**Preparation of Device & Patient**

- In addition to the device kit, gloves, lubricant and water or saline will be required.
- Using the syringe provided, remove the air that is in the balloon by attaching the Luer syringe to the white inflation port (marked “≤45ml”) and withdraw the plunger.
- Insert 3 or 4 Convatec Diamonds™ sachets, one at a time, into the bag opening.
- Grasp the catheter and gently insert the balloon end through the anal sphincter until the balloon is beyond the external orifice and inside the rectal vault.
- The finger may be removed or remain in place in the rectum during initial balloon inflation.
- Insert 3 or 4 Convatec Diamonds™ sachets, one at a time, into the bag opening and gently insert the catheter connector into the bag connector. Do not try the bag against the bag connector.
- Locate the three prongs on the bag connector and align them to the corresponding slots on the catheter connector.
- Gently push the catheter into the bag connector and keep clockwise to secure.
- Use your labels to write insertion date and time. Place on the allocated space at the end of bed step.

**Insertion of Device**

- Unless the length of the catheter to lay it flat on the floor, submerge the collection bag toward the foot of the bed.
- Insert a lubricated gloved finger into the blue position indicator line (the finger post is located above the position indicator line).
- Coat the balloon end of the catheter with lubricant.
- Grasp the catheter and gently insert the balloon fully into the retainer so that the pin is visible.
- With the insertion finger removed, the green dome will indicate the optimal fill level for the anatomy. Stop inflation once the green dome has signalled optimal fill.
- Under no circumstances should the balloon be inflated with more than 45ml of fluid.
- With the insertion finger removed, the green dome will indicate the optimal fill level for the anatomy. Stop inflation once the green dome has signalled optimal fill.
- Position the length of the flexible catheter along the side of the rectum and gently pull on the soft catheter to check that the balloon is secure in the rectum and that it is positioned against the rectal floor.
- Regularly observe changes in the location of the position indicator line as a means to determine movement of the retention balloon in the patient's rectum. This may indicate the need for the balloon or device to be repositioned.

**Irrigation, Maintenance & Removal of Device**

- To irrigate the device, fill the syringe with water at normal temperature, attach the purple ENFit™ syringe to the purple ENFit™ irrigation/medication port (marked “IRRIG.Rx”) and slowly depress the plunger.
- Clinicians should take extra care to use the purple ENFit™ irrigation/medication port only when irrigating.
- DO NOT irrigate through the white inflation port (marked “≤45ml”) 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.
- To remove the collection bag, push the catheter connector into the bag connector and then hold counter-clockwise to disengage. Gently pull the catheter connector from the collection bag. Use the thumb to push the back of the cap into the bag connector which is to be held in place from the rear of the collection bag using the line and index fingers. Use thumb to press around the cap to ensure full bag closure.
- Discard used bags according to institutional protocol for disposal of medical waste.
- Observe the device frequently for obstructions from lint, solid fecal particles or external pressure.
- To remove the catheter from the rectum, the retention balloon must first be deflated.
- Attach the Luer syringe to the white inflation port (marked “≤45ml”) and slowly withdraw all fluid from the retention balloon.
- Disconnect the Luer syringe 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 purple ENFit™ syringe and flush the irrigation line with 10ml of water.
- Prepare a new purple ENFit™ syringe with prescribed medication.
- Position the cinch clamp loosely on the catheter at the blue indicator line. Connect syringe to the purple ENFit™ irrigation/medication port (marked “IRRIG.Rx”) and administer medication.
- Clinicians should take extra care to use the purple ENFit™ irrigation/medication port only when delivering medication.
- DO NOT administer medication through the white inflation port (marked “≤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 (the secure 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. DO NOT administer medication through the white inflation port (marked “≤45ml”) as this would lead to over inflation of the retention balloon.
- To remove the cinch clamp.
- Flush the irrigation line with 10ml of water.
- Dispose of the syringe according to institutional policy.

**Sampling**

- To collect a sample from the catheter, open the dark blue sample port cap.
- Prise the tip of a Luer-slip syringe (aka catheter tip or “Timmer” syringe) through the aid inside of the sampling port to access the interior of the catheter.
- Withdraw the Luer-slip syringe plunger to collect the sample.
- Withdraw the Luer-slip syringe and close the dark blue sampling port cap.
**Directions for Use**

**Product Description**
The Flexi-Seal™ PROTECT PLUS Fecal Management System with ENFit™ Connector includes:
1. Self-closing soft catheter tube assembly;
2. Luer-Lock syringes;
3. Purple ENFit™ syringes;
4. cinch clamp;
5. Privacy™ collection bag with filter;
6. ConvaTec Diamonds™ gelling and odor control sachets.

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 recess under the balloon for the clinician’s finger allowing the device to be positioned digitally.

A purple and a white port are attached to the side of the catheter. The white port, marked “safety”, is used to inflate the retention balloon after the device has been inserted into the patient’s rectum. The purple port is equipped with two fill indicating domes, green color (i.e. the dome closest to the catheter tubing) and red color (i.e. the dome furthest from the catheter tubing). The green fill indication dome provides a visual and tactile indication when the balloon over-inflation occurs. A white cap is provided to close off the white inflation port after the balloon inflation. The purple ENFit™ port, marked “IRID”, “IR” is used to flush the device if needed and administer medication, if prescribed. A dark blue sampling port is also present if stool samples are required to be taken by the clinician.

**Indications**
For use to manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications. The device is intended for use in adult patients.

**Contraindications**
1. This product is not intended for use:
   - for more than 29 consecutive days
   - for pediatric patients as its use has not been tested in this population
2. The Flexi-Seal™ PROTECT PLUS Fecal Management System with ENFit™ Connector should not be used on individuals who:
   - have suspected or confirmed rectal mucosal impairment, i.e. severe proctitis, ischemic proctitis, mucosal ulcerations
   - have had rectal surgery within the last year
   - have any rectal or anal injury
   - have hemorrhoids 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 misconceivability with connectors from other healthcare applications, such as intravenous equipment, breathing and driving gas systems, ventilator tubing or infusion devices and other enteral and gastric applications.
- **Warning:** Not following these instructions for use may increase the likelihood of an adverse event.
- **Warning:** Patients should be monitored daily for and 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. If the output appears darker than usual and/or may contain black flecks. This is a visible indication of the ConvaTec Diamonds™. If monitoring output color, please use the sampling port or catheter. In case of contact with eyes, rinse immediately with clean water and seek medical advice. Store the ConvaTec Diamonds™ in a cool dry place. Do not open sachet.

**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 extent of surgery (e.g. location of 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 PLUS FMS with ENFit™ Connector and do not insert any other devices into the rectum when the Flexi-Seal™ PROTECT PLUS FMS with ENFit™ Connector is in place.
5. Ensure that the patient does not lie or sit on the catheter as this could lead to localized pressure damage and contribute to the development of anal skin breakdown and/or restrict fecal flow.
6. Solid or soft-formed stool cannot pass through the catheter and will obstruct the opening. The 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.
8. If the catheter becomes blocked with feces, it can be rinsed with water using the irrigation port only (see “Irrigation, Maintenance & Removal of Device”).
9. Do not use the white inflation port (marked “545ml”) to irrigate. If obstruction of the catheter is due to solid stool, use of the device should be discontinued.
10. Clinicians should take extra care to use the purple ENFit™ irrigation/medication port only when irrigating and delivering medication. DO NOT irrigate or administer medication through the white inflation port (marked “545ml”).
11. Discontinue the use of the device if the patient’s bowel control, consistency and frequency of stool begin to return to normal.
12. If the patient is regularly and closely monitored, patients may be seated for short periods i.e. for up to 2 hours, as part of daily nursing care. During this period of seating, regular monitoring should be made to ensure the tubing is never blocked or kinked and to check for and avoid pressure damage to the anal/peri-anal region. Clinicians should be alert that for some patients seating time needs to be reduced due to the possibility of pressure damage to the anal/peri-anal region - Adjust balloon fill volume in case the red indication dome pops.
13. As with the use of any rectal device, the following adverse events could occur:
   - Leakage of stool around the device
   - Recalctal 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

**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 or content are visibly damaged, do not use.
- For more detailed instructions refer to the Directions for Use provided in the device package.

**MRI Safety Information**
Non-clinical testing has demonstrated that the Flexi-Seal™ PROTECT PLUS with ENFit™ Connector is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial gradient of 2000 gauss/cm (20 Tm)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) or 4 W/kg (First Level Controlled Operating Mode)

The presence of this device may produce an image artifact.

**Ordering Codes**

| Flexi-Seal™ PROTECT PLUS FMS kit with ENFit™ Connector | 421703 |
| Flexi-Seal™ Protect Plus Privacy™ Collection Bag with APS Filter | 422291 |

**www.flexi-seal.convatec.com**

**IFU Training Video**