SYMBOL	SYMBOL TITLE (STANDARD REFERENCE)	EXPLANATORY TEXT
Symbols immediately below are derived from the following standard: ISO 15223-1:2021 - Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.		
	Manufacturer (5.1.1)	Indicates the medical device manufacturer
LOT	Lot number (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
REF	Catalog number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Use by (5.1.4)	Indicates the date after which the medical device is not to be used
NON STERILE	Non-sterile (5.2.7)	Indicates a medical device that has not been subjected to a sterilization process
	Do not use if package is damaged and consult instructions for use (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Single use (5.4.2)	Indicates a medical device that is intended for one single use only
eifu.bd.com	Consult instructions for use or consult electronic instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use
Symbols immediately below are derived from the following standard: ISO 7000 – Graphical symbols for use on equipment		
	Packaging unit (2794)	To indicate the number of pieces in the package
Symbols immediately below are derived from the following standard: ASTM F2503 – Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment		
MR	Magnetic Resonance (MR) Conditional (7.4.6.1)	An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.
Other		
NRL	Not made with Natural Rubber Latex	Indicates that the medical device is not made with natural rubber latex

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PK2459599 12/2023

BD PureWick™ Flex
Female External Catheter
Instructions for Use

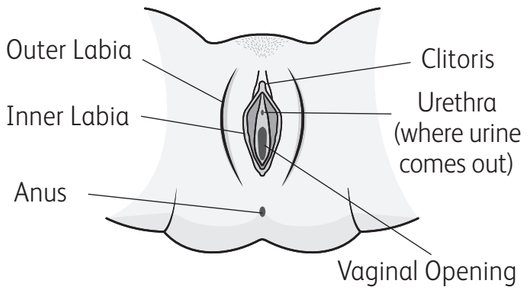
Indications
The PureWick™ Flex Female External Catheter is intended for non-invasive urine output management in adult users with female anatomy, for conditions such as urinary incontinence.

Contraindications
Users with urinary retention.

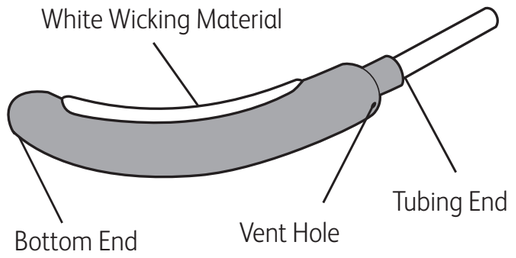
Warnings
- The PureWick™ Flex Female External Catheter is designed for single-use only. Trying to wash, sanitize or reuse it may lead to risk of infection or illness. This may damage the product and materials. The product may not work and cause injury or illness.
- To avoid potential skin injury, never push or rub the product against the skin during placement or removal.
- Do not block airflow to the product (e.g., blocking the vent hole, bedpan, barrier creams)
- Do not insert the product into vagina, anus, or other body orifice.
- Stop use if an allergic reaction occurs.
- After use, this product may be a potential biohazard. Dispose of in accordance with applicable local, state, and federal laws and regulations.
- Do not use on users with frequent episodes of stool incontinence without a fecal management system in place.
- Do not use on users with skin irritation or breakdown at the site.
- Use with caution on users who had recent surgery of the external female anatomy.
- Do not use on users with moderate/heavy menstruation who cannot use a tampon.

MRI Warnings
- **Always disconnect the PureWick™ Flex Female External Catheter from wall suction or the PureWick™ Urine Collection System prior to an MRI procedure.**
- **It is important to closely follow these specific conditions that have been determined to permit the examination to be conducted safely. Any deviation may result in injury to the user.**
- Non-clinical testing demonstrated that the PureWick™ Flex Female External Catheter is MR Conditional. A user with one of these PureWick™ Flex Female External Catheters can be scanned safely under the following conditions:

THE FEMALE ANATOMY



THE PRODUCT



Non -KIT IFU

- Static magnetic field of 1.5-Tesla or 3-Tesla only
- Maximum spatial gradient magnetic field of 40-T/m (4000-Gauss/cm)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2-W/kg for up to 60 minutes of continuous scanning in the Normal Operating Mode
- Under the scan conditions defined, the PureWick™ Flex Female External Catheter is expected to produce a maximum temperature rise of 1.5 degrees Celsius after 15-minutes of continuous scanning.
- There are no circularly polarized (quadrature-driven) RF coil restrictions.

Precautions

- Use with caution on users who are agitated, combative or uncooperative and might remove the product.
- Do not use barrier cream on the surfaces where the product will be placed. Barrier cream may reduce suction.
- Keep suction on while removing the product. This helps prevent leaks during removal.

Recommendations

- Check position of the product after repositioning the user.
- Users may transition (e.g., bed to chair), but the product should be removed if they are up and walking.
- Reposition the product and check the user's skin at least every 2 hours.
- Placing the product snugly between the inner labia and buttocks holds it in place for most users. Breathable underwear may be useful for securing the product for some patients.
- Change the suction tubing and canister per facility protocol or per PureWick™ Urine Collection System Instructions for Use.
- Before connecting the product to facility wall suction tubing, verify suction function by covering the open end of the suction tubing with one hand and looking at the pressure dial. If the pressure does not increase when the line is covered, make sure that the tubing is secured, connected, and not kinked.

Instructions for Use

Wash hands before and after this procedure. If placing or removing this product for another person, wear gloves.

Setup

1 **If using continuous wall suction**, always use the minimum amount of suction necessary. Connect the canister setup per facility protocol. Set suction to 40 mmHg and adjust as needed. Different setups require higher suction typically between 60-100 mmHg.

NOTE: *If hospital policy allows and if using a graduated canister, captured urine may be used for approximate urine output measurement.*

If using the PureWick™ Urine Collection System, make sure all tubing connections are snug, and **turn it on**. Pressure adjustments are not necessary. Consult the PureWick™ Urine Collection System Instructions for Use as needed.

NOTE: *Ensure all connections are air-tight and check for possible cracks, leaks, kinks, or occlusions.*

2 Before placing the product, curve it to fit the user's anatomy. This helps the product stay in place.

3 **If using continuous wall suction**, securely connect the product to the suction tubing.

NOTE: *Keep track of how long the product has been in place by writing down the date and time it was placed.*

If using the PureWick™ Urine Collection System, securely connect the PureWick™ Flex Female External Catheter to the collector tubing.

Placement

4 Have the user lie on their back with knees bent and thighs apart (frog legged) or on their side before placing the product.

With their legs open, check the skin for irritation or breakdown, and clean the female anatomy.

NOTE: *If skin irritation or breakdown is seen, do not use the product.*

5 Spread the inner labia and keep them spread while placing the product.

With white wicking material side facing the user, place the bottom end of the product between the buttocks, but not as far back as to cover the anus.

Gently tuck white wicking material side between the inner labia, directly against the urethra (where the urine comes out).

NOTE: *Make sure the urethra is at least one inch down from the top of the white wicking material.*

6 Make sure the inner labia wrap **around** the product and are not tucked under it.

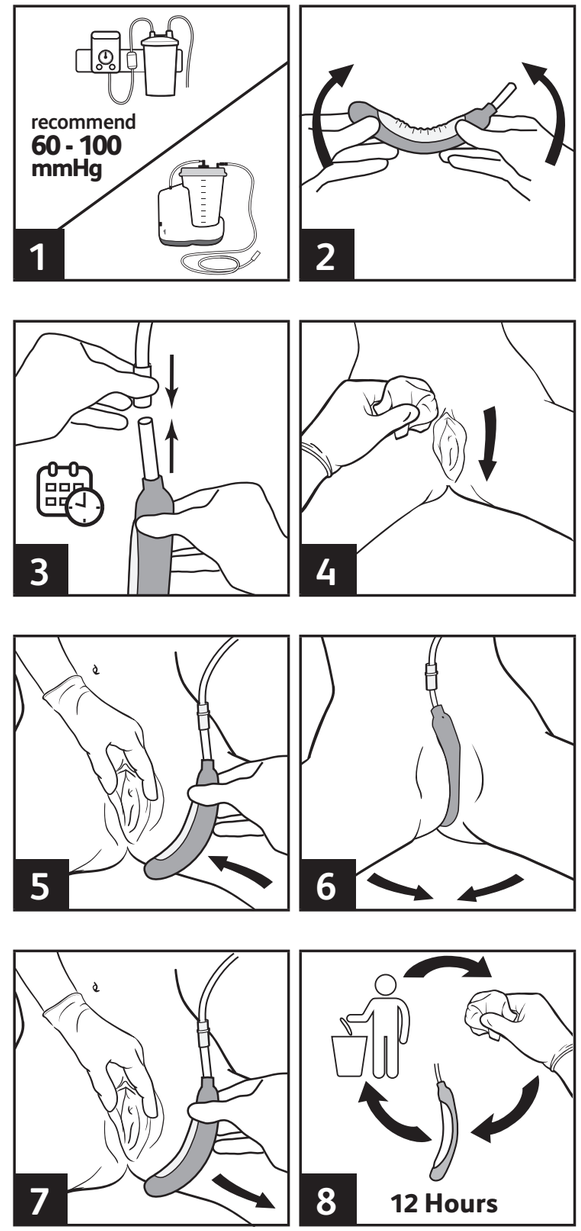
Once the product is in place, slowly close the legs and **make sure the vent hole is not covered**. See product diagram on page 1 for vent hole location.

NOTE: *For users with **larger** labia, less of the product will be visible. For users with **smaller** labia, more of the product will be visible.*

Removal

7 Open the legs and gently spread the labia. Gently pull the product away from the body. Keep suction on while removing the product.

After use, this product may be a potential biohazard. Dispose of in accordance with applicable local, state, and federal laws and regulations.



Maintenance:

8 Replace the product every 12 hours or if soiled with feces or blood.