Directions for Use

Flexi-Seal™ PROTECT PLUS with ENFit™ connector

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.

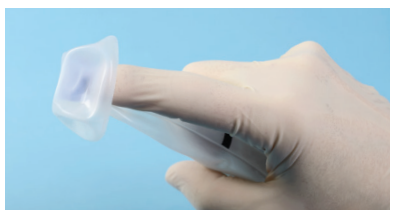
- Remove the supplied Luer syringe and fill it with only 45ml of water or saline and connect the syringe to the white inflation port of the catheter.

- Insert 3 or 4 ConvaTec Diamonds™ sachets, one at a time, into the bag opening.
- **Do not tear open the sachets**. **Do not force the sachets**, if resistance is met then gently move the sachet sideways ensuring they are placed at the bottom of the bag.
- **WARNING: DO NOT use the bag content for source of clinical information on stool color or consistency as it is modified by the gelling agent. Do not open sachet**.

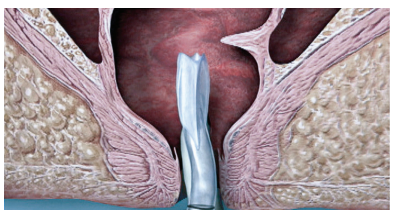
- Position the catheter connector at a 90 degree angle to the bag connector opening and gently insert the catheter connector into the bag connector. Do not trap the bag against the bag connector.
- Locate the three pins on the bag connector and align them to the three corresponding slots on the catheter connector.
- Gently push the catheter connector into the bag connector and twist clockwise to securely couple the two parts.
- Use your labels to write insertion date and time. Place on the allocated space at the end of bead strap.

- 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.

Insertion of Device



- Unfold 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.



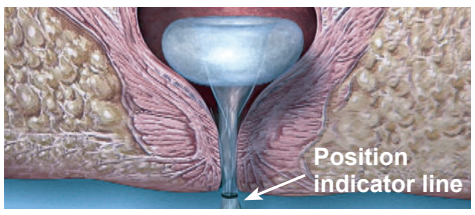
- Grasp the catheter and gently insert the balloon end through the anal sphincter until the balloon is beyond the external orifice and well inside the rectal vault.
- The finger may be removed or remain in place in the rectum during initial balloon inflation.

- Begin inflating with water or saline by slowly depressing the Luer syringe plunger.
- **Never inflate the retention balloon with more than 45ml of water.**

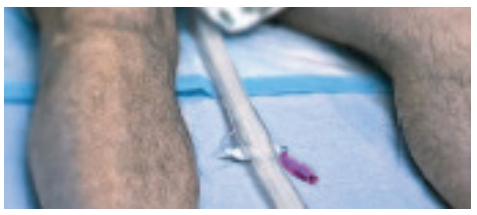
- With the insertion finger removed, the green dome will indicate once the balloon has reached the optimal fill level for the anatomy. Stop inflation once the green dome has signalled optimal fill.
- **Under no circumstances should the balloon be inflated with more than 45ml of fluid.**

- If the green 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 indication dome will start to indicate if the balloon is overfilled beyond the maximum 45ml of fluid. If the red indication dome starts to inflate, assess patient’s position, fully deflate the balloon and repeat the balloon inflation process. Stop inflation once green dome has signalled optimal fill.

- Remove the Luer syringe from the inflation port, 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.
- Take note of the position indicator line relative to the patient’s anus.
- 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.



- In the event of expulsion of the device, deflate the balloon fully; rinse the balloon end of the catheter and reinsert following the instructions for ‘Insertion of Device’.
- A rectal exam should be conducted prior to re-insertion to verify that no stool is present.
- If expulsion continues for more than three episodes discontinuation of the device should be considered.

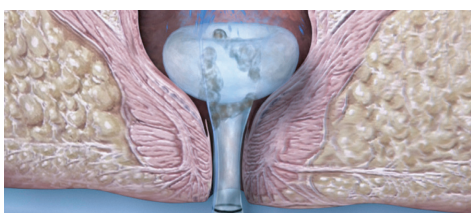


- Position the length of the flexible catheter along patient’s leg avoiding kinks and obstruction.

- Hang the bag by the bead strap on the bedside at a position lower than that of the patient.

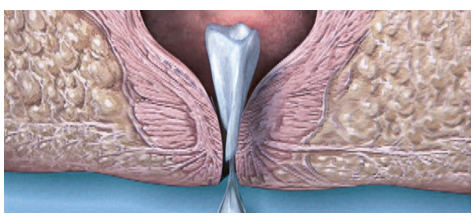
Irrigation, Maintenance & Removal of Device

- To irrigate the device, fill the syringe with water at room 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 twist 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 fore 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 kinks, 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 black indicator line. Connect syringe to the purple ENFit™ irrigation/medication port (“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 (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.
- 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.
- 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 Luer-slip syringe plunger to collect the sample.
- Withdraw the Luer-slip syringe and close the dark blue sampling port cap.

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Directions for Use

Flexi-Seal™ PROTECT PLUS
with ENFit™ connector

Product Description

The Flexi-Seal™ PROTECT PLUS Fecal Management System with ENFit™ Connector contains:

1 Self-closing soft catheter tube assembly;
1 Luer-Lock syringe; 1 Purple ENFit™ syringe; 1 cinch clamp
1 Privacy™ collection bag with filter;
4 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 "≤45ml" is used to inflate the retention balloon after the device has been inserted into the patient's rectum. This white inflation 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 as to when the low pressure retention balloon is filled to its optimal volume. A red-dome fill indicator 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 "IRRIG. /Rx" 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 misconnections with connectors from other healthcare applications, such as intravenous equipment, breathing and driving gas systems, urethral/urinary, limb cuff inflation neuraxial 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 product.
- **Warning:** The output may appear 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 while 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 localised 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").

   Do not use the white inflation port (marked "≤45ml") to irrigate. If obstruction of the catheter is due to solid stool, use of the device should be discontinued.
9. **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 "≤45ml").**
10. Discontinue the use of the device if the patient's bowel control, consistency and frequency of stool begin to return to normal.
11. 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.
12. As with the use of any rectal device, the following 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 stool in a 24 hour period then the following actions should occur: irrigation (see "Irrigation, Maintenance & Removal of Device"), or removal of the device.
15. The collection bag should be coupled to the catheter in the correct orientation as shown on the previous page. Reading measurements of the collection bag is approximate only.
16. Do not use if package is damaged. Do not use Diamonds™ sachets if sachets are significantly broken.

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 field gradient of 2,000 gauss/cm (20 T/m)
- 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.

Consult instructions for use	Do not re-use	Do not use if packaging is damaged	Rx ONLY	CE
			Federal (U.S.A.) law restricts this device to sale by or on the order of a physician	

Ordering Codes	
Flexi-Seal™ PROTECT PLUS FMS Kit with ENFit™ Connector (1 kit/box, 1bag)	421703
Flexi-Seal™ Protect Plus Privacy™ Collection Bag with APS Filter (5/box)	422291

www.flexi-seal.convatec.com

IFU Training Video

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