A flexible urine collection device for use with both male and female patients, and methods of use, are disclosed.
NON-INVASIVE URINE COLLECTION DEVICE

BACKGROUND

[0001] In-dwelling catheters are often used to control urine disposal for people who cannot easily get out of bed (e.g., bed-bound hospital patients). However, such catheters are invasive, can be painful, and can cause urinary tract infections and bladder infections. Thus, the use of in-dwelling catheters with people who cannot easily get out of bed (or their wheelchair) but who are cognitively aware enough to otherwise manage their personal waste elimination, can lead to undue medical and comfort issues. Alternatives to in-dwelling catheters include condom catheters, and hard plastic urinals or bed pans, which can be difficult to manipulate and are prone to spillage.

SUMMARY

[0002] The present invention provides a non-invasive urine collection device that can be used by both male persons and female persons. For example, the urine collection device may be configured to seal around the human pelvic area to sanitarily and non-invasively collect urine. The urine collection device may be removed from about the pelvic area when not in use.

[0003] In one aspect, the present invention provides a non-invasive urine collection device comprising: (i) a collection funnel defining a funnel opening having a shape configured to receive urine there through, the collection funnel comprising a raised ring (e.g., an inflated member) at the funnel opening configured to be positioned about a human pelvic area for collecting urine, and wherein the collection funnel is configured to be flexed to alter a shape of the funnel opening; and (ii) a tube connected to the collection funnel at a drain opening in the funnel, the tube configured to receive the collected urine.

[0004] In some cases, the collection funnel is configured to be flexed between a male urine collection mode and a female urine collection mode. In some embodiments, the collection funnel comprises at least three distinct flexible portions configured to flex upon application of force to an exterior side of the collection funnel to alter the shape of the funnel opening. In some embodiments, the collection funnel comprises a first firm portion at a lower portion of the collection funnel, a second firm portion positioned to one side of an upper portion of the collection funnel, and a third firm portion positioned on an opposite side of the upper portion of the collection funnel. In at least one embodiment, the collection funnel further comprises a first flexible portion disposed between the first firm portion and the second firm portion, a
second flexible portion disposed between the first firm portion and the third firm portion, and
a third flexible portion disposed between the second firm portion and the third firm portion.

[0005] In one embodiment, the non-invasive urine collection device comprises a collection
funnel that may be configured in at least a first mode and second mode, wherein in the first
mode, the funnel opening is more elongated and/or elliptical that in the second mode, the first
mode configured for positioning about a female pelvic area and for collecting urine
therefrom, and in the second mode, the funnel opening is more circular than in the first mode,
the second mode configured for positioning about a male pelvic area and for collecting urine
therefrom. In some cases, the funnel opening will return to the second mode when pressure
to the sides of the funnel is released. In some embodiments, the funnel opening will retain
the shape of the first mode when pressure to the sides of the funnel is released, and can be
returned to the shape of the second mode by applying outward pressure to the interior sides of
the funnel.

[0006] In some cases, the raised ring is configured to seal about the human pelvic area for
collecting urine. In some instances, sealing the raised ring (e.g., an inflated member) about
the human pelvic area is configured to prevent urine from leaking out of the funnel opening.

[0007] In some embodiments, the tube is disposed at a posterior end of the collection
funnel, the posterior end being opposite the funnel opening. In some cases, the device further
comprises a valve disposed at the first end of the collection funnel, in the tube, or between the
collection funnel and the tube. In at least one embodiment, the valve is a backflow
prevention valve.

[0008] In some embodiments, the tube and the collection funnel are configured to apply
vacuum pressure to seal the collection funnel member about the human pelvic area.

[0009] In some cases, the device further comprises a handle. In some cases, the handle is
an integrated solid fin as illustrated in Fig. 1. In some cases, the handle is a blade as
illustrated in Fig. 4.

[0010] In various embodiments, the collection funnel comprises a polymer or silicon
material, optionally BPA-free. In some cases, the material is biodegradable.

[0011] In another aspect, the present invention provides a non-invasive method for
collecting urine from a human, the method comprising: (i) providing the urine collection
device as discussed above or herein; (ii) positioning the urine collection device such that the
funnel opening is about a human pelvic area; (iii) receiving urine into the funnel opening; and
(iv) removing the urine collection device from about the human pelvic area.
[0012] In another aspect, the present invention provides an ornamental design for a urine collection device, as illustrated in Figs. 7-13.

[0013] Any of the features or embodiments discussed above or herein may be combined in alternative embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Fig. 1 is a side view of a urine collection device, in accordance with an example embodiment.

[0015] Fig. 2 is a front view of a urine collection device configured in a male collection mode, in accordance with an example embodiment.

[0016] Fig. 3 is a front view of a urine collection device configured in a female collection mode, in accordance with an example embodiment.

[0017] Fig. 4 is a side view of a urine collection device, in accordance with another example embodiment.

[0018] Fig. 5 is a front view of a urine collection device configured in a male collection mode, in accordance with another example embodiment.

[0019] Fig. 6 is a front view of a urine collection device configured in a female collection mode, in accordance with another example embodiment.

[0020] Fig. 7 is a rear perspective view of a urine collection device.

[0021] Fig. 8 is a front perspective view of a urine collection device.

[0022] Fig. 9 is a front view of a urine collection device.

[0023] Fig. 10 is a rear view of a urine collection device.

[0024] Fig. 11 is a top view of a urine collection device.

[0025] Fig. 12 is a side view of a urine collection device. The opposite side is identical.

[0026] Fig. 13 is a bottom view of a urine collection device.

DETAILED DESCRIPTION OF EXAMPLE EMBODIMENTS

[0027] The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the invention are shown. Indeed, the invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Like numbers refer to like elements throughout.

[0028] Figs. 1-3 and Figs. 4-6 illustrate example embodiments of a non-invasive urine collection device 100. In example embodiments, the urine collection device 100 comprises a collection funnel 10 and a tube 20 secured to a first end of the collection funnel 10. In
example embodiments, the collection funnel 10 comprises a funnel opening 1 at a second end of the collection funnel 10 and configured for receiving urine there through. The collection funnel 10 directs the collected urine into the tube 20. The tube 20 is configured to provide the collected urine to an appropriate disposal facility (e.g., to a drain, to a urine storage/disposal device, and/or the like). In some cases, the tube directs urine to a collection bag (optionally vented). In some cases, the tube is integrated with the bag. In some cases, the tube can be removed from the urine collection device and/or the collection bag. In some cases, flexible tubing is connected to the tube 20 to direct urine or other fluid to the collection bag.

[0029] In example embodiments, a valve 25 is disposed at or near the junction of the collection funnel 10 and the tube 20. For example, the valve 25 may be disposed in the first end of the collection funnel 10, within the tube 20, and/or between the first end of the collection funnel 10 and the tube 20. In example embodiments, the valve 25 is a one-way valve, a back-wash valve, and/or the like configured to permit urine or other fluid to flow from the collection funnel 10 into the tube 20, and to prevent urine or other fluid from crossing from the tube 20 into the collection funnel 10. In some cases, the tube 20 is a flat tube that impedes backflow of the urine or other fluid. In example embodiments, the urine collection device 100 may further comprise a handle 30. In some cases, the handle 30 may be configured for aiding a person using and/or operating the urine collection device 100 to hold the urine collection device 100 against their pelvic area. In some cases, the handle is an integrated part (e.g., a fin or blade) of the collection device.

[0030] Example embodiments of the collection funnel 10 comprise a raised ring 5. The raised ring 5 may be configured to seal the funnel opening 1 about the user's pelvic area. In some cases, the raised ring 5 may be inflatable (an inflated member), and for example, when the funnel opening 1 is positioned about a user's pelvic area, the inflated member may be inflated to seal the funnel opening 1 about the user's pelvic area. In some embodiments, the raised ring 5 forms a ring around the circumference of the opening 1 of the collection funnel 10 to be placed against an individual's pelvic area. In some cases, the raised ring 5 is comprised of an air-filled chamber or foam material that flexes when placed against a user's pelvic area to form a seal. For example, the raised ring 5 may be configured to reduce and/or prevent leakage of urine from the funnel opening 1 when the urine collection device 100 is in use to collect urine.

[0031] In example embodiments, the collection funnel 10 and/or the raised ring 5 may be divided into a plurality of portions. For example, the collection funnel 10 and/or the raised ring 5 may comprise a posterior portion 7a and an anterior portion 6a. Additionally, the
collection funnel 10 and/or the raised ring 5 may comprise first and second side portions 6b, 6c, and first and second anterior side portions 7b, 7c. In example embodiments, one or more portions of the collection funnel 10 and/or the raised ring 5 may be flexible portions 6 (e.g., 6a, 6b, 6c) and one or more portions of the collection funnel 10 and/or the raised ring 5 may be firm portions 7 (e.g., 7a, 7b, 7c). For example, the posterior portion 7a, the first anterior side portion 7b, and/or the second anterior side portion 7c may be firm portions. For example, the anterior portion 6a, the first side portion 6b, and the second side portion 6c may be flexible portions. In example embodiments, the firm portions 7 (e.g., 7a, 7b, 7c) and the flexible portions 6 (e.g., 6a, 6b, 6c) may be configured to allow the urine collection device 100 to effectively seal about the user's pelvic area. For example, the posterior portion 7a may be a firm portion to aid the user in maintaining the urine collection device 100 sealed against the user's pelvic area. In some cases, the bottom portion of the collection funnel 10 (opposite the optional handle 30) is angled from the posterior portion 7a to the tube 20 (or optional back flow valve 25) to cause urine or other fluid to flow from the funnel opening 1 toward and into the tube 20. This configuration aids in preventing leakage when a user (e.g., a bed-bound patient) is in a lying position (e.g., supine).

[0032] In example embodiments, the firm portions 7 (e.g., 7a, 7b, 7c) and the flexible portions 6 (e.g., 6a, 6b, 6c) may be configured to allow the collection funnel 10 to change shape so as to change the shape of the funnel opening 1 defined thereby. For example, the shape of the funnel opening 1 may be configurable based on flexing of the collection funnel 10 and/or the raised ring 5. For example, the collection funnel 10 and/or the raised ring 5 may be re-shaped, thereby re-shaping the funnel opening 1. For example, the shape of the funnel 10 (and the funnel opening 1 and the raised ring 5) may be changed to accommodate the pelvic area, urethra configuration and/or the like of the specific user from which urine is to be collected. For example, the collection funnel 10 (and the funnel opening 1 and the raised ring 5) may be switched, flexed, and/or the like between a male collection mode (shown in Figs. 2 and 5) for collecting urine from a male user, and a female collection mode (shown in Figs. 3 and 6) for collecting urine from a female user. In example embodiments, the shape of the funnel opening 1 may be rounder in the male collection mode than in the female collection mode. In example embodiments, the shape of the funnel opening 1 may be more elongated, elliptical, and/or oblong in the female collection mode than in the male collection mode. In example embodiments, the collection funnel 10 (and the funnel opening 1 and the raised ring 5) in the male collection mode or in the female collection mode may be adjusted therefrom to provide a better fit (e.g., a better seal) about the user's pelvic area. For example, the
collection funnel 10 may be configured to smoothly flex between the male collection mode and the female collection mode such that the funnel opening 1 is shaped to provide a personalized seal about the user's pelvic area. In one embodiment, the collection funnel 10 is originally configured in the male collection mode and may be re-configured into the female collection mode by pressing together the outer edges of side portions 6b and 6c, release of which will cause the collection funnel 10 to resume the original shape associated with the male collection mode.

[0033] In various embodiments, the collection funnel can be made from flexible polymer materials and foams. The materials can be non-absorbant or comprise an outer surface that is non-absorbant. In some cases, the urine collection device is comprised of a single integrated piece composed of a uniform material throughout, optionally excepting the firm portions 7 (e.g., 7a, 7b, 7c), which can be comprised of a denser form of the same material.

[0034] In use, the non-invasive urine collection device is (i) configured into a male or female collection mode, (ii) placed against the user's pelvic area while the user evacuates his or her bladder, and (iii) removed from the user's pelvic area. In some cases, a caregiver (e.g., hospital staff) may configure the device, place the device against a patient's pelvic area while the patient evacuates his or her bladder, and then remove the urine collection device. In some embodiments, in which the raised ring is an inflated member (e.g., an air-filled chamber), the inflated member can be inflated prior to placing the collection device against the user's pelvic area. In some embodiments, the urine collection device can be used for an individual in a seated position. In some cases, the dimensions of the urine collection device can be scaled to accommodate smaller individuals (e.g., children).

[0035] Many modifications and other embodiments of the invention set forth herein will come to mind to one skilled in the art to which the invention pertains having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the invention is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation, unless otherwise noted.
What is claimed is:

1. A non-invasive urine collection device comprising:
   a collection funnel defining a funnel opening having a shape configured to receive
   urine there through, the collection funnel comprising a raised ring at the funnel opening
   configured to be positioned about a human pelvic area for collecting urine, and wherein the
   collection funnel is configured to be flexed to alter a shape of the funnel opening; and
   a tube connected to the collection funnel at a drain opening in the funnel, the tube
   configured to receive the collected urine.

2. The non-invasive urine collection device of claim 1, wherein the collection
   funnel is configured to be flexed between a male urine collection mode and a female urine
   collection mode.

3. The non-invasive urine collection device of claim 1, wherein the collection
   funnel comprises at least three distinct flexible portions configured to flex upon application
   of force to an exterior side of the collection funnel to alter the shape of the funnel opening.

4. The non-invasive urine collection device of claim 1, wherein the collection
   funnel comprises a first firm portion at a lower portion of the collection funnel, a second firm
   portion positioned to one side of an upper portion of the collection funnel, and a third firm
   portion positioned on an opposite side of the upper portion of the collection funnel.

5. The non-invasive urine collection device of claim 4, wherein the collection
   funnel further comprises a first flexible portion disposed between the first firm portion and
   the second firm portion, a second flexible portion disposed between the first firm portion and
   the third firm portion, and a third flexible portion disposed between the second firm portion
   and the third firm portion.

6. The non-invasive urine collection device of claim 1, wherein the raised
   ring is configured to seal about the human pelvic area for collecting urine.

7. The non-invasive urine collection device of claim 1, wherein sealing the
   raised ring about the human pelvic area is configured to prevent urine from leaking out of the
   funnel opening.
8. The non-invasive urine collection device of claim 1, wherein the tube is disposed at a posterior end of the collection funnel, the posterior end being opposite the funnel opening.

9. The non-invasive urine collection device of claim 8, further comprising a valve disposed at the first end of the collection funnel, in the tube, or between the collection funnel and the tube.

10. The non-invasive urine collection device of claim 9, wherein the valve is a backflow prevention valve.

11. The non-invasive urine collection device of claim 1, wherein the tube and the collection funnel are configured to apply vacuum pressure to seal the collection funnel member about the human pelvic area.

12. The non-invasive urine collection device of claim 1, further comprising a handle.

13. The non-invasive urine collection device of claim 1, wherein (a) the collection funnel may be configured in at least a first mode and second mode, (b) in the first mode, the funnel opening is more elongated and/or elliptical that in the second mode, the first mode configured for positioning about a female pelvic area and for collecting urine therefrom, and (c) in the second mode, the funnel opening is more circular than in the first mode, the second mode configured for positioning about a male pelvic area and for collecting urine therefrom.

14. A non-invasive method for collecting urine from a human, the method comprising:
   providing the urine collection device of any one of claims 1-13;
   positioning the urine collection device such that the funnel opening is about a human pelvic area;
   receiving urine into the funnel opening; and
   removing the urine collection device from about the human pelvic area.
INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/59081

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61 F 5/44 (2017.01)
CPC - A61 F 5/44; A61 G 9/006

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)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 4,771,484 A (MOZELL, MAXWELL M.) September 20, 1988, figures 1-3, column 3, lines 15-19.</td>
<td>1-4, 6-8, 14/1-14/4, 14/6-14/8</td>
</tr>
<tr>
<td>Y</td>
<td>US 6,342,049 B1 (NICHOLS, LAURA L.) January 29, 2002, figures 2, 6; column 3, lines 25-26, column 4, lines 57-60; column 5, lines 1-11.</td>
<td>13, 14/13</td>
</tr>
<tr>
<td>Y</td>
<td>US 4,784,654 A (BEECHER, WILLIAM H.) November 15, 1988, column 9, lines 53-60.</td>
<td>11, 14/11</td>
</tr>
<tr>
<td>Y</td>
<td>DE 20 2008 000 667 U1 (ISBERNER, ERIKA) March 27, 2008, see machine translation, figure 3.</td>
<td>12, 14/12</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C. 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: 27 December 2017 (27.12.2017)
Date of mailing of the international search report: 26 JAN 2018

Name and mailing address of the ISA/Authorized officer
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300
Shane Thomas
PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)