Female Urinary Pouch External Collection Device

General Information

The Female Urinary Pouch is a cut-to-fit, vinyl, self-adhering pouch, intended to be a conduit for urine collection, via tubing, into a gravity drainage collection device. The adhesive is synthetic. The pouch is meant to be worn by non-ambulatory women, and is available with the SoftFlex[™] skin barrier. The female urinary pouch may be an alternative when indwelling catheters are not an option. Do not use this product if the perineal skin is compromised, or if the patient sits in a chair, or is ambulatory.



Preparation

- Position the patient on her back with legs apart. Wash genital area with a mild soap and water.
- Trim the pubic hair. Rinse and dry thoroughly.
- If desired, wipe the skin that will be in contact with the skin barrier with a skin protective wipe (not included). Please refer to the instructions for use packed with that product.
- Be sure the drain cap is place on the pouch drain.



Application

Separate the labia (minora and majora) and push back firmly to expose the vulva.

- 1. Check that the pre-cut opening on the barrier will encompass the urinary and vaginal orifices. This is best done by folding the skin barrier in half and holding it close to the vulva. If it needs to be enlarged mark the backing paper with a pencil.
- 2. Using scissors, modify the opening in the skin barrier so that it corresponds with the mark on the backing paper. Do not cut beyond the line indicated on the backing paper. Remove the protective release paper from the skin barrier.
 - If desired, place a small amount of barrier paste (not included) on the edge of the skin barrier that will adhere to areas where the skin surface is creased or uneven. Please refer to the instructions for use packed with that product.
- 3. With the labia in a normal position, apply the narrow (distal) end of the barrier to the perineum. Gently press the barrier material against the skin working from the perineum upward until the skin barrier contacts the skin at all points.
- 4. Gently hold the barrier material against the skin so that the user's body heat will soften the barrier material and enhance its adhesive properties. Allow the patient to assume a normal comfortable position.
 - If desired, apply microporous adhesive strips (not included) around the barrier edges for an added sense of security. Please refer to the instructions for use packed with that product.
- Remove the drain cap at the bottom of the pouch and attach the tubing to a drainage bag (not included).







To dispose (Figs. 6-10):

Please follow all local disposal regulations.











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FREQUENTLY ASKED QUESTIONS	
What type of drainage bag should be used?	Select either a bedside drainage bag or larger capacity leg bag for the immobile individual.
Can a bedside drainage bag and leg bag be interchanged for day wear and night wear?	To minimize the risk of bacteria entering the tubing system, select just one type of collection bag and use it continuously.
How do I ensure gravity drainage into the collection bag?	A side-lying rather than supine position for the patient will help prevent urine from pooling around the labia minora as it sits in the opening of the pouch. Enure that the tubing or end of the pouch is not twisted, and that the drainage bag is well below the bladder level. A catheter tubing securement device may be used to help stabilize the tubing and prevent undue tension on the pouch.
When does the pouch need to be changed?	Remove the pouch immediately if any skin irritation is assessed while the pouch is in place or if urine is undermining the skin barrier and urine leaks from beneath the barrier.

Indications and Intended Use

The pouch is intended to collect and contain urine for individuals with urinary incontinence.

WARNINGS

Reuse of a single use product may create potential risk to the user such as poor adhesion. Reprocessing, cleaning, disinfection, and sterilization may compromise the product. This may result in odor or leakage. Ensure proper fit as instructed. If the barrier opening is incorrect or leakage occurs, skin damage may occur (e.g., irritation, broken skin, rash, or redness). This may decrease wear time.

Contraindications

Use of the urinary pouch may not be advisable for women with urinary tract, vaginal or other chronic infections, active genital herpes. or chronic urinary retention.

PRECAUTIONS

A urinary pouch should only be used under supervision of healthcare professional. Discontinue use if any of the following symptoms occur:

- Swelling, severe redness. itching or pain in vulva or perinea] area
- Fever or abnormal vaginal discharge

Notes

To help ensure proper adhesion, apply to clean, dry intact skin. Do not use oils or lotions. These products may interfere with adhesion of the skin barrier. Contact a healthcare practitioner for help with continence care products. In case of serious injury (incident) in relation to your use of the product, please contact your local distributor or manufacturer and your local competent authority. For more information, see www.hollister.com/authority or contact EC Rep or local distributor.

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Hollister Incorporated 2000 Hollister Drive Libertyville, Illinois 60048 1.800.323.4060

www.hollister.com

