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 and/or penile shaft complications, including but not limited to:
  - Open Lesions
  - Skin Irritations
  - Ulcers
  - Inflammation

WARNINGS

1. Do not use the QiVi Lite-Male External Urine Management device with any other energy source or outlet that compresses the device or does not allow for sufficient fluid/air flow.

2. Prepare skin prior to use, be gentle during application and removal to avoid any potential skin injury.

3. Discontinue use if an allergic reaction is observed. After use, this product may be a optional 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 supra-pubic care prior to placement of this product
5. To avoid paper cuts from the liner, handle adhesive with care.
6. Make sure that the tubing is securely connected to the device as well as the collection bag to avoid leakage
7. The collection bag must be kept a level below the device, to initiate drainage through gravity assisted siphon erect.

UNIT

SINGLE USE


DO NOT USE
IF PACKAGE IS
DAMAGED

NOT MADE WITH
NATURAL RUBBER
LATEX


CONSULT
INSTRUCTIONS
FOR USE

QiVi Lite™ CAUTI Prevention

INSTRUCTIONS FOR USE

Read all Instructions for Use before using the product.

PRODUCT DESCRIPTION

The QiVi Lite- male external urine management device is a non invasive product designed to aid in urine diversion in semi to non-ambulatory patients in long term care settings.

The device consists of 3 main parts- an adhesive patch designed to secure the device to the patient's anatomy, a dual chamber pouch to collect and prevent urine back-flow and a drainage tube, that connects to an external collection bag where the urine output is diverted.

The device has been internally configured in such a manner that urine is channeled out of the device in a unidirectional path, away from the anatomy into the external collection bag, using gravity assisted siphon erect and no other external aid.

INDICATIONS FOR USE

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

CM Technologies, Inc.
2165, San Diego Ave.
San Diego, CA 92110
Tel: (800) 520 4714

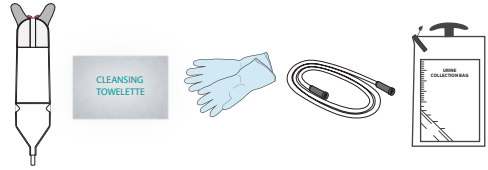
info@consuremedical.com
www.consuremedical.com

consure MEDICAL

QiVi, QiVi Lite logo, and Consure Medical logo are trademarks of CM Technologies, Inc. All Rights Reserved.
IFU-22021-001-00

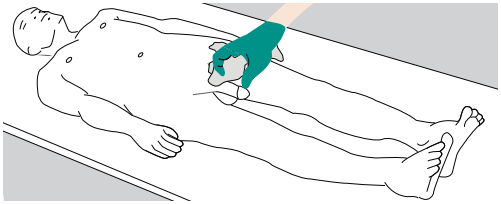
PREPARATION OF DEVICE

1. In addition to QiVi Lite- Male External Urine Management Device, an external urine collection bag and associated tube is required.
2. Always wear gloves before handling the patient.
3. Unpack the device and set up station close to the patient.



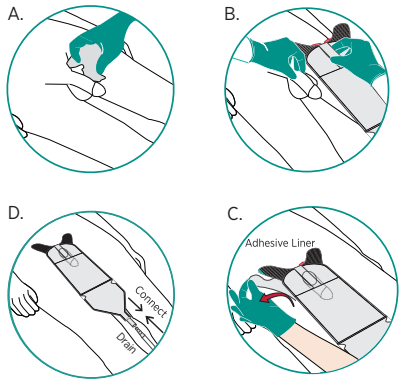
PREPARATION OF THE PATIENT

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 easily accessible.
3. Perform supra-pubic care and assess skin integrity (document as per institutional protocol).
4. It is advisable to trim pubic hair to improve product performance



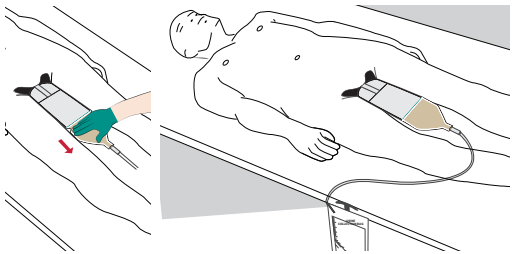
PLACEMENT OF DEVICE

1. Hold the top layer of the device to create space within the pouch lumen.
2. Hold the base of the penile shaft and push down against abdominal wall to expose full length.
3. Carefully slide the penile shaft through the pouch orifice all the way until the orifice is flush at the base of the shaft.
4. 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 supra-pubic region.
5. 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.
6. Repeat the process for the second half of the adhesive liner.
7. Connect the device to the external collection bag.
8. Ensure all connections are secure.
9. The collection bag must be placed a level below the device to initiate gravity assisted siphon erect.
   Return the patient to natural position



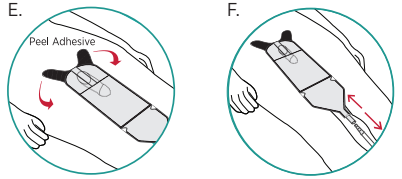
MAINTENANCE OF DEVICE

1. Perform skin assessment periodically as per institutional protocol.
   Ensure tube is connected at all times while device is in use.
2. Assess device periodically to ensure proper placement, particularly after turning or repositioning the patient.
3. Ensure the collection bag being placed a level below the device for effective drainage through siphon erect.
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 external collection bag 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 easily accessible.
3. Starting from one end, gently remove the adhesive patch.
4. Carefully retract the penis from the pouch orifice and remove the device.
5. Drain all fluid into the collection bag, disconnect device and discard as per institutional protocol.
6. Perform supra-pubic care if required.



consure MEDICAL