Qora®

Stool Management Kit

Directions For Use

READ ALL INSTRUCTIONS CAREFULLY BEFORE USING THE KIT

ATTENTION: This poster only provides a quick reference for proper use of Qora®SMK.
Qora®SMKs are indicated for fecal management by diverting and collecting liquid or semi-formed stool to minimize skin contact in bedridden patients. The device is for use in patients 18 years and older only.

Please consult product IFU for further information.

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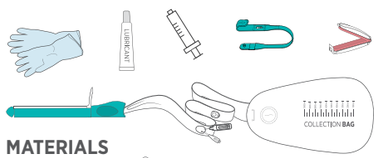
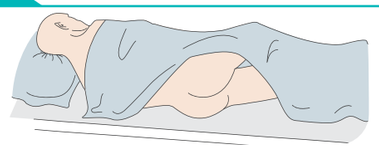
email: sales@consuremedical.com

Access the product use video!

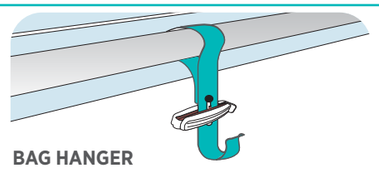
PREPARATION



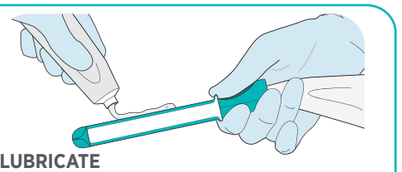
MATERIALS
Set up the Qora® Stool Management Kit, lubricant, syringe, gloves, and bag hanger near the patient.



PATIENT POSITION
Position the patient in left lateral Sims', or a posture where the anal opening is directly accessible.

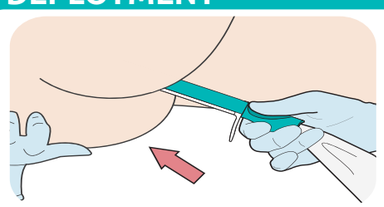


BAG HANGER
Fix the bag hanger on the side of the bed rail. Ensure it is tightly snapped and the hook is facing outwards. Attach the clamp for easy access.

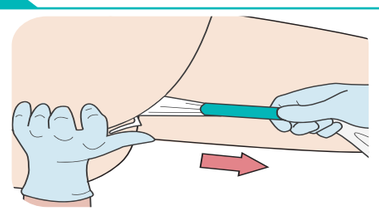


LUBRICATE
Hold the applicator as indicated and apply lubricant generously over the applicator.

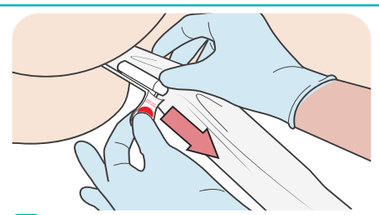
DEPLOYMENT



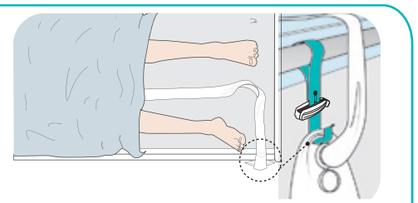
1 INSERT APPLICATOR
While the white tab is facing the patient's back, insert the applicator into the patient's anal opening until the white tab touches the coccyx.



2 REMOVE GREEN SLEEVE
Holding the white tab firmly against the patient, gently remove the green part of the applicator from the patient.

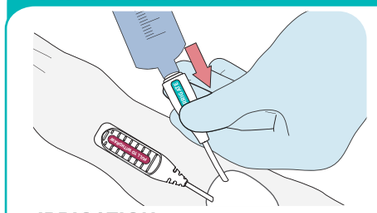


3 REMOVE WHITE SLIDER
Secure the transit sheath with one hand and carefully remove the white slider.

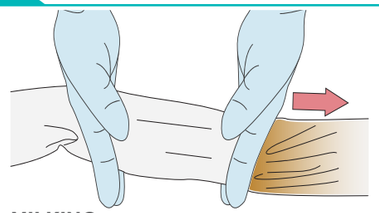


4 SECURE BAG
Open the strap and unroll the device. Ensure there are no folds or kinks in the sheath. Carefully mount the bag on the hanger. Extra slack in the sheath can be placed loosely on the bed.

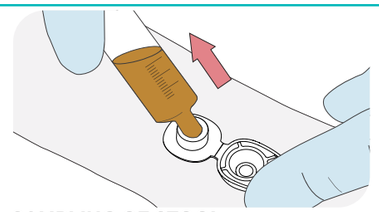
MAINTENANCE



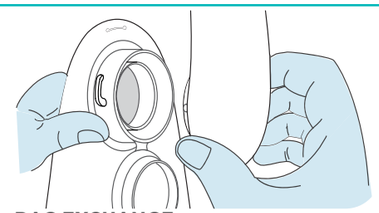
IRRIGATION
- Flush 30-60ml of saline through the irrigation port using a luer lock syringe. Ensure there are no twists or kinks in the fluid delivery tube.
- Repeat at least once every 4 to 8 hours or more frequently as needed.



MILKING
- Firmly hold the sheath near the anal canal with one hand.
- Gently divert the fecal matter into the bag using other hand.
- Repeat at least once every 4 to 8 hours or more frequently as needed.

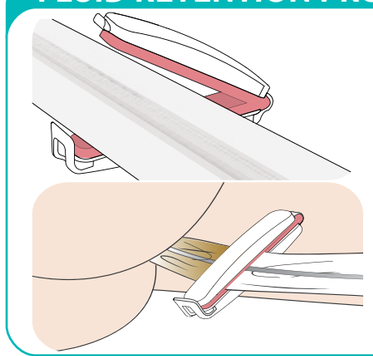


SAMPLING OF STOOL
- Milk the transit sheath to collect fecal matter around the sample port.
- Uncap the sample port and aspirate fecal matter using a slip tip syringe.
- Placing the fluid retentation clamp after sample port can help in sampling.



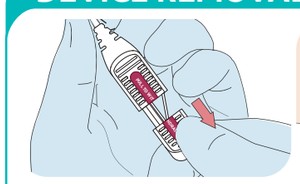
BAG EXCHANGE
- Hold the bag and sheath connectors in a horizontal position.
- Rotate the bag counter-clockwise to disengage from the transit sheath.
- Cap and dispose of the used bag.

FLUID RETENTION PROCEDURES

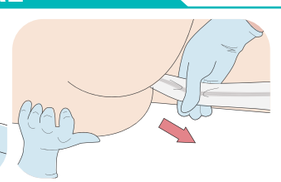


- Place the fluid retention clamp on the transit sheath near the anal opening before delivering the fluid.
- Maintain the patient in lateral position for retention of small volumes of fluids within the rectum. It is recommended to utilize Trendelenburg position for retention of large volumes of fluid.
- Detach the fluid retention clamp and milk the transit sheath as needed to drain any residual fluid or fecal matter into the collection bag.

DEVICE REMOVAL



1 PULL WHITE CAP
Pull cap of the port marked "PULL TO WITHDRAW" towards yourself until the white tether is taut.



2 WITHDRAW SHEATH
Slowly remove the device by holding the transit sheath close to the patient's body.

3 DISPOSE OF DEVICE
Dispose the used device as per institutional protocol.

CONTRAINDICATIONS

The Qora®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 rectal bleeding or anal injury
- 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 to or allergic to any components within the kit

WARNINGS

Qora®Stool Management Kit has a luer port with the potential to misconnect with small bore and other connectors from the following healthcare applications:
- Intravenous
- Breathing systems and driving gases
- Urethral/urinary
- Limb cuff inflation
- Neuraxial applications

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 contact 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.

PRECAUTIONS AND OBSERVATIONS

1. CAUTION: The United States federal law restricts the sale of this device by or on the order of a licensed physician or a licensed practitioner.
2. The device must be inserted immediately after the patient has passed stool or after the rectum is confirmed to be void of stool.
3. This device is for single use only and should not be re-used. Once deployed, the inherent design of the device does not allow re-use. Do not attempt to reposition the indwelling diverter using transit sheath or any other section of the device in case of device migration or otherwise. If attempted, device damage and/or patient injury may occur.
4. The physician must use their discretion in using the device after having assessed the patient's medical history and size of hemorrhoid(s).
5. Caution must be exercised in patients with an inflammatory bowel condition or a previous history of anorectal surgery.
6. Care should be exercised while inserting the device in patients who have a tendency to bleed from either anticoagulant/antiplatelet therapies or from an underlying condition/treatment.
7. Notify a physician immediately if any of the following occurs:
   - rectal pain
   - rectal bleeding
   - abdominal discomfort
8. 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.
9. The diverter can be flushed using the irrigation port or the sheath can be milked to break down or move fecal discharge in case the device lumen becomes occluded with fecal material. Repeat the irrigation procedure as often as necessary to maintain proper functioning of the device. If repeated flushing with saline does not return the flow of stool through the transit sheath, the device should be inspected to ascertain that there is no external obstruction (i.e. pressure from a body part, a piece of equipment, etc.). If no source of obstruction of the device is detected, use of the device should be discontinued.
10. There is an inherent risk in handling fecal discharge and bodily secretions. Adequate precautions, per hospital guidelines, must be exercised while handling the device.
11. 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.
12. Some leakage of moisture or fecal discharge may be visible along the periphery of the device in patients with severe diarrhea or if the collection bag is full.
13. The patient may involuntarily expel the device if any of the following happens:
    - stool consistency changes to normal/formed stool
    - device lumen gets occluded with fecal material
    - rectum is not void of stool before device deployment
14. If any blood is visible along the periphery of the device or any wet redness of stool is observed in the transit sheath or collection bag, discontinue the use of the device and notify the physician.
15. Ensure that the fluid retention clamp is detached from the transit sheath after a fluid retention procedure is complete.