CONTRAINDICATIONS

DO NOT use the product on patients who:

- Have urinary retention
- Have male anatomy
- Have allergy to adhesive or any other device material
- Have a break in skin integrity around the perineum / suprapubic region, including but not limited to:
  - Open lesions
  - Ulcers
  - Skin irritations
  - Inflammation

WARNINGS

1. Do not use the QiVi – Female External Urine Management device with any other product that interferes with functionality of the device or does not allow for sufficient fluid/air flow.
2. Prepare skin prior to use of this product, and be gentle in its application and removal to avoid any potential skin injury.
3. Discontinue use if an allergic reaction is observed.
4. After use, this product may be a potential biohazard, dispose it in accordance to your institutional protocol.

PRECAUTIONS

1. Not recommended for patients who are:
   - Agitated, restless, or uncooperative and may remove the product while in use.
   - Experiencing skin irritation or breakdown at the site.
   - Experiencing moderate/heavy menstruation and cannot use a tampon
   - Having frequent episodes of bowel incontinence without a fecal management system in place
2. Not to be used for stool collection.
3. Barrier cream may impede adequate device functioning.
4. Proceed with caution in patients who have undergone recent surgery of the external urogenital area.
5. Always assess skin integrity and perform perineal care prior to placement of this product.
6. Maintain suction until the product is fully removed from the patient to avoid any urine backflow.

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QiVi™
CAUTI Prevention
Female External Urine Management

INSTRUCTIONS FOR USE

Read all Instructions for Use before using the product.

PRODUCT DESCRIPTION

The QiVi - Female External Urine Management device contains:
A. One QiVi - Female External Urine Management device
B. One Cleansing Towelette

A.

B.

The QiVi – Female External Urine Management device is a non-invasive product designed for the management of urine in semi and non-ambulatory female patients.

The primary components of the device are an adhesive patch, designed to secure the product around the patient's suprapubic region and a urine collection chamber that contours over the anatomy to collect and divert urine as it passes from the patient.

The internal configuration of the device is designed to continuously divert fluid from the collection chamber to an external container, via tubing connected to a wall vacuum unit, typically found in critical care facilities.

INDICATION FOR USE

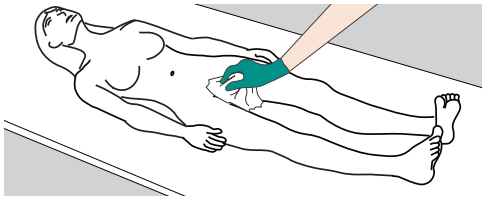
The QiVi – Female External Urine Management device is indicated for non-invasive urine management in non-ambulatory female patients and in those with limited mobility, by collecting and diverting urine away from the patient's body.

PREPARATION OF DEVICE

1. In addition to the QiVi – Female External Urine Management device, suction canister/bag and associated tubing will be required.
2. Wear gloves before handling the patient.
3. Unpack the device and set up station near the patient.
4. Connect the canister to wall suction and set pressure at a minimum 40mmHg of continuous suction. Connect the tube with the canister.

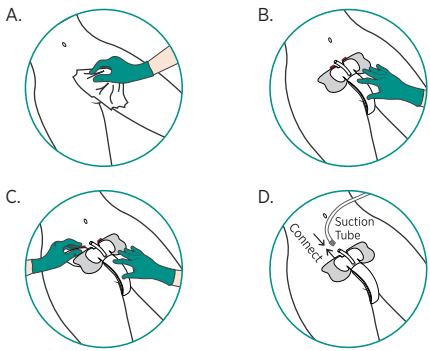
PREPARATION OF PATIENT

1. Position the patient in supine position with legs slightly spread apart.
2. Position yourself such that the patient's urogenital region is clearly visible and direct access is possible.
3. Perform perineal care and assess skin integrity (document per institutional protocol).
4. It is advisable to trim pubic hair to improve product performance.



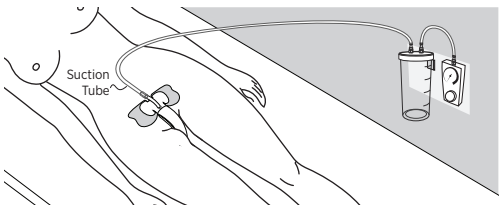
PLACEMENT OF DEVICE

1. Hold the device upright with the cranial tube on top.
2. Align the distal end at the perineum and place the device taut over the labia with the collection chamber contouring the urethral opening.
3. While holding the device in place, use the peel tabs to remove the adhesive liner and place the adhesive patch at the suprapubic region.
4. With the distal end connected to suction canister, connect the suction tube with the QiVi device. Ensure all connections are secure.
5. Return the patient to natural position. Ensure the suction tube is not obstructed by patient load.



MAINTENANCE OF DEVICE

1. Perform skin assessment periodically as per institutional protocol.
2. Ensure tube is connected at all times while device is in use.
3. Assess device periodically to ensure proper placement, particularly after turning or repositioning the patient.
4. Replace device every 12 to 24 hours. Dispose the device as per institutional protocol.
5. Replace tube and empty and/or replace suction canister as per institutional protocol.



REMOVAL OF DEVICE

1. Position the patient in supine position with legs slightly spread apart.
2. Position yourself such that the patient's urogenital region is clearly visible and direct access is possible.
3. Starting from the proximal end, gently peel the adhesive patch and remove the device.
4. Disconnect the device from the suction tube and discard device as per institutional protocol.
5. Assess skin integrity and perform perineal care if required.