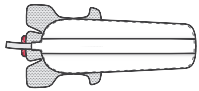
QiVi®
CAUTI Prevention
Male External Urine Management

INSTRUCTIONS FOR USE

Read all Instructions for Use before using the product.

PRODUCT DESCRIPTION

The QiVi - Male External Urine Management device contains:
A. One Male External Urine Management device
B. One Skin-prep Wipe



A.

B.

The QiVi - Male External Urine Management device is indicated for non-invasive urine management in semi and non-ambulatory adolescent and adult male patients by diverting and collecting urine away from the patient's body.

The primary components of the device are an adhesive patch designed to secure the product around the patient's anatomy and a pouch designed to collect and divert urine as and when discharged by the patient.

The internal configuration of the pouch is designed to continuously divert fluid from the pouch to an external collection unit, connected to either a wall vacuum system - typically found in health care facilities, or an external portable suction unit.

INDICATION FOR USE

The QiVi - Male External Urine Management device is indicated for non-invasive urine management in semi and non-ambulatory male patients by collecting and diverting urine away from the patient's body.

CONTRAINDICATIONS

DO NOT use the product on patients who:
- Have urinary retention
- Have female anatomy
- Have allergy to adhesive or any other device material
- Have glans penis and/or penile shaft complications, including but not limited to the following:
  - Open lesions
  - Ulcers
  - Skin irritations
  - Inflammation

WARNINGS

1. Do not use the QiVi - Male External Urine Management device with any other product that compresses 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 bio-hazard, 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.
2. Not to be used for stool collection.
3. Proceed with caution in patients who have undergone recent surgery of the external urogenital area.
4. Always assess skin integrity and perform perineal care prior to placement of this product.
5. Maintain suction until the product is fully removed from the patient to avoid any urine backflow.

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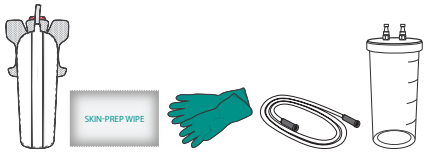
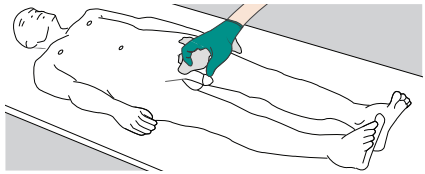
PREPARATION OF DEVICE

1. In addition to the QiVi - Male External Urine Management device, suction canister/bag and associated tube 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.



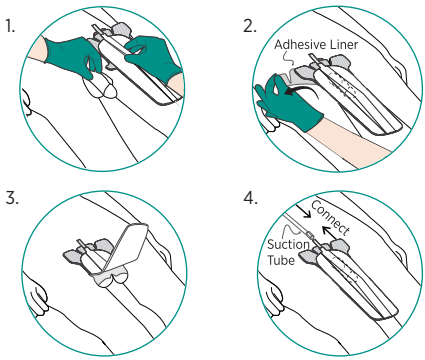
PREPARATION OF PATIENT

1. Position the patient in supine position with their 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.



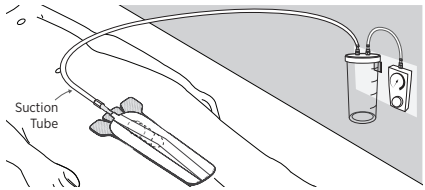
PLACEMENT OF DEVICE

1. Hold the top layer of the device to create space within the pouch lumen. Hold penile shaft at the base and push down against abdominal wall to expose full length. Carefully slide the penile shaft through the pouch orifice all the way until the orifice is flush at the base of the shaft.
2. While holding the device in place, starting from the top, remove the first half of the adhesive liner and smoothly adhere the adhesive over the suprapubic region.
3. While removing the liner towards the bottom, adhere the adhesive around scrotum such that a tight seal is formed between the skin and the adhesive. Repeat the process for the second half of the adhesive liner.
4. Using standard suction tube, connect the device to the collection canister. Ensure all connections are secure.
5. Ensure suction tube does not run under the patient.
6. Return the patient to natural position.



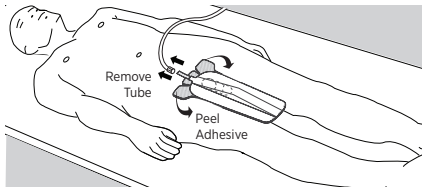
MAINTENANCE OF DEVICE

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 or shift change. 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 their 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 one end, gently remove the adhesive patch.
4. Carefully retract the penis from the pouch orifice and remove the device.
5. Disconnect device from suction tube and discard device as per institutional protocol.
6. Assess skin integrity and perform perineal care if required.



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