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

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.

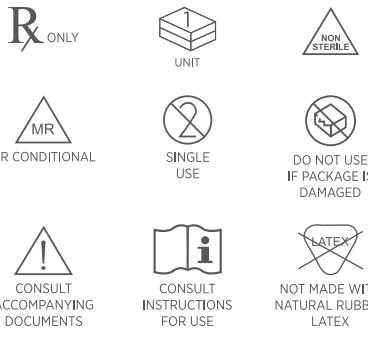
POSSIBLE ADVERSE EVENTS

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 device or collection bag replacement should be assessed every change in nursing shift or at least once every 8 hours.
3. Device irrigation and milking of the transit sheath should be performed every change in nursing shift or at least once every 8 hours.
4. The uninterrupted use for this device, including replacement with other same devices, should not exceed 29 days.
5. The device may be removed as needed to perform patient assessment.



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IFU-22014-001-03

Qora®
Stool Management Kit

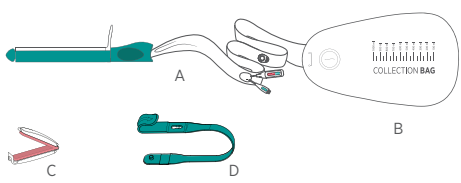
INSTRUCTIONS FOR USE

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.

Read all Instructions for Use before using the product.

PRODUCT DESCRIPTION

The Qora® Stool Management Kit (SMK) contains:
A. One pre-loaded fecal diverter
B. One odor-barrier collection bag
C. One fluid retention clamp
D. One collection bag hanger



The use of Qora® SMK helps maintain skin integrity, prevents soiling of the bedsheet and patient apparel, and does not interfere with normal physiological functioning of the rectum.

The applicator is used to hygienically insert and deploy the indwelling diverter of the collection device into the rectum to manage stool in bedridden patients suffering from fecal incontinence or diarrhea. When deployed using the applicator, the soft indwelling diverter self-expands in the rectum of the patient. The diverter contains and directs fecal material into an external collection bag. The collection bag can be replaced once filled with fecal material.

Along the transit sheath are three ports, each with a separate access. A sample port on the transit sheath allows for the collection of stool samples through a slip-tip syringe. Two ports attached to the transit sheath adapter are each used to irrigate the indwelling diverter and withdraw the device after use. The port marked IRRIGATE is used for irrigating/flushing the device through a Luer lock syringe. The port marked "HOLD HERE AND PULL" is used to activate the withdrawal mechanism. The withdrawal mechanism provides a trauma-free way to retrieve the indwelling diverter from the patient.

The fluid retention clamp is an accessory used to assist care providers in procedures requiring fluid retention within the rectum. The clamp is placed on the transit sheath, proximal to the patient, before administration of fluid through the irrigation port attached to the transit sheath adapter, and is to be removed after the procedure is complete.

INDICATIONS FOR USE

The Qora® Stool Management Kit is 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. Uninterrupted use for this device, including replacement with other same devices, should not exceed 29 days.

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 or allergic to any components within the kit

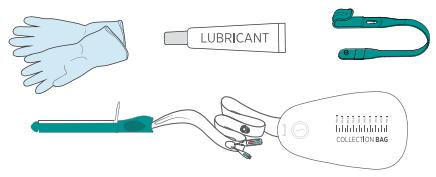
MRI SAFETY INFORMATION

Non-clinical testing demonstrated that the Qora® Stool Management Kit is MR Conditional. A patient with this device may be scanned safely under the following conditions. Failure to follow these conditions may result in injury to the patient.

Static Magnetic Field	1.5-T and 3.0-T
Maximum Spatial	9-T/m
Field Gradient	(900-gauss/cm)
Type of RF Excitation	Cicularly Polarized (CP)
Transmit RF Coil Info.	No transmit RF coil restriction. Following may be used: Transmit body RF coil and all receive-only RF coil combinations. In addition the following may be used: Transmit/receive head, knee, wrist RF coil, etc.
Operating Mode of MR	Normal Operating mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal operating mode)
Limits on Scan duration	Whole body averaged SAR : 2W/kg for 60 minutes of continous RF exposure.
MR Image artifact	The presense of the device produces an image artifact. Carefully select pulse sequence parameters if it is located in the area of interest.

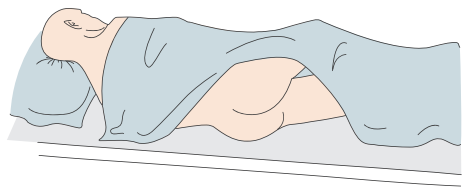
PREPARATION OF DEVICE

1. In addition to the Qora® Stool Management Kit, lubricant and gloves will be required.
2. Ensure the nurse/trained hospital or nursing home personnel inserting the device is wearing gloves.
3. Unpack the device and set up station near the patient. Unfold the length of the device to lay flat on the bed, extending the collection bag towards the foot of the bed.



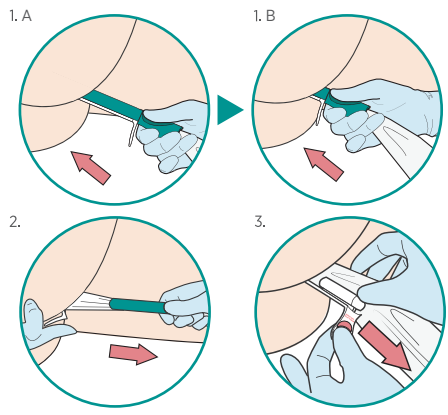
PREPARATION OF PATIENT

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.



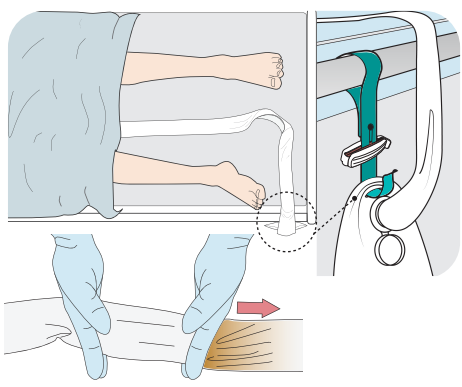
INSERTION OF DEVICE

1. Apply lubricant generously along the distal half of the applicator and gradually insert it into the anal opening until the white applicator stopper of the device touches the coccyx bone of the patient. Ensure that the applicator stopper is facing towards the patient's backside during insertion. If the applicator cannot be fully inserted until the white stopper touches the coccyx bone, discontinue the procedure and discard the device according to institutional protocol.
2. Firmly hold the white applicator stopper against the patient. Gradually withdraw the green applicator sleeve towards yourself over the transit sheath until the applicator sleeve is completely removed from inside the patient. The diverter has now self-expanded inside the patient's rectum and does not require any secondary operation for expansion.
3. Gradually withdraw the white applicator stopper over the transit sheath towards yourself until it is completely removed from inside the patient. Discard all components of the applicator according to institutional protocol.



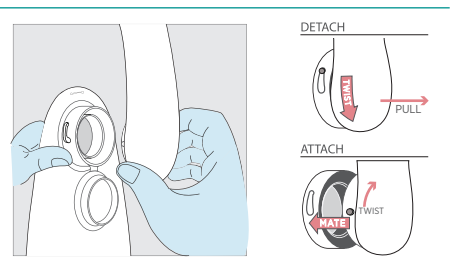
MAINTENANCE OF DEVICE

1. Lay the device flat on the bed, in between the patient's legs when resting in the supine position, or behind the patient when resting in lateral position. Ensure that the transit sheath is flat and straight on the bed to prevent lumen occlusion. The collection bag should be hung off the side of the patient's bed using the collection bag hanger.
2. Ensure there are no kinks or twists along the length of the device and the transit sheath is laid straight towards the foot of the bed. Make appropriate adjustments to the patient's attire if needed.
3. No portion of the device, including the ports, transit sheath, and collection bag, should be under the patient.
4. When repositioning or maneuvering the patient, first move the collection bag to a location in which excessive tension will not be placed on the device and then reposition the patient.
5. Gently milk the transit sheath as needed to drain any residual fecal matter into the collection bag.



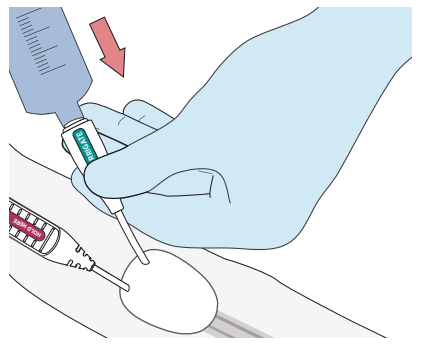
EXCHANGE OF COLLECTION BAG

1. To exchange the bag, hold the bag and sheath connectors upright.
2. Disengage the collection bag by carefully rotating the bag connector counterclockwise from the transit sheath connector.
3. Close the bag connector lid and discard the used bag according to institutional protocol.
4. To add a fresh bag, mate the collection bag connector to the transit sheath connector and rotate clockwise until they are locked together.



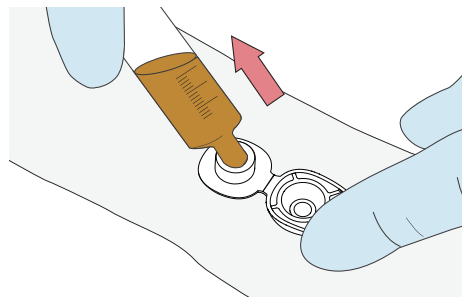
IRRIGATION OF DEVICE

1. To irrigate the device, you will need to obtain a female Luer lock syringe. This is not included in the device packaging.
2. Fill the Luer lock syringe with 30-60 ml of saline solution at room temperature.
3. Attach the Luer lock syringe to the port marked IRRIGATE, and depress the plunger. Ensure there are no twists or kinks in the fluid delivery tube.
4. Detach the Luer lock syringe from the irrigation port.
5. 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.



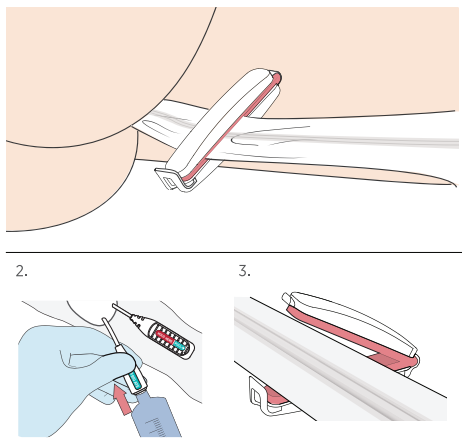
SAMPLING OF STOOL

1. In preparation for stool sampling, you will need to obtain a slip-tip syringe. This is not included in the device packaging.
2. Tilt or milk the transit sheath to collect fecal matter around the sample port.
3. Uncap the sample port and insert the slip-tip syringe into the sample port valve and draw the appropriate sample of fecal matter into the syringe. Withdraw the syringe.
4. Secure the cap back onto the sample port.
5. Transfer the stool sample into a collection device according to institutional protocol.
6. Discard the stool-sampling syringe according to institutional protocol.



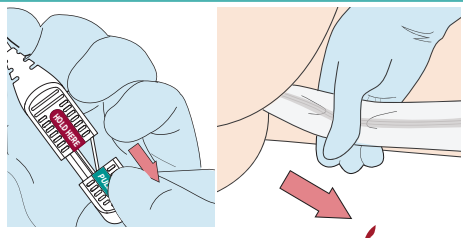
FLUID RETENTION PROCEDURE

1. In preparation for procedures requiring fluid retention, you will need to obtain the fluid retention clamp and a Luer lock syringe. Luer lock syringes are not included in the device packaging.
2. Prepare the fluid as required for the procedure and fill the Luer lock syringe with the prescribed volume of fluid.
3. Position the patient in Sims' position. Attach the fluid retention clamp on the transit sheath, proximal to the anal orifice. Ensure the sheath is free of creases, kinks, and folds.
4. Attach the Luer lock syringe to the port marked IRRIGATE, and depress the plunger to instill the prescribed volume of fluid.
5. After fluid administration is complete, detach the Luer lock syringe from the irrigation port.
6. Maintain the patient in Sims' position for retaining small volume fluids within the rectum.
7. For large volume fluid retention, it may be beneficial to position the patient in Trendelenburg position.
8. Let the fluid dwell in the rectum for the prescribed duration.
9. Detach the fluid retention clamp and milk as needed to drain any residual fluid or fecal matter into the collection bag.



REMOVAL OF DEVICE

1. Ensure you are wearing gloves and the patient is in a left lateral Sims' (side-lying) or a 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.
2. Hold the cap of the port marked "PULL" with your dominant hand and grasp the port/body "HOLD HERE" with your other hand. Pull the cap towards yourself until the white tether is taut.
3. The indwelling diverter has collapsed in the rectum. Release the cap and using your dominant hand, slowly retrieve the device by holding the transit sheath close to the anatomy.
4. Discard the device according to institutional protocol.



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