figures 1-5; paragraphs [0014], [0017], [0018], [0020]</td>
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<td>US 6716181 B2 (SPENCER et al.) 6 April 2004</td>
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<td>Column 2, line 67-column 3, line 10</td>
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<td>Y</td>
<td>US 5755236 A (DANN et al.) 26 May 1998</td>
<td>4, 5</td>
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<td>P, X</td>
<td>NZ 571020 B (KHAMBATTA) 26 September 2008</td>
<td>1-53</td>
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**INTERNATIONAL SEARCH REPORT**

**Box No. II**  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [ ] Claims Nos.:
   because they relate to subject matter not required to be searched by this Authority, namely:

2. [X] Claim No.: 54
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
   Claim 54 does not comply with PCT Rule 6.2(a) because it relies on references to the description and drawings.

3. [ ] Claims Nos.:
   because they are dependent claims and are hot drafted in accordance with the second and third sentences of Rule 6.4(a)

**Box No. III**  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

<table>
<thead>
<tr>
<th>Invention</th>
<th>Claims</th>
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<tbody>
<tr>
<td>1:</td>
<td>1-26 and 34-53</td>
</tr>
<tr>
<td>2:</td>
<td>27-33</td>
</tr>
</tbody>
</table>

See Supplemental Box for full reasoning.

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [X] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.
INTERNATIONAL SEARCH REPORT

Supplemental Box
(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-26 and 34-53. These claims define a urinary aid to be positioned by a female user to allow the user to urinate with control and a method of making a urinary aid. The claims are directed to solving the problem of leakage of urine when using a urinary aid by a female user. It is considered that the provision of a locator element wherein the locator element comprises an inner locator element and an outer locator element (such that the outer locator element deflects in response to deflection of the inner locator element) which together function to provide an effect sealing configuration about the user's urethral opening comprises a first distinguishing feature.

- Claims 27-33. These claims define a urinary aid to be positioned by a female user to allow the user to urinate with control. The claims are directed to solving the problem of leakage of urine when using a urinary aid by a female user. It is considered that the provision of a first annular seal and a second annular seal which together function to provide an effect sealing configuration about the user's urethral opening comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention a priori.

The International Searching Authority believes that a search and examination for the second invention will not involve more than negligible additional search and examination effort over that for the first invention and no additional search fee is required in order to search and examine that invention.
This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX