**Directions for Use**

### Preparation of Device & Patient

- In addition to the device kit, gloves and lubricant will be required.
- Using the syringe provided, remove the air that is in the balloon by attaching the syringe to the white inflation port (marked “x<45mL”) and withdraw the plunger.
- Remove the supplied syringe and fill it with only 45mL of water or saline and connect the syringe to the white inflation port of the catheter.
- Securely attach the collection bag to the connector at the end of the catheter. The small hook on the catheter is designed to help secure connection from the bag to the connector.
- Use your date printed labels to write insertion date and time. Place on the allocated space at the end of bead strap.

### Insertion of Device

- Untie the length of the catheter to lay it flat on the bed, extending the collection bag toward the foot of the bed.
- Insert a lubricated gloved finger into the blue finger pocket for digital guidance during device insertion (the finger pocket is located above the position indicator line).
- Coat the balloon end of the catheter with lubricant.
- If the PROTECT dome indicates at less than 30mL of fluid, withdraw the fluid and reposition the balloon in the rectal vault.
- After repositioning, fill the balloon as described above. DO NOT fill with more than 45mL of fluid.
- The red PROTECT indication dome will start to indicate if the balloon is overfilled beyond the maximum 45mL of fluid. If the red PROTECT indication dome is fully inflated, assess patient’s position, fully deflate the balloon and repeat the balloon inflation process. Stop inflation once green dome has signalled optimal fill.
- Grasp the catheter and gently insert the balloon end through the anal sphincter until the balloon is beyond the external orifice and well inside the rectal vault.
- The finger may be removed or remain in place in the rectum during initial balloon inflation.

### Irrigation, Maintenance & Removal of Device

- To irrigate the device, fill the syringe with water at room temperature, attach the syringe to the blue irrigation/medication port (marked “IRRIG./Rx”) and slowly depress the plunger.
- Clinicians should take extra care to use the blue irrigation/medication port only when irrigating.
- DO NOT irrigate through the white inflation port (marked “x<40mL”) as this would lead to over-inflation of the retention balloon and the device would not be irrigated as intended.
- If repeated flushing with water does not return the flow of stool through the catheter, the device should be inspected to ascertain that there is no external obstruction (i.e. pressure from a body part, piece of equipment, or resolution of diarrhea).
- If no source of obstruction of the device is detected, use of the device should be discontinued.
- Change collection bag as needed. Discard used bags according to institutional protocol for disposal of medical waste.
- Observe the device frequently for obstructions from kinks, solid fecal particles or external pressure.
- To remove the catheter from the rectum, the retention balloon must first be deflated.
- Attach the syringe to the white inflation port (marked “x<45mL”) and slowly withdraw all fluid from the retention balloon.
- Disconnect the syringes and discard.
- Grasp the catheter as close to the patient as possible and slowly remove from the anus.
- Dispose of device in accordance with institutional protocol for disposal of medical waste.

### Medication Administration

- Attach the supplied syringe and flush the irrigation line with 10mL of water.
- Prepare a new syringe with prescribed medication.
- Position the cinch clamp loosely on the catheter at the black indicator line. Connect syringe to the Blue irrigation/medication port (“IRRIG./Rx”) and administer medication.
- Clinicians should take extra care to use the blue irrigation/medication port only when delivering medication.
- DO NOT administer medication through the white inflation port (marked “x<45mL”) as this would lead to over-inflation of the retention balloon and the patient would not receive medication as intended.
- To ensure delivery of medication into the rectum immediately flush the irrigation line with at least 50mL of water.
- Tighten the cinch clamp on the catheter to ensure no flow through the catheter (ensure the second notch is engaged; squeeze tightly using forefinger and thumb of both hands to ensure a good seal).
- Allow the medication to dwell in the rectum for the desired amount of time as dictated by the prescribing physician.
- Remove the cinch clamp.
- Attach a new syringe (not supplied) and flush the irrigation line with 10mL of water.
- Dispose of the syringe according to institutional policy.
- To collect a sample from the catheter, open the dark blue sample port cap.
- Press the tip of a Luer-slip syringe (aka catheter tip or “Toomey” syringe) through the slit inside of the sampling port to access the interior of the catheter.
- Withdraw the syringe plunger to collect the sample.
- Withdraw the syringe and close the dark blue sampling port cap.

### Fecal Management System

- Position the patient in left side-lying position; if unable to tolerate, position the patient so access to the rectum is possible.
- Perform a digital rectal exam to evaluate suitability for insertion of device.
- The rectum should have adequate anal tone and be free of solid stool or any in-dwelling or anal device prior to insertion.
Directions for Use

Product description
The Flexi-Seal® PROTECT Fecal Management System contains:
1. soft catheter tube assembly,
2. Luer-Lock Syringe,
3. collection bags with filter, and 1 cinch clamp.

The soft catheter is inserted into the rectum for fecal management to contain and divert fecal waste in order to protect the patient’s skin and keep the bedding clean. There is a low-pressure retention balloon at the distal end and a connector for attaching the collection bag at the other end. There is a re-use under the balloon for the clinician’s finger allowing the device to be positioned digitally.

A blue and a white port are attached to the side of the catheter. The blue port, marked “IRRIG. /Rx” is used to flush the device if indication when the balloon over-inflation occurs. A white cap when the low pressure retention balloon is filled to its optimal indication dome provides a visual and tactile indication as to color (i.e. the dome closest to the catheter tubing) and red color two fill indicating domes (PROTECT indicator domes), green color – Abdominal symptoms such as distension/pain – Rectal bleeding

• for pediatric patients (patients under 18 years of age) as its use has not been tested in this population
• for more than 29 consecutive days

2. The Flexi-Seal® PROTECT Fecal Management System should not be used in individuals who
• have had rectal surgery within the last year
• have any rectal or anal injury
• have calibre of significant size and/or symptoms
• have a rectal or anal stricture or stenosis
• have a suspected or confirmed rectal/ anal tumor
• have any in-dwelling rectal or anal device (e.g. thermometer) or delivery mechanism (e.g. suppositories or enemas) in place
• are sensitive to or who have had an allergic reaction to any component within the system

Warnings
• Warning: Clinicians should be aware that there are very limited clinical data on the use of in-dwelling fecal management systems after 14 days continued use.
• Warning: There is a potential risk of misconnections with connectors from other healthcare applications, such as intravenous equipment, breathing and driving gas systems, urethral/urinary, limb cuff inflation neural devices and other enteral and gastric applications.
• Warning: Fatality following these instructions for use may increase the likelihood of an adverse event.
• Warning: Patients should be monitored daily for a physician notified immediately if any of the following occur - Rectal pain - Rectal bleeding - Abdominal symptoms such as distension/pain
• Warning: Over inflation of the retention balloon has the potential to increase the risk of adverse events including rectal pain, bleeding, ulcerations, and possible perforations.
• Warning: There is a danger of fecal obstructions with this device.

Precautions and observations
1. Close attention should be exercised with the use of the device in patients who have inflammatory bowel conditions or who have had rectal surgery. The physician should determine the degree and location of inflammation or wound of surgery (e.g., local or anastomosis) within the colon/rectum prior to considering use of this device in patients with such conditions.
2. Care should be exercised in using this device in patients who have a tendency to bleed from either anti-coagulant/ antiplatelet therapy or underlying disease. If signs of rectal bleeding occur, remove the device immediately and notify a physician.
3. The device should be used with caution in patients with spinal cord injury because of the possibility of the development of autonomic dysreflexia.
4. Remove any indwelling or anal device prior to insertion of the Flexi-Seal® PROTECT FMS and do not insert any other device within the rectum while the Flexi-Seal® PROTECT FMS is in place.
5. Ensure that the patient does not lie or sit on the catheter as this could lead to localised pressure damage and contribute to the development of anal skin breakdown and/or rectal fissure.
6. Solid or soft-formed stool cannot pass through the catheter and will obstruct the opening. Use of the device is not indicated for solid or soft-formed stool.
7. Small amounts of moisture or seepage around the catheter is anticipated. To avoid skin irritation, initiate an appropriate institutional skin care protocol. At a minimum, the skin should be kept clean, dry and protected with a moisture barrier product.

General Guidelines
The device may be changed as needed to perform normal patient assessment.

The device is not intended for use for more than 29 consecutive days.
If the product packaging is damaged, do not use.

Ordering information

Product Ordering Codes

Flexi-Seal® PROTECT FMS Kit* (1 kit/box, 1bag)
APS Filter (10/box) 411108
Privacy™ Collection Bag with APS Filter (10/box) 421630
411108

To learn more, call: 1-800-422-8811
Mon-Fri, 8:30 AM-7:00 PM
www.convatec.com

* This device is for single use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination. Physical properties of the device may no longer be optimal for intended use.

1. Care should be exercised in using this device in patients who have a tendency to bleed from either anti-coagulant/ antiplatelet therapy or underlying disease. If signs of rectal bleeding occur, remove the device immediately and notify a physician.
2. The Flexi-Seal® PROTECT FMS should be discontinued.
3. Clinicians should take extra care to use the blue irrigation/medication port only when irrigating and delivering medication. DO NOT irrigate or administer medication through the white inflation port marked “≤45ml”.
4. The device is intended for liquid to semi-liquid stool only. Discontinue the use of the device if the patient’s bowel control, consistency and frequency of stool begin to return to normal.
5. Adverse events could occur:

- Leakage of stool around the device
- Rectal/anal bleeding due to pressure necrosis ulceration of rectal or anal mucosa
- Peri-anal skin breakdown
- Temporary loss of anal sphincter muscle tone
- Infection
- Bowel obstruction
- Perforation of the bowel

13. This device is for single use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination. Physical properties of the device may no longer be optimal for intended use.

14. If there is no flow of stools in 24hr period then the following actions should occur,

- Irrigation (see section D. Irrigation of the device, in Directions for use) or
- removal of the device