ConvaTec

Dignity for patients, Freedom for nurses

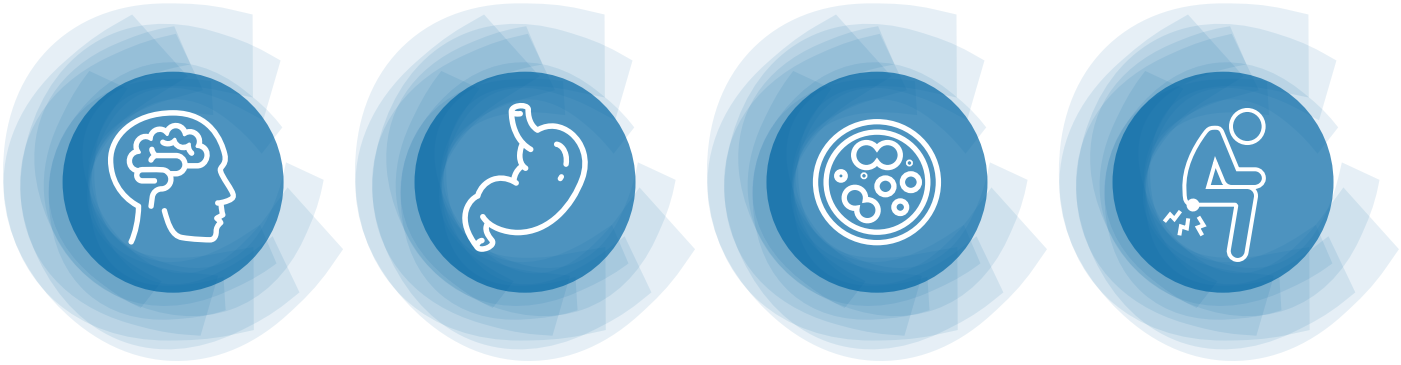
THE BURDEN OF FECAL INCONTINENCE

Prevalence

33% of the hospitalized patients had experienced fecal incontinence

58% of the ICU patients had experienced fecal incontinence

Common causes



Neurological Diseases	Disorders of Gut Motility	Clostridium Difficile Infection	Anal Sphincter Dysfunction
40.3%	**30.3%**	**11.3%**	**5.9%**

Complications of fecal incontinence pose great risk to patients

1. Pressure ulcers

Hospitalized adults with fecal incontinence are 22 times more likely to have pressure ulcers than patients without fecal incontinence, and patients with pressure ulcer spent 4 more days in average in the hospital than patients without pressure ulcer.

2. Incontinence-associated Dermatitis

According to a systematic review, the prevalence of incontinence-associated dermatitis range from 5.6% to 50%.

3. Clostridium Difficile Infection

The odds of Clostridium Difficile infection was 4.08 times greater among FI patients than non-FI patients Clostridium Difficile infection poses greater risk of cross infection among patients and healthcare professionals through fecal-oral transmission.

Stokes, A.L., et al., Prevalence of Fecal Incontinence in the Acute Care Setting. J Wound Ostomy Continence Nurs, 2016. 43(5): p. 517-22.
Bliss, D.Z., et al., Fecal incontinence in hospitalized patients who are acutely ill. Nursing Research, 2000. 49(2): p. 101-108.
Schiffmann, L., K. Kostev, and M. Kalder, Fecal and urinary incontinence are major problems associated with rectal cancer. Int J Colorectal Dis, 2020. 35(1): p. 35-40.
Beeckman, D., et al., Prevention and treatment of incontinence-associated dermatitis: literature review. Journal of advanced nursing, 2009. 65(6): p. 1141-1154.
https://dermnetnz.org/topics/incontinence-associated-dermatitis/#:~:text=Incontinence-induced%20dermatitis%20that%20has%20spread%20to%20involve%20the%20lower%20trunk
Kyne, L., et al., Underlying disease severity as a major risk factor for nosocomial Clostridium difficile diarrhea. Infection Control & Hospital Epidemiology, 2002. 23(11): p. 653-659.
Curcio, D., et al., Clostridium difficile-associated Diarrhea in Developing Countries: A Systematic Review and Meta-Analysis. Infect Dis Ther, 2019. 8(1): p. 87-103.
https://en.wikipedia.org/wiki/Clostridioides_difficile_infection#/media/File:How_C._difficile_spreads.png
Zhan, C. and M.R. Miller, Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. Jama, 2003. 290(14): p. 1868-1874.

MANAGE THE CAUSE, NOT THE SYMPTOMS

FLEXI-SEAL™ FMS – the most widely used fecal management system[3] is designed to effectively contain fecal waste and helps protect the patient's skin from breakdown that can lead to the development of pressure ulcers.

For Patients

- Designed to reduce the risk of skin breakdown and spread of infection.
- Better management of fecal incontinence can enhance patient comfort and dignity.*[4]
- Designed to manage unpleasant odor.

For Caregivers

- Designed to reduce the risk of skin breakdown and development of pressure ulcers.[5]
- Designed to effectively contain fecal waste which may contain C. difficile and other potentially pathogenic bacteria.
- Easy to insert and remove (see package insert for full instructions for use)

For ICU managers

- Designed to help reduce the risk of skin breakdown and spread of infection that can lead to extended length of stay and increased treatment costs.[1,2,6]
- Better management of fecal incontinence may help reduce mortality and morbidity.*[4]
- Flexi-Seal™ FMS may save labor and material resources.[7]

*Compared to traditional fecal incontinence management

Value and Advantage of FLEXI-SEAL™ FMS

		FLEXI-SEAL™ FMS	Traditional	Summary
Cost	**Hospital 1**	$CDN93.74	$CDN143.89	The use of FMS method would save $3,100-$3,400 dollars for FI patients during a 29-day period
	Hospital 2	$CDN61.15	$CDN104.85	
Caring time	**Normal patient**	120 minutes	348 minutes	The average caring time for health professionals per FI patient per day is shorter with FMS method than traditional method
	Complex patient	240 minutes	760 minutes	
Satisfaction rate (I was satisfied with the method)		77.8%	0%	The overall satisfaction rate in FMS is much greater than traditional method

Langill, M., et al., A budget impact analysis comparing use of a modern fecal management system to traditional fecal management methods in two canadian hospitals. Ostomy/wound management, 2012. 58(12): p. 25-33.
Pittman, J., et al., Methods of bowel management in critical care: a randomized controlled trial. J Wound Ostomy Continence Nurs, 2012. 39(6): p. 633-9.

FLEXI SEAL™ SIGNAL™ FMS

Sampling port

- Provides access to the catheter for safe and easy stool collection
- Designed to help decrease risk of exposure to infectious stool

Irrigation port

- Equipped to deliver prescribed medication rectally via the irrigation port
- Simple delivery process without complicating the use of the device

New end-to-end odor barrier in catheter – Zeolite

- Adopt to a range of bed sizes
- Accomodates a variety of patient heights and weights

Signal™ indicator

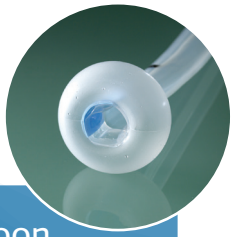
- Aids in assuring a comfortable and customized seal
- Indicates maximum fill capacity of soft retention balloon, at any volume ≤45ml, based on size of the rectal vault*

Flexible beat strap hanger

Patented blue finger pocket for ease of insertion

Charcoal-filtered with air vent bag

- 5 adhesive labels with date printing format, available in kit pack



Soft retention balloon with catheter & irrigation lumen allows for irrigation of medication into rectum, using medication clamp

*Maximum fill volume is ≤45ml. Signal indicator could pop before 45ml if the rectal.
For further information, please refer to the IFU.

PATIENT SELECTION CRITERIA FLOW CHART

Patient with temporary faecal incontinence

Yes

Contraindications (See box below)

Patient meets contraindication criteria

Not a candidate for FLEXI SEAL™ SIGNAL™ FMS[1]

No

Is the patient bedridden?

No

Not a candidate for FLEXI SEAL™ SIGNAL™ FMS[1]

Yes

Is the stool liquid or semi liquid?

No

Not a candidate for FLEXI SEAL™ SIGNAL™ FMS[2]

Yes

- Discuss FLEXI SEAL™ SIGNAL™ FMS option
- Digital rectal exam conducted by MD or healthcare professional to assess sphincter tone.

Based on digital rectal exam, is patient determined to be capable of retaining the device?

No

Not a candidate for FLEXI SEAL™ SIGNAL™ FMS[2]

Yes

Prior to inserting device, does the exam show signs of stool impaction?

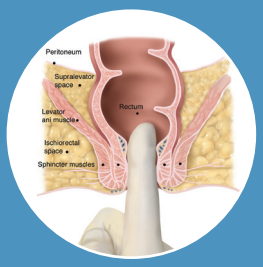
Yes

- Resolve stool impaction
- Reassess use of FLEXI SEAL™ SIGNAL™ FMS[2]

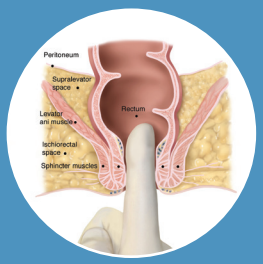
No

Insert FLEXI SEAL™ SIGNAL™ FMS per Directions of Use in package insert (not intended for use beyond 29 days)

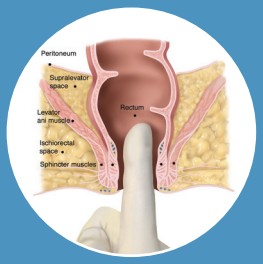
Rectal Sphincter Tone



Good



Fair



Poor

CONTRAINDICATIONS

Contraindicated for use with paediatric patients and in patients with:

- Large bowel or rectal surgeries within the last year
- Rectal or anal injuries
- Rectal or Anal stenosis or stricture
- Suspected or confirmed rectal mucosa impairment e.g. severe proctitis, ischemic proctitis and mucosal ulcerations
- Suspected or confirmed rectal/anal tumours
- Haemorrhoids of significant size
- Faecal impaction
- Indwelling, external rectal or anal device is in situ
- A need for rectal or anal procedures exists
- Allergies to product components

References:
1. FLEXI SEAL™ SIGNAL™ FMS Guidelines, CCC147.
2. FLEXI SEAL™ SIGNAL™ FMS Directions of Use / Package insert.

APPLICATION STEPS

Scan to view the application steps

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 "≤45ml") and withdrawing the plunger.

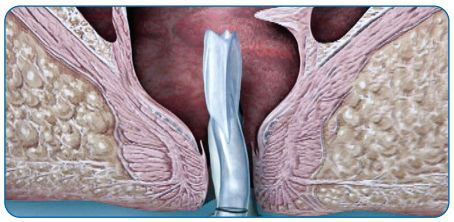
- Remove the supplied syringe and fill it with only 45ml of water or saline and connect the syringe to the white inflation port of the catheter.

- 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 date printed 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 deviceprior 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.



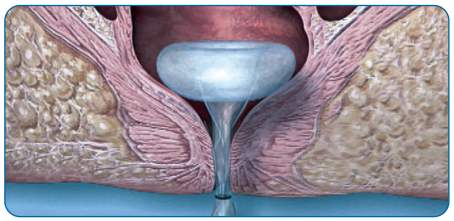
- Grasp the catheter and gently insert the balloon end through the anal sphincter until the balloon is beyond the external orifice and well inside the rectal vault.
- The finger may be removed or remain in place in the rectum during initial balloon inflation.

- Inflate the balloon with up to 45ml of fluid 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.**

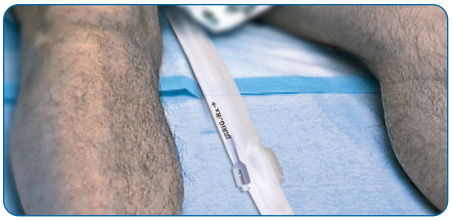
- If the SIGNAL® dome indicates at less than 30ml of fluid, withdraw the fluid and reposition the balloon in the rectal vault.
- After repositioning, fill the balloon as described above. **DO NOT fill with more than 45ml of fluid.**



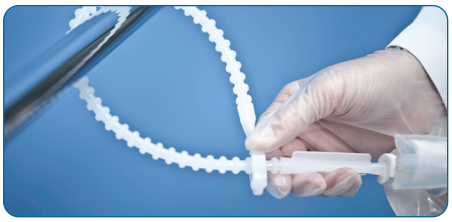
- Remove the syringe from the inflation port, and gently pull on the soft catheter to check that the balloon is securely in the rectum and that it is positioned against the rectal floor.
- Take note of the position indicator line relative to the patient's anus.
- Regularly observe changes in the location 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 re-positioned.

continue >>

- 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.



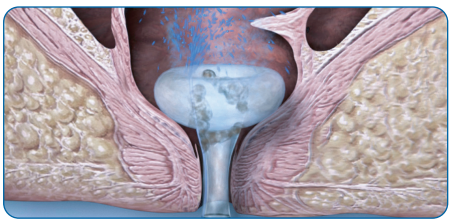
- Position the length of the flexible catheter along patient's leg avoiding kinks and obstruction.



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

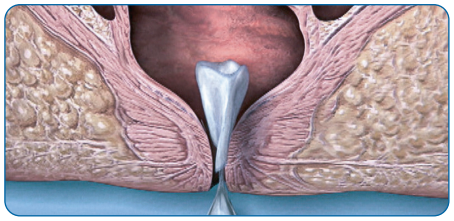
Irrigation, Maintenance & Removal of Device

- To irrigate the device, fill the syringe with water at room temperature, attach the 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 "≤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.

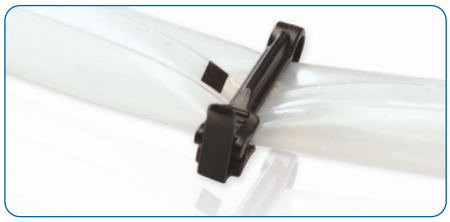
- Change collection bag as needed.
- Discard used bags according to institutional protocol for disposal of medical waste.
- Observe the device frequently for obstructions from kinks, solid faecal particles or external pressure.



- To remove the catheter from the rectum, the retention balloon must first be deflated.
- Attach the syringe to the white inflation port (marked "≤45ml") and slowly withdraw all fluid from the retention balloon.
- Disconnect the 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 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 "≤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.

Sampling

- To collect a sample from the catheter, open the 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 sampling port cap.

PRODUCT DESCRIPTION

The Flexi-Seal® SIGNAL® Faecal Management System contains:
1 soft catheter tube assembly,
1 Luer-Lock Syringe,
3 collection bags with filter, and
1 cinch clamp

The soft catheter is inserted into the rectum for faecal management to contain and divert faecal 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 also provides a visual and tactile indication as to when the low pressure retention balloon is filled to its optimal volume. The blue port, marked "IRRIG./Rx" is used to flush the device if needed and administer medication, if prescribed.

INDICATIONS

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

CONTRAINDICATIONS

1. This product is not intended for use
   - for more than 29 consecutive days
   - for pediatric patients (patients under 18 years of age) as its use has not been tested in this population
2. The Flexi-Seal® SIGNAL® Faecal 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 (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

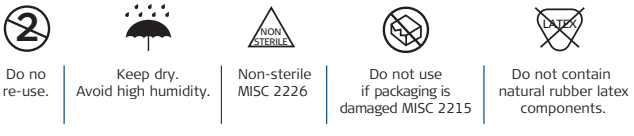
- **Warning: Clinicians should be aware that there are very limited clinical data on the use of in-dwelling faecal management systems after 14 days continued use.**
- **Warning: There is a potential risk of misconnections with connectors from other healthcare applications, such as intravenous equipment, 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. Never inflate the retention balloon with more than 45ml of water.**

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 anal skin breakdown and/or restrict faecal 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 faeces, it can be rinsed with water using the irrigation port only (see Direction for Use "Irrigation of the 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 blue irrigation/medication port only when irrigating and delivering medication. DO NOT irrigate or administer medication through the white inflation port (marked "≤45ml").**
10. This 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.
11. As long as the patient is regularly and closely monitored at all times, 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. For some patients, the length of the period of seating to avoid pressure damage to the anal/peri-anal region could be much shorter and the clinician should be alert to this possibility.
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 reused. 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.

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.



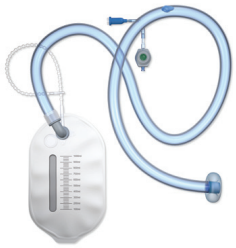
PROCEDURE CHECKLIST (PRE, DURING, POST PROCEDURE)

Flexi-Seal® SIGNAL™ Fecal Management System (FMS) Competency Checklist for Healthcare Professionals

Name _____ Title _____

Facility _____ Unit _____

Evaluator _____ Date _____



CRITICAL COMPETENCIES		MET	NOT MET	COMMENTS
Patient Selection				
1	Checks for appropriate patient selection criteria • Liquid to semi-liquid stool • Adequate sphincter tone • No contraindications (identified in package insert)			
2	Performs a digital rectal examination to evaluate suitability for insertion of device			
3	Obtains physician order per facility policy			
Insertion Competencies				
1	Obtains appropriate equipment • Flexi-Seal® SIGNAL™ Fecal Management System kit • Gloves • Incontinent pad • Lubricant • Protective barrier			
2	Pre-assembles the system, removes air from the balloon and fills syringe with no more than 45 ml of tap water or saline			
3	Positions patient in left-side lying position or other appropriate position			
4	Demonstrates proper insertion technique and positions balloon beyond the external orifice/rectal sphincter and well inside the rectal vault before inflating			
5	Understands the retention balloon must be filled with water or saline			
6	Describes the appearance of the Signal™ indicator when the balloon is properly inflated			
7	Understands that once the retention balloon has been filled with the optimal volume of water or saline the control valve will shut off, preventing the over-inflation of the balloon.			
8	Checks for proper positioning of the balloon against the rectal floor by gently pulling on the catheter			
9	States the position of the black indicator line after insertion and makes a note of the location in the patient's chart			
10	Understands that the insertion date of the system should be recorded on the date sticker provided in the kit. Demonstrates the proper placement of the sticker on the 'landing zone' of the beaded strap.			
11	Demonstrates how to hang the collection bag at the bedside			
Maintenance Competencies				
1	Demonstrates how to correctly irrigate the catheter			
2	Demonstrates method for changing collection bag per hospital protocol			
3	Demonstrates procedure for stool sampling according to hospital protocol			
4	Demonstrates procedure for the administering of medication via the irrigation port			
Removal Competencies				
1	Describes clearly the indications for removal of the device			
2	Demonstrates how to deflate the balloon prior to removal of the device			
3	Describes how to dispose of the device according to institutional protocol for disposal of medical waste			
4	Cites the maximum length of use of Flexi-Seal® SIGNAL™ FMS as 29 consecutive days			

Please see package insert for complete Directions for Use.

ConvaTec

FAQs

Q	A
1. With the Flexi-Seal™ SIGNAL™ FMS device, how do I know that the balloon is properly inflated?	1. The balloon is inflated to the indicated volume when the recessed dome on the signal indicator pops outward.
2. Can I fill the device with more than 45 mL?	2. Fill volume for each patient is based on clinical judgment and should never exceed 45 mL.
3. Sometimes the indicator pops on initial fill and then retracts after a few minutes. Is this a leak?	3. The signal indicator may pop temporarily if the patient's rectum is contracted during insertion. If the signal indicator has retracted, add water until it is just popped and never add more than 45 mL total.
4. Why doesn't the Flexi-Seal™ SIGNAL™ FMS device have the odor control lining?	4. The Advanced Odor Control version of the Flexi-Seal™ FMS device was made to address the rare occurrence of extreme odor, i.e. Indole. The Flexi-Seal™ SIGNAL™ FMS device has been initially introduced in the far more frequently used unlined version.
5. Can a patient sit in a chair while using a Flexi-Seal™ SIGNAL™ FMS device?	5. A patient can sit in a chair while a bed is being changed and care should be taken to ensure that the tubing is not applying local pressure to the patient's skin, and/or tubing is not obstructed.
6. Can I use unfiltered bags with the Flexi-Seal™ SIGNAL™ FMS device?	6. Yes, but the bags will have to be "burped" to release any gas accumulation. Also, the connector hook will not engage with the bag, but this is not required for use.
7. Where do you hook the end of the strap for bed side hanging?	7. The end of the strap is passed around a bed rail or similar bed side feature and then hooked on itself between any of the bumps on the strap.
8. What are the blank labels in the package for?	8. A blank label can be written on and affixed to the hanging strap near the bag connector.
9. Can medications be administered via larger lumen?	9. Flexi-Seal™ FMS is not approved for administration of medications. The increased lumen size aids in the administration of liquids to facilitate irrigation.
10. If the signal indicator pops at a fill volume less than 45 mL should I continue to fill up to 45 mL?	10. Stop filling for a few minutes to see if the signal indicator collapses back. If so, the popping was likely due to contraction. Continue to fill until the signal indicator is just popped. If it does not collapse, do not add more fluid. Under no circumstances, should you inflate with more than 45 mL total.
11. Are there special bags for the Flexi-Seal™ SIGNAL™ FMS product?	11. The bags for the Flexi-Seal™ SIGNAL™ FMS product are the same as the bags for the Flexi-Seal™ FMS Advance Odor Control version. All the filter bags will have flanges that can hook onto the signal connector. Any bag can be used with the Flexi-Seal™ SIGNAL™ FMS device but the lack of a gas filter means the bag must be "burped" frequently.
12. The indicator was popped but collapsed when I removed my finger. Should I add more liquid?	12. Yes, the final fill with the signal indicator should be determined without a finger in the finger pocket.

PRODUCT ORDERING INFORMATION

Ordering Information

Flexi-Seal™ SIGNAL™ FMS	
Flexi-Seal™ SIGNAL™ FMS Kit* (1 kit/box)	418000
Flexi-Seal™ Privacy Collection Bag (10/box)	411108

* Each kit comes with 3 collection bags.

Do not re-use.

Keep dry. Avoid high humidity.

Non-sterile MISC 2226

Do not use if packaging is damaged MISC 2215

Do not contain natural rubber latex components.

Our products are now available online at
www.convatec.com.my

ConvaTec Malaysia
For more information call **1-800-8806-01**

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