**Directions for Use**

**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 syringe to the white inflation port (marked “545mL”) and withdrawing 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 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 tone and be free of solid stool or any in-dwelling or anal device prior to insertion.**

**Insertion of Device**

- **Remove any in-dwelling or anal device prior to insertion of Flexi-Seal™ SIGNAL™ FMS 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.**
- **Begin inflating with water or saline by slowly depressing the syringe plunger. Never inflate the retention balloon with more than 45mL of water.**
- **With the insertion finger removed, the SIGNAL™ dome will indicate once the balloon has reached the optimal fill level for the anatomy. There may be cases where the SIGNAL™ dome will not indicate if the space in the rectum is large.**
- **Under no circumstances should the balloon be inflated with more than 45mL of fluid.**

**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 “545mL”) 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 catheter from the rectum, the retention balloon must first be deflated.**
- **Attach the syringe to the white inflation port (marked “545mL”) and slowly withdraw all fluid from the retention balloon.**
- **Discard the syringe and discard.**
- **Hang the bag by the bead strap on the bedside at a position lower than that of the patient.**
- **To remove the catheter from the rectum.**
- **Position the length of the flexible catheter along patient’s leg avoiding kinks and obstruction.**
- **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 “545mL”) 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.**

**Sampling**

- **To collect a sample from the catheter.**
- **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 sampling port cap.**
Directions for Use

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™ SIGNAL™ FMS and do not insert any other devices into the rectum while the Flexi-Seal™ SIGNAL™ 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 skin breakdown and/or restrict fecal flow.
6. Solid or soft-formed stool cannot pass through the catheter and will obstruct the opening. For a minimum, the skin should be kept clean, dry and protected with a moisture barrier product.
7. Small amounts of moisture or seepage around the catheter may no longer be optimal for intended use. If obstruction of the catheter is due to solid stool, use of the device should be discontinued.

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, urostomy/ileostomy, 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. Never inflate the retention balloon with more than 45ml of water.

Product Description
The Flexi-Seal™ SIGNAL™ Fecal Management System contains:
1. soft catheter tube assembly,
2. Luer-Lock Syringe,
3. collection bags with filter, and
4. 1 chirch clamp.
The soft catheter is inserted into the rectum for 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.

Contraindications
1. This product is not intended for use in individuals who:
   • have had rectal surgery within the last year
   • have a suspected or confirmed rectal/anal injury
   • have any rectal or anal injury
   • have had rectal surgery (e.g. suppositories or enemas) in place
   • have had rectal surgery within the last year
   • have any rectal injury
   • have had rectal surgery within the last year
   • have had rectal surgery within the last year

2. The Flexi-Seal™ SIGNAL™ 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 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

Indications
For use to manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications.

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.