# Directions for Use

Flexi-Seal™ SIGNAL™

## Preparation of Device & Patient

- In addition to the device kit, gloves and lubricant will be required.
- **Remove any residual air** from the balloon by attaching the syringe to the inflation port and withdrawing the plunger.

- Expel any air from the syringe.
- Fill the empty syringe with 45ml tap water or saline.
- Do not overfill beyond 45ml.
- Attach the syringe to the white inflation port **(marked ≤ 45ml).**

- Securely snap the collection bag to the connector at the end of the catheter.

- 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.

## Insertion of Device

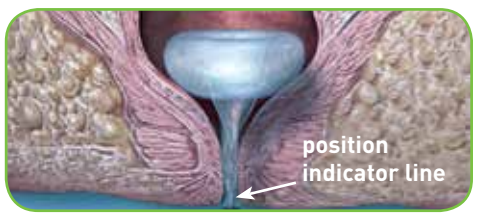
- Remove any indwelling or anal device prior to insertion of Flexi-Seal™ SIGNAL™ FMS device.
- Unfold the length of the catheter to lay flat on the bed, extending the collection bag towards the foot of the bed.
- Insert a lubricated gloved index finger into the blue retention balloon cuff finger pocket.
- Coat the balloon end of the catheter with lubricating jelly.

- Gently insert the balloon through the anal sphincter until it is beyond the external orifice and well inside the rectal vault.
- The finger may be removed or remain in the rectum during balloon inflation.

- Inflate the balloon with water or saline by slowly depressing the syringe plunger.
- **Never inflate the balloon with more than 45ml!**


- Once the balloon has reached the optimal fill level (up to 45ml) the indicator bubble on the inflation port will pop.
- SIGNAL™ indicator could pop before the 45 ml has been inflated, if the space available for the balloon is smaller than the balloon. Filling should stop when the indicator pops out and stays out.
- The indicator bubble will remain popped while the balloon is at its optimal level.


- If the indicator bubble does not pop, the balloon is under-filled. Withdraw the liquid and re-fill the balloon as described.
- If the indicator bubble pops or expands significantly at less than 30ml, withdraw the liquid and reposition the balloon in the rectal vault. After repositioning, re-fill the balloon as described.
- Should the indicator bubble deflate or appear excessively inflated, the retention balloon is no longer at the optimal level. Withdraw the fluid and re-fill the balloon as described.




- Remove the syringe from the inflation port.
- Gently pull on the silicone catheter to check that the balloon is securely positioned in the rectum, against the rectal floor.
- Take note of the position indicator line relative to the patient's anus.
- Observe changes in the location of the position indicator line 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.

- Position the length of the silicone catheter along the patient's leg.
- Make sure to avoid kinks and obstructions.

- Hang the collection bag by the beaded strap on the bedside.
- Make sure to position the collection bag at a level lower than that of the patient, ensuring an unobstructed flow.

## Irrigation, Maintenance & Removal of Device


- Rinse catheter by filling syringe with tap water at room temperature, attaching the syringe to the **blue irrigation port (marked IRRIG)** and depressing the plunger.
- Ensure syringe is not inadvertently attached to the white balloon inflation port **(marked ≤ 45ml).**
- Observe the device frequently for obstruction from kinks, solid faecal particles or external pressure.
- Only flush device when needed to maintain the unobstructed flow of stool into collection bag.

- Repeat irrigation procedure whenever necessary to maintain proper functioning of device.
- If repeated flushing does not return the flow of stool through the catheter, device should be inspected to ascertain that there is no external obstruction (e.g. pressure from body part or piece of equipment, or resolution of diarrhea).
- If no source of obstruction is detected, use of the device should be discontinued.

- Change collection bag as needed.
- Snap the cap onto each used bag.
- Discard according to institutional protocol for disposal of medical waste.

- Before removing catheter from the rectum, retention balloon must be deflated.
- Attach syringe to inflation port and slowly withdraw all water from balloon.
- Disconnect syringe and discard.
- Grasp catheter as close to the patient as possible and slowly slide it out of the anus.
- Dispose of device in accordance with institutional protocol for disposal of medical waste.

## Medication Administration

- Prepare the device for the administration of medication, by flushing the irrigation line with 10mls of room temperature water.
- Remove the cinch clamp from the kit packaging. Note that the cinch clamp has two notches and therefore two closure positions. Without closing, position the cinch clamp around the catheter, at the black indicator line. The closure end of the clamp should be positioned on the same side as the black indicator line.
- Close the cinch clamp to the first closure position. You should hear one click to confirm that the clamp is closed.
- Prepare a new syringe with the medication, as prescribed by the physician. Dosage needs to be controlled by the physician.
- Connect the medication syringe to the blue irrigation port (marked "IRRIG."). Depress the syringe plunger to administer the medication, as prescribed by the physician.
- Once all the medication has been instilled, remove the syringe and dispose of it according to your institution's policy. To ensure the delivery of medication into the rectum, immediately flush irrigation line with at least 50ml of room temperature tap water.
- Next, tighten the cinch clamp completely, by closing to the second closure position. You will hear a second click to confirm that the clamp is fully tightened. Ensure no medication flows back through the catheter.
- Allow the medication to dwell in the rectum for the desired amount of time as dictated by the prescribing physician.
- Then open the cinch clamp and remove it from the catheter. Flush the irrigation line once again with 10mls of water.

## Sampling

- In preparation for stool sampling, you'll need to obtain a slip/catheter tip syringe. This is not included in the device packaging.
- Locate the sample port on the catheter and open the sample port cap. Remove any residual air in the slip/catheter tip syringe by depressing the plunger before inserting it into the sample port.
- Press the tip of the syringe through the slit inside of the sampling port to access the interior of the catheter.
- Withdraw the syringe plunger to collect the stool sample.
- Remove the syringe and close the sampling port cap.
- Transfer the stool sample into a collection device per your institution's policy.
- Dispose of the stool sampling syringe according to your institution's policy.

ConvaTec

# Directions for Use

Flexi-Seal™ SIGNAL™

## 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." 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 paediatric patients
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 haemorrhoids 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

## 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. 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.
3. Notify a physician immediately if any of the following occur:
   - Rectal pain
   - Rectal bleeding
   - Abdominal symptoms such as distension/pain
4. 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.
5. 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.
6. 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 ≤ 45ml white inflation port to irrigate. If obstruction of the catheter is due to solid stool, use of the device should be discontinued.
7. If the patient's bowel control, consistency and frequency of stool begin to return to normal, discontinue use of the device. 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 or ulceration of rectal or anal mucosa
   - Peri-anal skin breakdown
   - Temporary loss of anal sphincter muscle tone
   - Infection
   - Bowel obstruction
   - Perforation of the bowel
8. 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.

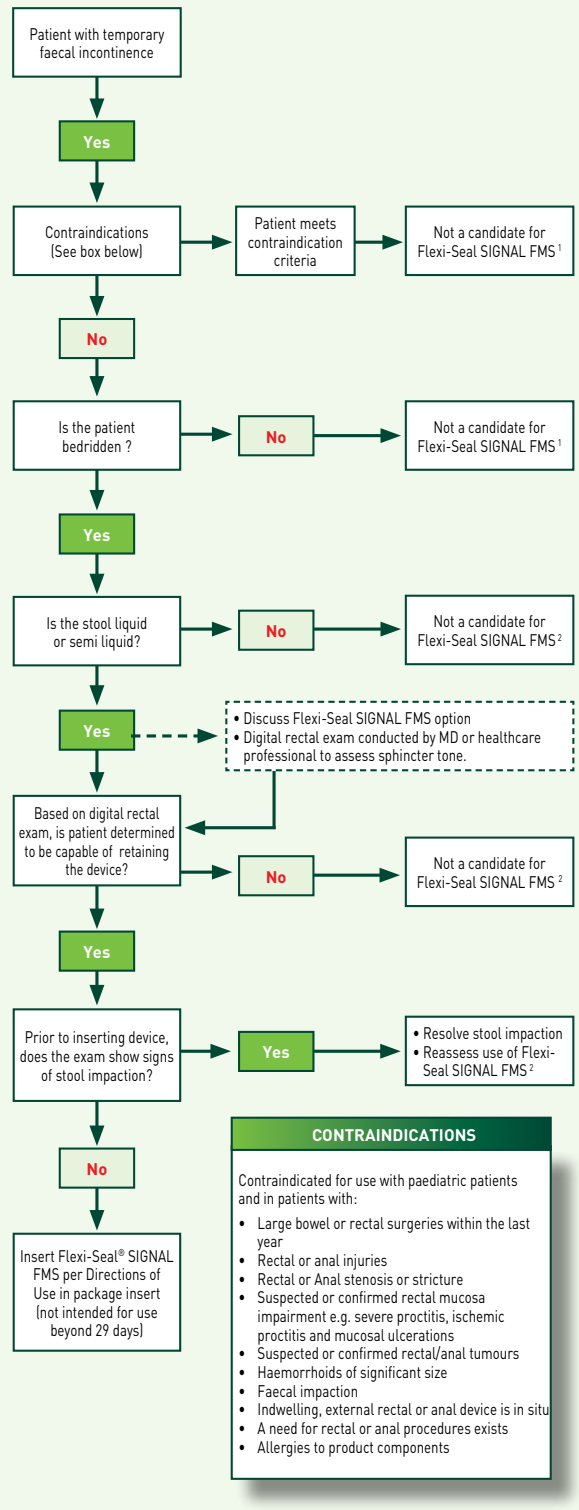
### General Guidelines

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.

## Patient Selection Criteria





**References:**
1. Flexi-Seal SIGNAL FMS Guidelines, CCC147
2. Flexi-Seal® SIGNAL FMS Directions of Use / Package insert.


## Ordering information

| Flexi-Seal™ SIGNAL™ FMS | |
|---|---|
| Flexi-Seal™ SIGNAL™ FMS Kit* (1 kit/box) | 418000 |

## Collection Bag Information

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|---|---|
| Flexi-Seal™ FMS Collection Bag with Charcoal Filter (10/box) | 411102 |
| Privacy™ Collection Bag with APS filter (10 Bags) | 411108 |

* Each kit comes with 3 Flexi-Seal™ FMS Collection Bag with Charcoal Filter.


To learn more, call Australia:

**1800 339 412**

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**www.convatec.com.au**


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