PRECAUTIONS AND OBSERVATIONS

1. The device must be inserted immediately after the patient has passed stool or after the rectum is confirmed to be void of stool.
2. In the event of expulsion of the device, rinse the receptacle and re-insert following instructions from the 'Insertion of Device' section.
3. The physician must use their discretion in using the device after having assessed the patient's medical history and size of hemorrhoid(s).
4. Caution must be exercised in patients with an inflammatory bowel condition or a previous history of anorectal surgery.
5. Care should be exercised while inserting as well as using the product on patients who tend to bleed from either anticoagulant/antiplatelet therapies or from an underlying condition/treatment.
6. Notify a physician immediately if any of the following occurs:
   • rectal pain
   • rectal bleeding
   • abdominal discomfort
7. If a patient appears to be having significant anal discomfort or if bleeding is visualized during the insertion of the device, the insertion procedure should be discontinued, and the physician should be notified.
8. The Qoramatic™ uses systematic irrigation and suction to divert fecal exudate from the rectal vault. The patient may feel the sensation of "fullness" or foreign body sensation during use.
9. There is an inherent risk in handling fecal discharge and bodily secretions. Adequate precautions, per hospital guidelines, must be exercised while handling the device.
10. If the patient's bowel control, consistency, and frequency of stool begins to return to normal/formed stool or the patient becomes ambulatory, discontinue use of the device.
11. Some leakage of moisture or fecal discharge may be visible along the periphery of the device in patients with severe diarrhea or if the tube is obstructed.
12. The patient may involuntarily expel the device if any of the following happens:
    • stool consistency changes to normal/formed stool
    • device receptacle gets occluded with fecal material
    • rectum is not void of stool before device deployment
13. If any blood is visible along the periphery of the device or any wet redness of stool is observed in the transit tubing or drainage bag, discontinue the use of the device, and notify the physician.

POSSIBLE ADVERSE EVENTS

As with the use of any rectal device, the following adverse events could occur with the use of this device:
• rectal or anal bleed
• constipation or fecal impaction
• erythema of the rectal mucosa
• perforation of the anorectal region
• skin aggravation, pressure injury due to prolonged exposure with rigid portions of the device unless maneuvered regularly

In the event of any adverse events such as those listed above, please notify a physician immediately.

GENERAL GUIDELINES

1. If the product packaging is damaged, do not use.
2. The need for the drainage bag replacement should be assessed at least once in every 4-8 hours.
3. The uninterrupted use for this device, including replacement with other same devices, should not exceed 29 days.
4. The device may be removed as needed to perform patient assessment and reinserted after rinsing the receptacle.

℞ ONLY

UNIT

LATEX
NOT MADE WITH NATURAL RUBBER LATEX

CONSULT INSTRUCTIONS FOR USE

DO NOT USE IF PACKAGE IS DAMAGED

SINGLE USE

NON STERILE

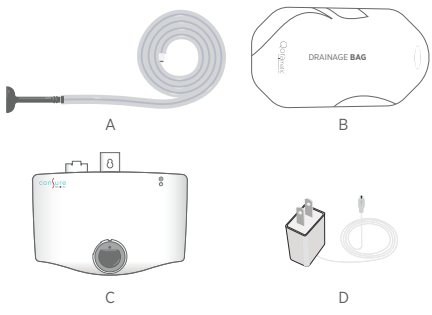
Qoramatic™
Stool Management Kit

INSTRUCTIONS FOR USE

Read all Instructions for Use before using the product.

PRODUCT DESCRIPTION

The Qoramatic™ Stool Management Kit (SMK) contains:
A. One receptacle attached to transit tube
B. One odor-barrier drainage bag
C. Matic hub
D. Power Adapter



A B C D

The Qoramatic™ SMK is an automated and easy-to-use stool management device that requires minimal to no manual intervention to manage Fecal Incontinence or diarrhea in bedridden patients. This device employs a soft and pliable receptacle that rests inside the rectal vault and diverts fecal exudate into a drainage bag by systematically voiding the rectum using automated irrigation and suction.

The indwelling receptacle is attached to a transit tube which connects to the matic hub at the other end. The disposable drainage bag connects to the matic hub has 2 chambers. The Irrigation Fluid Chamber is meant to be filled with approx. 500ml of distilled water/saline and the Stool Collection Chamber collects the fecal exudate diverted via the transit tube. The matic hub has a one touch Start/Stop power button and an indicator light at the front, and is hung at the bedside using integrated hangers.

INDICATIONS FOR USE

The Qoramatic™ Stool Management Kit is indicated for fecal management by diverting and collecting liquid or semi-formed stool in bedridden patients 18 years and older only. Uninterrupted use of this device, including replacement with other same devices, should not exceed 29 days.

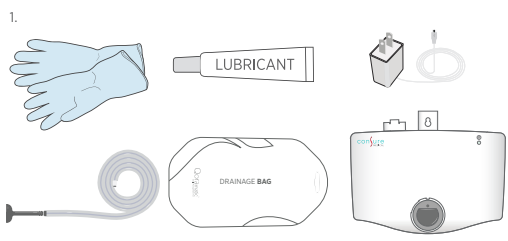
CONTRAINDICATIONS

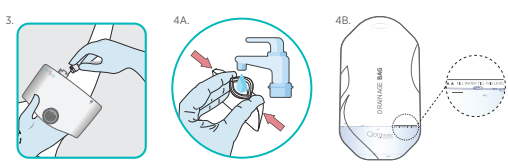
The Qoramatic™ Stool Management Kit should NOT be used on individuals who:

- Have suspected or confirmed rectal mucosal impairment or pathology (i.e., severe proctitis, ischemic proctitis, mucosal ulcerations, etc.)
- Have had rectal surgery within the last year
- Have any GI bleeding, anal injury or have tendency to bleed
- Have hemorrhoids of significant size
- Have a rectal or anal stricture or stenosis
- Have or suspected to have tumor in the rectum or anal canal
- Have or suspected to have impacted stool
- Have or suspected to have constipation
- Have any indwelling rectal or anal device or delivery mechanism in place
- Are known to be sensitive or allergic to any components within the kit

PREPARATION OF DEVICE

1. In addition to the Qoramatic™ Stool Management Kit, lubricant, gloves, and approx. 500ml distilled water/saline will be required.
2. Ensure the nurse/trained hospital staff inserting the device is wearing gloves.
3. Unfold the length of the device to lay flat on the bed, connect the other end of the transit tube to the matic hub. Looping the tube around the bed rail ensures it does'nt get tugged off the matic hub.
4. Fill the irrigation fluid chamber of the drainage bag with approx. 500ml of distilled water/saline, connect the bag to the matic hub and hang the matic hub at the bedside using the integrated hanger.
5. Plug in the Qoramatic™ Stool Management Kit using the Power adapter provided in the box.





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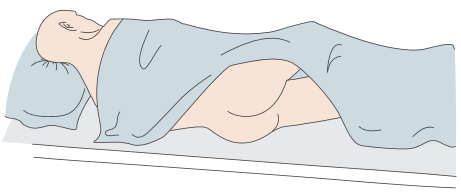
PREPARATION OF PATIENT

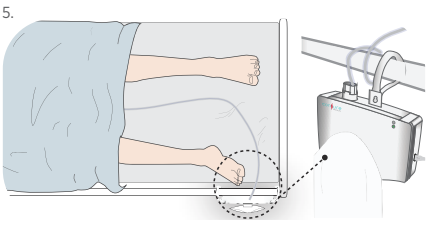
1. Position the patient in a left lateral Sims' (side-lying) or a right lateral Sims' position, depending on which the patient finds more comfortable. In the event the patient is not able to move, position the patient and the care provider such that the anal opening is visible and direct access is possible.
2. Ensure that the patient's rectum is void of fecal matter prior to device deployment. If needed, at the discretion of a trained healthcare practitioner, institutional protocol can be followed to ensure the rectum is empty.

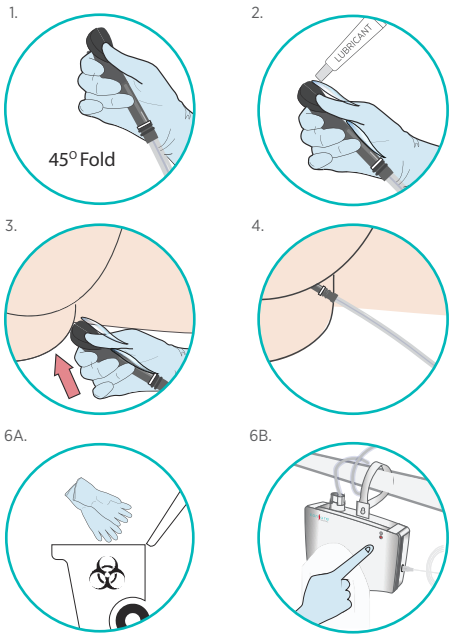


INSERTION OF DEVICE

1. Hold the receptacle between the thumb and index finger, fold it diagonally to create a smaller conical shape for easy insertion.
2. Generously coat the patient's anal opening and the tip of the receptacle with lubricant.
3. Gently insert the receptacle through the anal orifice until it is past the anal canal and above the ano-rectal junction.
4. The white indicator on the receptacle assists in correct placement of the device. In most patients, white line adjacent to the anal orifice ensures correct placement.
5. Place the tube flat along the length of the bed and avoid any twists or kinks. No portion of the tube should be obstructed under the patient or other heavy objects on the bed.
6. Discard the contaminated gloves according to institutional protocol. Press the Power button once to turn on the Qoramatic™ automated stool management kit.

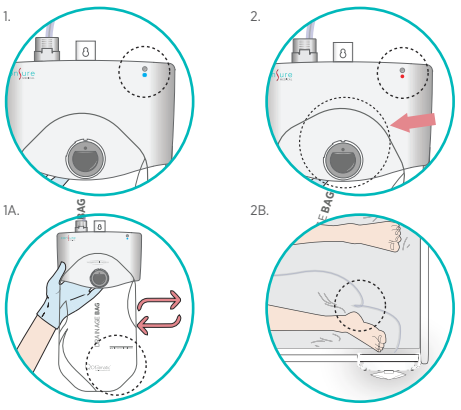
5.





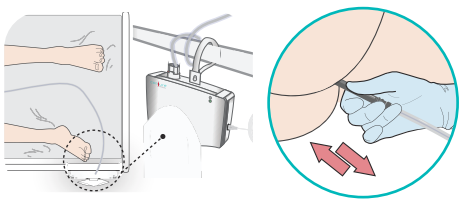
INDICATOR LIGHT

1. The matic hub has an indicator light at the front. The light turns green when the device is powered and is operating normally.
2. The light turns blue when the irrigation fluid chamber of the drainage bag is empty. Replace the drainage bag with a fresh bag with approx. 500ml of distilled water/saline filled inside the irrigation chamber.
3. The light turns red indicating improper device functioning. Check for any occlusions or twists along the length and of the device and ensure the transit tube and drainage bag are securely connected with the matic hub.



MAINTENANCE OF DEVICE

1. Ensure the transit tube is laid flat along the length of the bed with no twists or kinks. No portion of the tube should be obstructed under the patient or other heavy objects on the bed. Ensure the receptacle is adequately inserted inside the rectal vault and the other end of the transit tube is connected securely with the matic hub.
2. Place the transit tube between the patient's leg in supine and behind the patient in lateral position.
3. While repositioning or maneuvering the patient, relocate the matic hub at a location that avoids excessive tension.



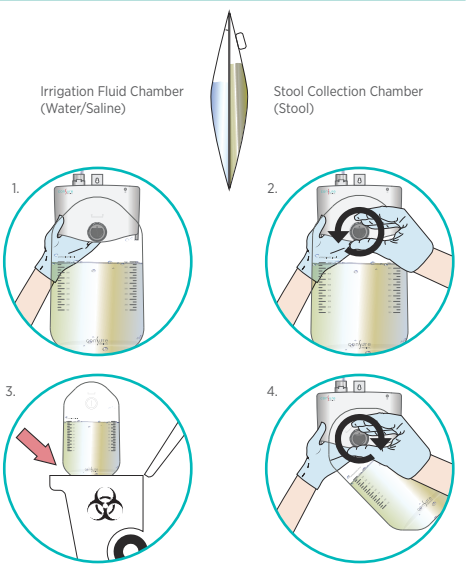
EXCHANGE OF COLLECTION BAG

The drainage bag of Qoramatic™ SMK has 2 chambers. The irrigation fluid chamber is meant to be filled with approx. 500ml of distilled water/saline at the time of device preparation or bag change. The stool collection chamber of the drainage bag collects the fecal exudate diverted via the transit tube. The stool collection chamber negates the amount of irrigation fluid and accurately depicts the volume of stool output on a 1000ml scale.

Assess the volume of the collection bag at least once every 4-8 hours. Remove the drainage bag in either of these scenarios :–

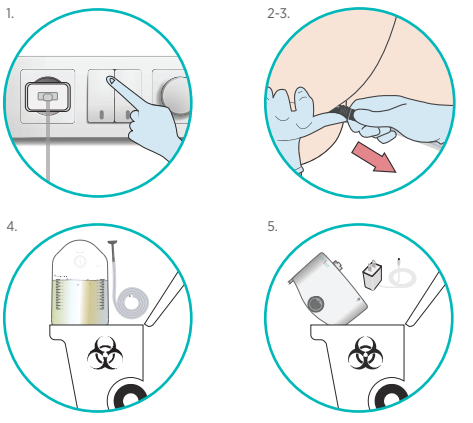
- Distilled water/saline in the irrigation fluid chamber is finished.
- The stool output in the stool collection chamber has crossed the 1000ml mark.

1. Get a fresh drainage bag and fill it with 500ml of distilled water/saline.
2. Turn OFF the device using the power button. Hold the bag and matic hub upright to avoid any impediments while changing the drainage bag. Carefully rotate the bag connector counterclockwise from the matic hub to disengage.
3. Discard the used bag according to institutional protocol.
4. To add a fresh bag (filled with 500 ml of irrigation fluid), mate the drainage bag with the matic hub and rotate clockwise until they are locked together.
5. Turn the device ON by pressing the power button



REMOVAL OF DEVICE

1. Turn OFF the device by pressing the power button once and disconnect the adapter from the matic hub and the power socket.
2. Ensure the nurse/trained hospital staff removing the device is wearing gloves and the patient is in a left lateral Sims' (side-lying) or right lateral Sims' position. In the event the patient is not able to move, position the patient and the care provider such that the anal opening is visible and direct access is possible.
3. Hold the receptacle close to the anal canal and slowly retrieve the receptacle from the anal orifice.
4. Discard the device according to institutional protocol.



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