United States Patent Application Publication	20250262086
Kind Code	A1
Publication Date	August 21, 2025
Inventor(s)	Hughett; James David et al.

FLUID COLLECTION ASSEMBLY INCLUDING A CUSTOMIZABLE EXTERNAL SUPPORT AND RELATED METHODS

Abstract

A fluid collection system may include a fluid collection device, a tube, a fluid collection container configured to receive fluid from the fluid collection device, and a vacuum source configured to pull an at least partial vacuum to draw the fluid from the fluid collection device through the tube into the fluid collection container. The fluid collection device may include a fluid impermeable barrier including an outer surface and an inner surface, the fluid impermeable barrier defining a chamber, at least one opening, and a fluid outlet. The fluid collection device may include a porous material disposed in the chamber and an external support coupled to the outer surface of the fluid impermeable barrier. The fluid impermeable barrier exhibits a first shape prior to shaping the external support and a second shape after shaping the external support with the first shape being different from the second shape.

Inventors: **Hughett; James David (Conyers, GA), Gloeckner; Claire (Lilburn, GA)**

Applicant: **PUREWICK CORPORATION** (Covington, GA)

Family ID: **1000008589769**

Appl. No.: **19/202862**

Filed: **May 08, 2025**

Related U.S. Application Data

parent US continuation 17749340 20220520 parent-grant-document US 12324767 child US 19202862
us-provisional-application US 63192274 20210524

Publication Classification

Int. Cl.: **A61F5/451** (20060101); **A61F5/44** (20060101); **A61M1/00** (20060101)

U.S. Cl.:

CPC **A61F5/451** (20130101); **A61F5/4401** (20130101); **A61F5/4405** (20130101); **A61M1/802** (20210501); A61F2250/0004 (20130101); A61M2202/0496 (20130101)

Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation of U.S. application Ser. No. 17/749,340 filed on May 20, 2022, which claims priority to U.S. Provisional Patent Application No. 63/192,274 filed on May 24, 2021, the disclosure of each of which is incorporated herein, in their entirety, by this reference.

BACKGROUND

[0002] An individual may have limited or impaired mobility such that typical urination processes are challenging or impossible. For example, the individual may have surgery or a disability that impairs mobility. In another example, the individual may have restricted travel conditions such as those experienced by pilots, drivers, and workers in hazardous areas. Additionally, fluid collection from the individual may be needed for monitoring purposes or clinical testing.

[0003] Bed pans and urinary catheters, such as a Foley catheter, may be used to address some of these circumstances. However, bedpans and urinary catheters have several problems associated therewith. For example, bedpans may be prone to discomfort, spills, and other hygiene issues. Urinary catheters be may be uncomfortable, painful, and may cause urinary tract infections. Conventional fluid collection devices also may be limited to use when a patient is confined to a bed in a supine position.

[0004] Thus, users and manufacturers of fluid collection devices continue to seek new and improved devices, systems, and methods to collect fluid.

SUMMARY

[0005] Embodiments disclosed herein are related to fluid collection assemblies and methods of using fluid collection assemblies. In an embodiment, a fluid collection assembly is disclosed. In an embodiment, a fluid collection assembly may include a fluid impermeable barrier including an outer surface and an inner surface. The fluid impermeable barrier may define a chamber, at least one opening, and a fluid outlet. The fluid collection device may further include a porous material disposed in the chamber and an external support coupled to the outer surface of the fluid impermeable barrier. The fluid impermeable barrier may exhibit a first shape prior to shaping the external support and a second shape after shaping the external support. The first shape may be different from the second shape.

[0006] In an embodiment, a fluid collection system includes a fluid collection device, a tube in fluid communication with the fluid collection device, a fluid collection container configured to receive fluid from the fluid collection device, and a vacuum source configured to pull at least a partial vacuum to draw the fluid from the fluid collection device through the tube into the fluid collection container. The fluid collection device may include a fluid impermeable barrier including an outer surface and an inner surface. The fluid impermeable barrier may define a chamber, at least one opening, and a fluid outlet. The fluid collection device may further include a porous material disposed in the chamber and an external support coupled to the outer surface of the fluid impermeable barrier. The fluid impermeable barrier may exhibit a first shape prior to shaping the external support and a second shape after shaping the external support. The first shape may be different from the second shape.

[0007] In an embodiment, a method to collect urine is disclosed. The method may include positioning a fluid collection assembly that has been shaped from a first shape to a second shape that is different from the first shape adjacent to a female urethra opening. The fluid collection assembly may include a fluid impermeable barrier including an outer surface and an inner surface, a porous material disposed in the chamber, and a moldable external support coupled mounted to the at least one outer surface of the fluid impermeable barrier. The fluid impermeable barrier may define a chamber, at least one opening, and a fluid outlet. The method may also include receiving urine from the female urethral opening into the chamber of the fluid collection assembly and applying suction with a vacuum source to draw the urine from the chamber via a tube and deposit the urine in a fluid storage container.
[0008] Features from any of the disclosed embodiments may be used in combination with one another, without limitation. In addition, other features and advantages of the present disclosure will become apparent to those of ordinary skill in the art through consideration of the following detailed description and the accompanying drawings.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0009] The drawings illustrate several embodiments of the present disclosure, wherein identical reference numerals refer to identical or similar elements or features in different views or embodiments shown in the drawings.
[0010] FIG. **1**A is a block diagram of a fluid collection system, according to an embodiment.
[0011] FIG. **1**B is an isomeric view of a fluid collection system, according to an embodiment.
[0012] FIG. **2**A is an isometric view of a fluid collection assembly, according to an embodiment.
[0013] FIG. **2**B is a cross-sectional view of the fluid collection assembly of FIG. **2**A.
[0014] FIG. **3**A is an isometric view of a fluid collection assembly, according to an embodiment.
[0015] FIG. **3**B is an isometric view of the fluid collection assembly of FIG. **3**A.
[0016] FIG. **4**A is an isometric view of an external support of a fluid collection assembly, according to an embodiment.
[0017] FIG. **4**B is an isometric view of the external support of FIG. **4**A.
[0018] FIG. **4**C is an isometric view of an external support, according to an embodiment.
[0019] FIG. **5** is a flow diagram of a method to collect urine, according to an embodiment.
DETAILED DESCRIPTION
[0020] Embodiments disclosed herein are related to fluid collection systems and related methods. Fluid collection devices may be soiled and require frequent changes. A fluid collection assembly may be form fitting to minimize leaks and improve comfort. To reduce the constant adjustment of the fluid collection assembly, an external support may be included. In some embodiments, the external support may be shaped so that the fluid collection assembly modified to the user's specific anatomy. The fluid collection device may then be changed out and a new fluid collection device may be placed into the external support. Users and caregivers, then, are benefited from a fluid collection system that does not need to be adjusted for proper fit with each change of the device. The user may benefit from a fluid collection assembly that is customized to fit to their body and also includes a component that is reusable, washable, and would make it easier to switch from one device to the next.
[0021] In many embodiments described herein, a fluid collection system may be customized to fit the anatomy of a user. Embodiments of the fluid collection assembly may include an external support that may be modified and/or adjustable. In some embodiments, the external support may include an elastomeric material being heat adjustable. The external support may be heated and shaped and then once cooled is rigid. In some embodiments, the external support may include a

semi-rigid spine and/or framework that may be bent into various shapes to have the fluid collection assembly fit the anatomy of the user. For example, the fluid collection assembly may include an external brace that allows the user to adjust the shape of the fluid collection assembly and then maintain the shape after the fluid collection device is replaced.

[0022] In some embodiments, the fluid collection system includes a fluid collection device configured to be positioned at least proximate to a urethra of a user and a tube in fluid communication with the fluid collection device. The fluid collection system may also include a fluid collection container configured to receive fluid from the fluid collection device and a vacuum source configured to pull an at least partial vacuum within the fluid collection system to draw fluid from the fluid collection device through the tube into the fluid collection container.

[0023] FIG. **1**A is a block diagram of a fluid collection system **10** and FIG. **1**B is an isomeric view of the fluid collection system **10**, according to an embodiment. The fluid collection system **10** may be included in embodiments of fluid collection systems described herein. As shown in FIGS. **1**A-**1**B, the system **10** includes a fluid (e.g., urine) collection device **12** (e.g., any of the fluid collection assemblies disclosed herein), a fluid collection container **14** (or reservoir), and a vacuum source **16** (e.g. a pump). The fluid collection device **10**, the fluid collection container **14**, and the vacuum source **16** may be fluidly coupled to each other via one or more tubes **18**. For example, fluid collection device **10** may be operably coupled to one or more of the fluid collection container **14** or the vacuum source **16** via the tube **18**. In some embodiments, the vacuum source **16** may be coupled directly to the fluid collection container **14**. Fluid (e.g., urine or other bodily fluids) collected in the fluid collection device **10** may be removed from the fluid collection device **10** via the tube **18** coupled to the fluid collection device **12**. Suction force may be introduced into the chamber of the fluid collection device **12** via the inlet of the tube **18** responsive to suction (e.g., vacuum) force applied at the outlet of the tube **18**.

[0024] The suction force may be applied to the outlet of the tube **18** by the vacuum source **16** either directly or indirectly. The suction force may be applied indirectly via the fluid collection container **14**. For example, the outlet of the tube **18** may be disposed within or fluidly coupled to an interior region of the fluid collection container **14** and an additional tube **18** may extend from the fluid collection container **14** to the vacuum source **16**. Accordingly, the vacuum source **16** may apply suction to the fluid collection device **12** via the fluid collection container **14**. The suction force may be applied directly via the vacuum source **16**. For example, the outlet of the tube **18** may be disposed within the vacuum source **16**. An additional tube **18** may extend from the vacuum source **16** to a point outside of the fluid collection device **12**, such as to the fluid collection container **14**. In such examples, the vacuum source **16** may be disposed between the fluid collection device **12** and the fluid collection container **14**.

[0025] The vacuum source **16** may be in fluid communication with the interior region of the fluid collection container **14** and may be configured to pull at least a partial vacuum on the interior region of the fluid collection container **14** effective to draw the fluid from the fluid collection device **12** through the tube **18** into the fluid collection container **14**. In some embodiments, the vacuum source **16** may be coupled directly to the fluid collection container **14**, or the tube **18** may fluidly couple the vacuum source **16** with the interior region of the fluid collection container **14**.

[0026] The vacuum source **16** may include one or more of a manual vacuum pump, and electric vacuum pump, a diaphragm pump, a centrifugal pump, a displacement pump, a magnetically driven pump, a peristaltic pump, or any pump configured to produce a vacuum. For example, the pump may include a diaphragm pump having a minimum pumping speed of 25 ml/second. In some embodiments, the vacuum source **16** includes a variable speed pump and/or a continuous pump. For example, the vacuum source **16** may include a variable speed pump. The vacuum source **16** may provide a vacuum or suction to remove fluid from the fluid collection device **12**. In some examples, the vacuum source **16** may be powered by one or more batteries operatively coupled to the pump. In some embodiments, the battery may include a lithium ion battery. In some embodiments, the battery may be alkaline or rechargeable.

[0027] The vacuum source **16** may provide a vacuum or suction to remove fluid from the fluid collection device **12**. In some examples, the vacuum source **16** may be powered by one or more of a power cord (e.g., connected to a power socket), one or more batteries, or even manual power (e.g., a hand operated vacuum pump). In some examples, the vacuum source **16** may be sized and shaped to fit outside of, on, or within the fluid collection device **12**. For example, the vacuum source **16** may include one or more miniaturized pumps or one or more micro pumps. The vacuum sources disclosed herein may include one or more of a switch, a button, a plug, a remote, or any other device suitable to activate the vacuum source **16**.

[0028] In some embodiments, the vacuum source **16** may be coupled directly to the fluid collection container **14**. The fluid collection container **14** may be sized and shaped to retain a fluid therein. The fluid collection container **14** may include a bag (e.g., drainage bag), a bottle or cup (e.g., collection jar), or any other enclosed container for storing bodily fluid(s) such as urine. In some embodiments, the fluid collection container **14** may include a generally rigid exterior housing and an interior portion configured to contain the fluid. The fluid collection container **14** may be opaque or clear according to different embodiments and may include a generally rectangular front or rear profile or be cylindrical. The fluid collection container **14** may be reusable and dishwasher safe, and may include a generally rigid material such as polycarbonate, plastic, rubber, metal, glass, combinations thereof, or any other suitable materials.

[0029] In some examples, the tube **18** may extend from the fluid collection device **12** and attach to the fluid collection container **14** at a first point therein. The tube **18** may include a flexible tube. In some embodiments, at least a portion of the tube **18** may be substantially opaque, thereby inhibiting viewing of the fluid within the tube **18**. An additional tube **18** may attach to the fluid collection container **14** at a second point thereon and may extend and attach to the vacuum source **16**. Accordingly, a vacuum (e.g., suction) may be drawn through fluid collection device **12** via the fluid collection container **14**. Fluid, such as urine, may be drained from the fluid collection device **12** using the vacuum source **16**.

[0030] Many embodiments of fluid collection systems described herein include a fluid collection assembly having a fluid collection device configured to be disposed adjacent to a urethral opening of a user. Turning to FIG. **2**A-**2**B, a fluid collection device **100** is shown. The fluid collection device **100** may include a fluid impermeable barrier **102** including an outer surface **104** and an inner surface, the fluid impermeable barrier defining a chamber **106**, at least one opening **108**, and a fluid outlet **110**. A porous material **112** may be disposed in the chamber **106** within the fluid impermeable barrier **102**. In some embodiments, a tube **114** may be at least partially disposed within the chamber **106**.

[0031] The inner surfaces of the fluid impermeable barrier **102** at least partially defines the chamber **106** within the fluid collection device **100**. The fluid impermeable barrier **102** temporarily stores the bodily fluids in the chamber **106**. The fluid impermeable barrier **102** may be formed of any suitable fluid impermeable material(s), such as a fluid impermeable polymer (e.g., silicone rubber, thermoplastic polyurethane, polyolefin, polyvinyl chloride etc.), a metal film, natural latex rubber, another suitable material, or combinations thereof. As such, the fluid impermeable barrier **102** substantially prevents the bodily fluids from passing through the fluid impermeable barrier **102**. In an at least one embodiment, the fluid impermeable barrier **102** may be air permeable and fluid impermeable, thus preventing leaks while allowing air flow through the chamber **106**. In such an example, the fluid impermeable barrier **102** may be formed of a hydrophobic material that defines a plurality of pores. At least one or more portions of at least the outer surface **104** of the fluid impermeable barrier **102** may be formed from a soft and/or smooth material, thereby reducing chaffing.

[0032] In some examples, the fluid impermeable barrier **102** may be tubular (ignoring the opening), such as substantially cylindrical (as shown), oblong, prismatic, or flattened tubes. During use, the outer surface **104** of the fluid impermeable barrier **102** may contact the wearer. The fluid impermeable barrier **102** may be sized and shaped to fit in the gluteal cleft between the legs of a female user.

[0033] The opening **108** may provide an ingress route for fluids to enter the chamber **106**. The opening **108** may be defined by the fluid impermeable barrier **102** such as by an inner edge of the fluid impermeable barrier **102**. For example, the opening **108** may be formed in and extend through the fluid impermeable barrier **102**, from the outer surface **104** to the inner surface, thereby enabling fluid(s) to enter the chamber **106** from outside of the fluid collection assembly **100**. The opening **108** may be an elongated hole in the fluid impermeable barrier **102**. For example, the opening **108** may be defined as a cutout in the fluid impermeable barrier **102**. The opening **108** may be located and shaped to be positioned adjacent to a female urethra.

[0034] The fluid collection device **100** may be positioned proximate to the female urethra and bodily fluid may enter the chamber of the fluid collection assembly **100** via the opening **108**. The fluid collection assembly **100** may be configured to receive the fluid(s) into the chamber **106** via the opening **108**. When in use, the opening **108** may have an elongated shape that extends from a first location below the urethral opening (e.g., at or near the anus or the vaginal opening) to a second location above the urethral opening (e.g., at or near the top of the vaginal opening or the pubic hair).

[0035] The fluid collection assembly **100** includes at least one porous material **112** disposed in the chamber **106**. The porous material **112** may cover at least a portion (e.g., all) of the opening **108**. The porous material **112** may be exposed to the environment outside of the chamber **106** through the opening **108**. The porous material **112** may be configured to wick and/or allow flow of any fluid away from the opening **104**, thereby preventing the fluid from escaping the chamber **106**. The permeable properties referred to herein may be wicking, capillary action, diffusion, or other similar properties or processes, and are referred to herein as “permeable” and/or “wicking.” Such “wicking” and “permeable” properties may not include absorption of fluid into the porous material **110**. Put another way, substantially no absorption or solubility of the bodily fluids into the material may take place after the material is exposed to the bodily fluids and removed from the bodily fluids for a time. While no absorption or solubility is desired, the term “substantially no absorption” may allow for nominal amounts of absorption and/or solubility of the bodily fluids into the porous material **112** (e.g., absorbency), such as less than about 30 wt. % of the dry weight of the porous material 112, less than about 20 wt. %, less than about 10 wt. %, less than about 7 wt. %, less than about 5 wt. %, less than about 3 wt. %, less than about 2 wt. %, less than about 1 wt. %, or less than about 0.5 wt. % of the dry weight of the porous material **112**.

[0036] In an embodiment, the porous material **112** may include at least one absorbent or adsorbent material. The porous material **112** disposed within the chamber **106** may include any material that may wick and/or allow flow of the fluid. For example, the porous material **112** may be formed from fibers from nylon (e.g., spun nylon fibers), polyester, polyethylene, polypropylene, wool, silk, linen, cotton (e.g., cotton gauze), felt, other fabrics and porous polymers, hydrophobic foam, an open cell foam polyurethane,, a coated porous material (e.g., hydrophobic coated porous material, materials with affinity to specific substances), polymeric sintered particles from polyethylene, polypropylene, polytetrafluoroethylene (PTFE), elastomeric particles, any other suitable porous materials, or combinations thereof. For example, the porous material **112** may include a body of spun nylon fibers with an outer fabric gauze layer that wraps around the body of spun nylon fibers. Forming the porous material **112** from gauze, soft fabric, and/or smooth fabric may reduce chaffing caused by the fluid collection assembly **100**. In some embodiments, the porous material **112** may at least substantially and/or completely fill the portions of the chamber **106** that may not be occupied by the tube **114**.

[0037] The tube **114** may be at least partially disposed in the chamber **106**. The tube **114** may be used to remove fluid form the chamber **106**. The tube **114** may be in fluid communication with the fluid outlet **110** of the fluid collection assembly **100**. The tube **114** may include a tube inlet **116** and a tube outlet (not shown) positioned downstream from the tube inlet **116**. The tube outlet may be operably coupled to a fluid collection container, such as fluid collection container **14** described in more detail above. Thus, the tube **114** may fluidly couple the chamber **106** with the fluid collection container (shown in FIG. **1**B). The tube **114** may be at least partially disposed in the chamber **106**. The tube **114** may be used to remove the bodily fluids from the chamber **106**. The bodily fluids that are in the chamber **106** may flow through the porous material **112** to a reservoir **117**. In some embodiments, the tube inlet **116** may be located in the reservoir **117**. In other embodiments, the tube inlet **116** may be flush with and/or incorporated within the porous material **112** or the tube inlet **116** may be located aft of the end of the porous material **112** that partially defines the reservoir **117**.

[0038] The reservoir **117** may be a substantially unoccupied portion of the chamber **106**. The reservoir **117** may be defined between the fluid impermeable barrier **102** and the porous material **112**. The bodily fluids that are in the chamber **106** may flow through the porous material **112** to the reservoir **117**. The reservoir **117** may temporarily retain of the bodily fluids therein.

[0039] The fluid impermeable barrier **102** may retain the bodily fluids in the reservoir **117**. While depicted in the distal end region in FIG. **2**B, the reservoir **117** may be located in any portion of the chamber **106** such as the proximal end region, proximate the fluid outlet **110**. The reservoir **117** may be located in a portion of the chamber **106** that is designed to be located in a gravimetrically low point of the fluid collection assembly when the fluid collection assembly is worn. Other embodiments of fluid collection assemblies, fluid porous materials, chambers, reservoirs, and their shapes and configurations are disclosed in U.S. Pat. Nos. 10,973,678; 10,390,989; 10,226,376; PCT Patent Application No. PCT/US2019/029608, filed on Apr. 29, 2019, the disclosure of each of which is incorporated herein, in its entirety, by this reference.

[0040] In some embodiments, the tube **114** may include a flexible material such as materials tubing (e.g., medical tubing). Such material tubing may include a thermoplastic elastomer, polyvinyl chloride, ethylene vinyl acetate, polytetrafluoroethylene, flexible metal, ceramic and composite material tubing etc. The tube **114** may include silicon or latex. In some embodiments, the tube **114** may be constructed of any suitable material. In some embodiments, the tube **114** may include one or more portions that are resilient, such as by having one or more of a diameter or wall thickness that allows the tube **114** to be flexible.

[0041] Referring now to FIG. **3**A, in some embodiments, a fluid collection device **100** may be configured to be positioned at least proximate to a urethra of a user. The fluid collection device **100** may be included as a component of a fluid collection assembly **118**. Generally, the fluid collection device **100** may include a surface sized to be positioned proximate or adjacent to the urethra and configured to wick urine and/or other fluids away from the user. To better shape the fluid collection device **100** to the user's anatomy, the fluid collection assembly **118** may include an external support **120** coupled to the outer surface **104** of the fluid impermeable barrier **102**. The external support **120** may be shaped in some embodiments such that when coupled to the fluid collection device **100**, the fluid impermeable barrier **102** may exhibit a first shape prior to shaping the external support **120** and a second shape after shaping the external support **120**. The first shape may be different from the second shape. For example, prior to shaping the external support **120**, the fluid impermeable barrier **102** may be generally straight and after shaping the external support **120**, the fluid impermeable barrier **102** may be semi-circular or semi-elliptical. In some embodiments, the external support **120** may be configured to conform at least the porous material **112** to the anatomy of a person adjacent to a female urethral opening. As such, the fluid collection device **100** when shaped appropriately may minimize and/or prevent leakage of fluid.

[0042] In some embodiments, a portion of the fluid impermeable barrier **102** may be shaped and/or bent to fit the anatomy of the user. For example, an upper portion may be bent such that the impermeable barrier **102** generally exhibits an “L” shape. In other examples, the fluid impermeable barrier **102** may be shaped by coupling the external support **120** to the outer surface **104** such that the fluid impermeable barrier **102** generally exhibits a "C" shape. In other words, the fluid impermeable barrier **102** may include a front side that defines the at least one opening **108** and a backside opposite the front side. The external support **120** may shape the fluid impermeable barrier **102** such that at least a portion of the fluid collection assembly **118** exhibits a concave curve relative to a point above the at least one opening. To ensure that the external support **120** is able to retain the fluid collection device **100** in a predetermined shape, the external support **120** is shaped such that the fluid collection device **100** is nested within the external support **120**. In some embodiments, the fluid collection device **100** may include at least one connector **122** configured to connect to the external support **120**.

[0043] FIG. **3**B illustrates the at least one connector **122** extending from the outer surface **104** of the backside of the fluid impermeable barrier **102**. The external support **120** may include at least one opening **124** (as shown in FIGS. **4**A-**4**C). The at least one connector **122** may be configured to be received by the opening **124** in the external support **120**. In some embodiments, the connector **122** may couple to the opening **124** via an interference fit. In some embodiments, the connector **122** may be an adhesive. In other embodiments, the connector may be a screw, Velcro, or other suitable fastener.

[0044] Referring now to FIGS. **4**A-**4**B, in some embodiments, the external support **120** may include an elastomeric material. The external support **120** may include at least one of ethylene vinyl acetate or a thermoplastic polyurethane. The external support **120** may include any suitable thermoplastic or blend of thermoplastics. Other suitable examples of thermoplastic materials may include polyethylene, polypropylene, polyvinyl chloride, polystyrene, polyamides, polyesters, and polyurethanes. High-temperature thermoplastics include polyether ether ketones, liquid crystalline polymers, polysulfones, and polyphenylene sulfide. In some embodiments, the external support **120** may include a polymer blend, a metal or alloy components, or any other suitable rigid or semi-rigid materials.

[0045] In some embodiments, the external support **120** may include a thermoformable material. The external support **120** may include any suitable thermoplastics that may be thermoformed. In some embodiments, the external support **120** may include Polystyrene, Polypropylene, amorphous polyethylene terephthalate (APET), Crystallized polyethylene terephthalate (CPET), and/or polyvinyl chloride (PVC). Ethylene vinyl alcohol (EVOH) may be incorporated in some embodiments; co-extrusions of the materials above may be commonly used to provide precise properties.

[0046] In some embodiments, the external support **120** may be shaped such that the fluid collection device **100** nests within the external support **120**. In some embodiments, the external support **120** may include a first end **126** and a second end **128**. The first end **126** may include a cup shape configured to retain the fluid collection device therein. In some embodiments, a portion of the fluid collection device **100** that does not include the fluid outlet **110** may be disposed within the first end **126** of the external support **120**. In some embodiments, the second end **128** of the external support **120** may include a first arm **130** and a second arm **132** that are configured to retain the portion of the fluid collection device **100** that includes the fluid outlet **110** by way of an interference fit. The second end **128** of the external support **120** is configured to retain the fluid collection device **100** in a preferred (e.g. curved) shape without kinking or bending the tube **114**. Other configurations may be suitable to shape the fluid collection assembly **118**.

[0047] The external support **120** may be configured to be shaped to the anatomy of the user by the body heat of the user. For example, a user may place the fluid collection assembly **118** in a preferred configuration and keep the fluid collection assembly in contact with the user's skin to heat the external support **120** to be at, near, or above the glass transition temperature of the external support **120**. The external support **120** may then form to the preferred shape and maintain the shape. In some embodiments, the external support **120** includes a glass transition temperature of about 37° C. (98° F.). In some embodiments, the external support may include an elastomeric resilience at a temperature of less than about 36° C. (97° F.). In other embodiments, the glass transition temperature may be higher than about 37° C. The glass transition temperature may be about 100° C. or less, such as about 90° C. or less, about 80° C. or less, about 70° C. or less, about 40° C. or less, or in ranges of about 30° C. to about 40° C., about 40° C. to about 60° C., about 50° C. to about 60° C., about 60° C. to about 90° C., or about 80° C. to about 100° C. In other embodiments, the glass transition temperature may be higher than about 37° C. The elastomeric resilience of the external support **120** may be about 100° C. or less, such as about 80° C. or less, about 60° C. or less, about 40° C. or less, about 30° C. or less, or in ranges of about 30° C. to about 40° C., about 40° C. to about 60° C., about 50° C. to about 60° C., about 60° C. to about 90° C., or about 80° C. to about 100° C. For example, in some embodiments, a user may place the external support **120** and/or the fluid collection assembly **118** in hot and/or boiling water (greater than 100° C.) such that the glass transition temperature is achieved. The user may then form the external support **120** to a preferred shape and allow the external support **120** to cool to below the temperature at which the external support **120** achieves an elastomeric resilience. Therefore, the external support **120** may retain the preferred shape when placed on the anatomy of the user. In some embodiments, the external support **120** may be configured to be generally straight prior to being heat formed (as shown in FIG. **4**A) and concavely curved after being heat formed (as shown in FIG. **4**B).

[0048] The external support **120** may include materials and/or components that assist the external support **120** in forming and/or retaining a preferred shape. Referring to FIG. **4**C, the external support **120** may include a semi-rigid wire **134** or other structure such as a mesh along the length of the external support **120**. In some embodiments, the semi rigid wire **134** may include copper, steel, aluminum, brass, bronze, or another suitable metal or alloy. In other embodiments, the semi-rigid wire **134** may include a polymer and/or any suitable plastic. The semi-rigid wire **134** may be monolithically formed of a single component. In some embodiments, the semi-rigid wire **134** may include more than one sections and/or elements. In some embodiments, the semi-rigid wire **134** may include a grid structure within the external support **120**. The grid structure may be located within the external support **120** or coupled to an exterior surface of the external support **120**. In some embodiments, the grid structure and/or the semi-rigid wire **134** may also retain the tube **114** in a predetermined shape. In some embodiments, the external support **120** may include only the grid structure.

[0049] FIG. **5** is a flow diagram of a method **200** to collect urine, according to an embodiment. The method **200** includes an act **210** of positioning a fluid collection assembly that has been shaped from a first shape to a second shape that is different from the first shape adjacent to a female urethral opening. The fluid collection assembly may include a fluid impermeable barrier including an outer surface and an inner surface, the fluid impermeable barrier defining a chamber, at least one opening, and a fluid outlet. The fluid collection assembly may further include a porous material disposed in the chamber and a moldable external brace mounted to the at least one outer surface of the fluid impermeable barrier.

[0050] The method **200** also includes an act **220** receiving urine from the female urethral opening into the chamber of the fluid collection assembly. The method **200** may also include an act **230** of applying suction with a vacuum source to draw the urine from the chamber via a tube and deposit the urine in a fluid storage container.

[0051] In some embodiments, the act **210** may include a fluid collection assembly shaped from a first shape to a second shape by heating the moldable external brace to at least a glass transition temperature of the moldable external brace and causing the fluid collection assembly to conform to an anatomy of a user adjacent to the female urethral opening. In other embodiments the fluid collection assembly may be shaped from a first shape to a second shape by: heating the moldable external brace having the first shape to at least a glass transition temperature of the moldable external brace and shaping the moldable external brace to the second shape such that the fluid collection assembly conforms to an anatomy of a user adjacent to the female urethral opening. The shape may be retained by cooling the moldable external brace below the glass transition temperature. The fluid collection assembly may then be positioned within the shaped and cooled moldable external brace. In other embodiments, heating the moldable external brace to at least a glass transition temperature of the moldable external brace may include heating the moldable external brace with the body heat of the user to shape the moldable external brace. In some embodiments, act **210** may include placing the external brace adjacent to a female urethral opening where the body heat of the user heats the external brace above the glass transition temperature of the material. In some embodiments, act **210** may include heating the moldable external brace with an external heat source and then applying the heated external brace to the user to shape the moldable external brace. The external heat source may include hot water. The external brace may be placed in water heated above the glass transition temperature of the external brace and then shaped to the anatomy of the user, and then allowed to cool.

[0052] The acts of the method of collecting fluids from a user described above are for illustrative purposes. For example, the acts of the method of collecting fluids from a user can be performed in different orders, split into multiple acts, modified, supplemented, or combined. In an embodiment, one or more of the acts of the method of collecting fluids from a user can be omitted from the method. Any of the acts of the method of collecting fluids from a user can include using any of the portable fluid collection systems disclosed herein.

[0053] As used herein, the term “about” or “substantially” refers to an allowable variance of the term modified by “about” or “substantially” by ±10% or ±5%. Further, the terms “less than,” “or less,” “greater than,” “more than,” or “or more” include, as an endpoint, the value that is modified by the terms “less than,” “or less,” “greater than,” “more than,” or “or more.”

[0054] While various aspects and embodiments have been disclosed herein, other aspects and embodiments are contemplated. The various aspects and embodiments disclosed herein are for purposes of illustration and are not intended to be limiting.

Claims

1. A fluid collection assembly, comprising: a fluid impermeable barrier defining a chamber, at least one opening, and a backside opposite the at least one opening; an external support coupled to an outer surface of the fluid impermeable barrier, wherein the external support is complementary shaped with the backside of the fluid impermeable barrier, wherein the fluid impermeable barrier exhibits a first shape prior to shaping the external support and a second shape after shaping the external support, wherein the first shape is different from the second shape.

2. The fluid collection assembly of claim 1, wherein the external support is configured to conform the at least one opening to an anatomy of a person adjacent to a female urethral opening.

3. The fluid collection assembly of claim 1, wherein the external support includes an elastomeric material.

4. The fluid collection assembly of claim 1, wherein the fluid impermeable barrier includes a front side that defines the at least one opening and the front side is opposite the backside, wherein the external support shapes the fluid impermeable barrier such that at least a portion of the fluid collection assembly exhibits a concave curve relative to a point above the at least one opening.

5. The fluid collection assembly of claim 1, wherein the fluid impermeable barrier includes at least one connector configured to connect to the external support.

6. The fluid collection assembly of claim 5, wherein the at least one connector extends from the outer surface of the backside of the fluid impermeable barrier.

7. The fluid collection assembly of claim 1, wherein the external support is configured to be generally straight prior to being thermoformed and concavely curved after being thermoformed.

8. The fluid collection assembly of claim 3, wherein the elastomeric material includes at least one of ethylene vinyl acetate or thermoplastic polyurethane.
9. The fluid collection assembly of claim 1, wherein the external support exhibits a glass transition temperature of about 37° C. (98° F.).
10. The fluid collection assembly of claim 1, wherein the external support is configured to be shaped to an anatomy of the user by body heat of a user.
11. The fluid collection assembly of claim 1, wherein the external support exhibits an elastomeric resilience at a temperature of less than about 36° C. (97° F.).
12. The fluid collection assembly of claim 1, wherein the external support includes a semi-rigid wire along a longitudinal length of the external support.
13. An external support, comprising: a body defining a recess shaped to receive an outer surface of a fluid collection device, wherein the external support is complementary shaped with the fluid collection device, wherein the external support comprises a flexible material such that the external support exhibits a first shape prior to shaping the external support and a second shape after shaping the external support, wherein the first shape is different than the second shape.
14. The external support of claim 13, wherein the external support comprises apertures configured to couple to least one connector disposed on the fluid collection device.
15. The external support of claim 14, wherein the at least one connector extends from the outer surface of the backside of the fluid collection device.
16. The fluid collection system of claim 13, wherein the first shape comprises a generally straight configuration and the second shape comprises a concavely curved configuration.
17. A method to collect urine, the method comprising: positioning a fluid collection assembly that has been shaped from a first shape to a second shape that is different from the first shape adjacent to a female urethral opening, the fluid collection assembly including: a fluid collection device defining a chamber, at least one opening, and a backside opposite the at least one opening; a moldable external brace mounted to the at least one outer surface of the fluid collection device, wherein the moldable external brace is complementary shaped with the backside of the fluid impermeable barrier; and receiving urine from the female urethral opening into the chamber of the fluid collection assembly.
18. The method of claim 17, wherein the fluid collection assembly is shaped from a first shape to a second shape by heating the moldable external brace to at least a glass transition temperature of the moldable external brace and causing the fluid collection assembly to conform to an anatomy of a user adjacent to the female urethral opening.
19. The method of claim 17, wherein the fluid collection assembly is shaped from a first shape to a second shape by: heating the moldable external brace having the first shape to at least a glass transition temperature of the moldable external brace; shaping the moldable external brace to the second shape such that the fluid collection assembly conforms to an anatomy of a user adjacent to the female urethral opening cooling the moldable external brace below the glass transition temperature; and positioning the fluid collection assembly within the moldable external brace.
20. The method of claim 18, wherein heating the moldable external brace to at least a glass transition temperature of the moldable external brace includes heating the moldable external brace with body heat of the user to shape the moldable external brace.
21. The method of claim 18, wherein heating the moldable external brace to at least a glass transition temperature of the moldable external brace includes heating the moldable external brace with an external heat source and applying the heated external brace to the user to shape the moldable external brace.