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 Luer syringe to the white inflation port (marked “≤45ml”) and withdraw the plunger.
- Position the cinch clamp loosely on the catheter
- Attach the supplied syringe and flush the irrigation line
- 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.)
- In addition to the device kit, gloves and

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 port for digital guidance during device insertion (the finger port 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.
- In the event of expulsion of the device, deflate the balloon fully, remove 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.
- 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 indentation dome will start to indicate if the balloon is overfilled beyond the maximum 45ml of fluid. If the red indentation dome starts to inflate, assess patient’s position, fully deflate the balloon and repeat the balloon inflation process. Stop inflation once green dome has signaled optimal fill.
- The blue sampling port cap.
- After repositioning, fill the balloon as described above. DO NOT fill with more than 45ml of fluid.
- If a digital rectal exam to evaluate suitability for insertion of device.
- Position the patient in left side-lying position; if unable to tolerate, position the patient on their back. 

Irrigation, Maintenance & Removal of Device

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 firmly 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 “≤45ml”) as this would lead to over inflation of the retention balloon and the device would not be irrigated as intended.
- No source of obstruction of the device is detected, use of the device should be discontinued.
- 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 green dome has signaled optimal fill. Under no circumstances should the balloon be inflated with more than 45ml of fluid.
- 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 catheter connector into the bag connector and align them to the two corresponding slots on the catheter connector. 
- Gently push the catheter connector into the bag connector and finish clockwise to securely couple the two parts.
- Use your date printed labels to write insertion date and time. Place on the allocated space at the end of bead strap.
- To remove the catheter from the rectum, the retention balloon must first be deflated.
- Attach the Laer syringe to the white inflation port (marked “≤45ml”) and slowly withdraw all fluid from the retention balloon.
- Disconnect the Laer 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.
- Observe the device frequently for obstructions from kinks, solid fecal particles or external pressure.

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 (marked “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 “≤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 “Trossey” syringe) through the slit made 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 contains:
1. Self-closing soft catheter tube assembly;
2. Luer-Lock syringe; 1 cinch clamp
3. Plastic™ collection bag with filter

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 blue 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 Luer-Lock connector in the blue housing, marked “RRIG/R/Rx” is used to flush the device if needed and administer medication, if prescribed. A dark blue sampling port is also present if stool is used to flush the device if needed and administer medication.

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 should not be used on individuals who:
   - have suspected or confirmed rectal mucosal impairment,
     - i.e. severe proctitis, ischemic proctitis, mucosal ulcerations
   - have anal incontinence due to impotence, diarrhea, or ileostomy
   - have any rectal pain
   - have hemorrhoids of significant size and/or symptoms
   - have a rectal or anal stricture or stenosis
   - have any suspected or confirmed rectal/anal tumor
   - have any in-dwelling rectal or anal device (e.g. thermometer) or delivery mechanism (e.g. suppository)
   - or 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 misconceptions with connectors from other healthcare applications, such as intravenous equipment, breathing and driving gas systems, urethral/urinary, limb cuff inflation neuromuscular 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 - 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, ulcers, 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. See indication of the CovAntaC™ 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 CovAntaC™ 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 the 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 FSM and do not insert any other devices into the rectum while the Flexi-Seal™ PROTECT PLUS FSM 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 tubing. The Flexi-Seal™ PROTECT PLUS FSM is not intended for use with solid or soft-formed stool.
7. Small amounts of moisture or seepage around the catheter should be reduced due to the possibility of 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.
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 red 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 blue irrigation/maintenance port (marked “RRIG/R/Rx”) only when irrigating and delivering medication. DO NOT administer irrigation 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. 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 24hr 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. Readings of 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 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) of 4 W/kg (First Level Controlled Operating Mode)

The presence of this device may produce an image artifact.

Ordering Information
Product Ordering Codes
Flexi-Seal™ PROTECT PLUS FSM Kit
(1 kit/box, 1bag)
422303
Flexi-Seal™ Protect Plus Privacy™ Collection Bag
with APS Filter (5/box)
422281

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

Consult instructions for use
Do not re-use
Do not use if packaging is damaged
Caution

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

IFU Training Videos

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