Guidelines

for the Management of Fecal Incontinence with Flexi-Seal® SIGNAL® Fecal Management System (FMS)



Flexi Seal SIGNAL
The seal of innovation™

ConvaTec

OBJECTIVE

To effectively divert and contain liquid and semi-liquid stool away from the body.

OUTCOMES (GOALS)

- Reduce the risk of skin breakdown by helping to keep the skin clean, dry and free from contaminants.
- Reduce the risk of spread of infection by containing infectious body waste within a disposable, closed system.
- Help to protect wounds, surgical sites, and burns from contamination by stool.
- Help improve patient comfort.
- Help reduce the cost of managing fecal incontinence.
- Help maintain patient dignity.

PATIENT ASSESSMENT

- Fecal incontinence management with Flexi-Seal® SIGNAL® FMS is appropriate for patients with liquid and semi-liquid stool (flowing). When stool begins to become solid, use of the device should be discontinued.
- Prior to use of Flexi-Seal® SIGNAL® FMS, a digital rectal assessment must be performed to rule out the possibility of a fecal impaction. If a fecal impaction is present, consult with patient's physician to determine if impaction removal is appropriate. The device can be inserted once the fecal impaction is removed.
- A digital rectal assessment should also confirm presence or absence of rectal tone, as poor or absent tone may increase leakage around the device or may contribute to the inability to retain the device.



RECTAL ASSESSMENT PROCEDURE

- Wash hands and put on gloves.
- Position patient on left side and flex hips.
- Separate buttocks and examine external area for fissures, skin tags, rectal prolapse, hemorrhoids or other abnormalities.
- Lubricate index finger of gloved hand.
- If patient is alert, ask patient to bear down for a moment or two to ease passage of index finger.
- Gently insert finger 3 centimeters and pause.

TIP: *3cm equates to about halfway between most distal "crease lines" on index finger.*

- At this point, rectal sphincter tone is determined.

TIP: *Good tone feels like a snug ring around the finger.*

- Fair tone feels like a snug ring around the finger but quickly loses its "grip" on the finger.
- There is little or no resistance with poor or absent tone.
- Pause for a second or two, you should feel the sphincter relax somewhat.
- Continue insertion of index finger until well into the rectal vault.

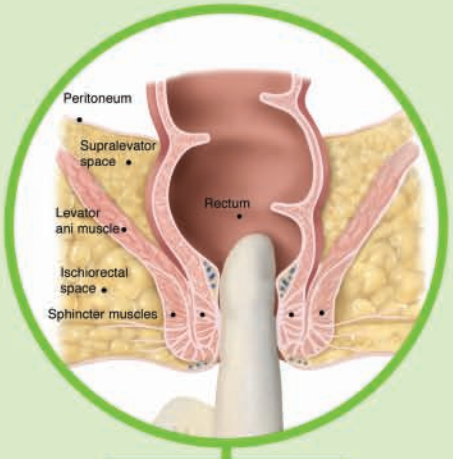
TIP: *If there is poor or absent rectal sphincter tone, the finger feels as if it was in a narrow passageway which then "opens up" into a cavern.*

- Gently sweep the rectal vault.

TIP: *Check for impacted stool.*

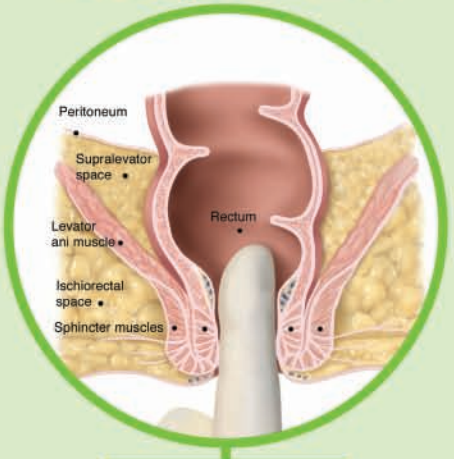
- Remove finger and wipe anus and buttocks of excess lubricant.

FEELS LIKE a snug ring around the finger



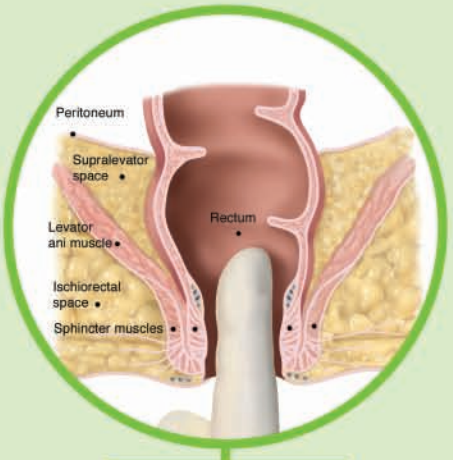
GOOD

FEELS LIKE a snug ring around the finger BUT quicky loses its grip on the finger



FAIR

FEELS LIKE there is little or no resistance



POOR

PRECAUTIONS AND OBSERVATIONS

- 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.
- Care should be exercised in using this device in patients who have a tendency to bleed from either anticoagulant/anti-platelet therapy or underlying disease. If signs of rectal bleeding occur, remove the device immediately and notify a physician. Remove any in-dwelling or external anal device prior to insertion of Flexi-Seal® SIGNAL® FMS device.
- Notify a physician immediately if any of the following occur:
  - rectal pain
  - rectal bleeding
  - abdominal symptoms such as distension/pain
- Solid or soft-formed stool cannot pass through the catheter and will obstruct the opening. The use of the device is not indicated in patients with solid or soft-formed stool.
- Small amounts of moisture or seepage around the catheter is anticipated. To avoid skin irritation, initiate an appropriate institutional skin care protocol. At minimum, the skin should be kept clean, dry and protected with a moisture barrier product. Patients with weak sphincter muscles may not be able to hold the device in place and may experience increased leakage of stool.
- If the catheter becomes blocked with feces, it can be rinsed with water using the **BLUE** irrigation port only (see Directions for Use "Irrigation of the device"). Do not use **WHITE** inflation port to irrigate. If obstruction of the catheter is due to solid stool, use of the device should be discontinued.
- 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

CONTRAINDICATIONS

- This product is not intended for use:
  - For more than 29 consecutive days
  - In pediatric patients
- The Flexi-Seal® SIGNAL® Fecal Management System should not be used on individuals who:
  - Have suspected or confirmed rectal mucosa impairment (e.g., severe proctitis, ischemic proctitis, and mucosal ulcerations)
  - Have had large bowel (colon) or rectal surgery within the last year
  - Have any rectal or anal injury
  - Have hemorrhoids of significant size
  - Have a rectal or anal stricture or stenosis
  - Have a suspected or confirmed rectal/anal tumor
  - Have any in-dwelling, external rectal or anal device (e.g., thermometer, external fecal collection pouch) or need for rectal or anal procedures (e.g., suppositories, enemas).
  - Are sensitive to or who have had an allergic reaction to any components within the kit

GENERAL GUIDELINES

- The device may be removed and reinserted as needed to perform normal patient assessment.



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 **(the SIGNAL® is marked with the less than/equal to symbol in front of the 45mL).**



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

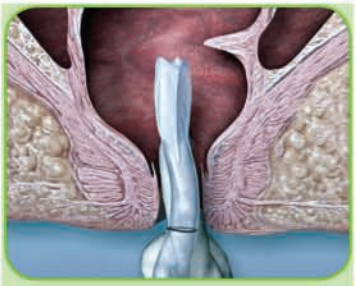


Position the patient in left side-lying position; if unable to tolerate, position the patient so access to the rectum is possible. Perform a digital rectal exam to evaluate suitability for insertion of device.

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!**

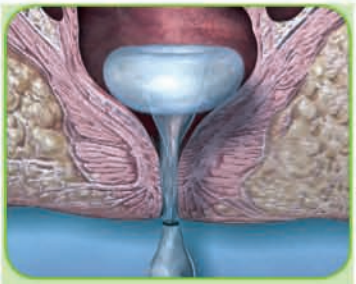


Once the balloon has reached the optimal fill level (up to 45ml) the indicator bubble on the inflation port will pop. Signal indicator could pop before the 45 ml has been inflated, if the space available for the balloon is smaller than the balloon. Filling should stop when the indicator pops out and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

INSERTION OF DEVICE (continued)



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



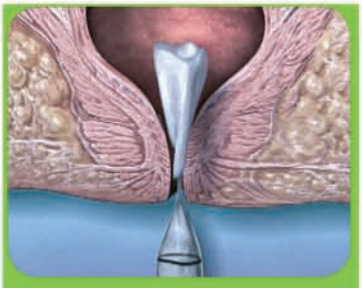
Rinse catheter by filling syringe with tap water at room temperature, attaching the syringe to the **blue irrigation port (marked IRRIG)** and depressing the plunger. Ensure syringe is not inadvertently attached to the white balloon inflation port (the SIGNAL® is marked with the less than/equal to symbol in front of the 45mL). Observe the device frequently for obstruction from kinks, solid fecal 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. Next, 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. You can now 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 that has been prescribed for the patient. Connect the medication syringe to the blue irrigation port (marked "IRRIG."). Depress the syringe plunger to



administer the medication that has been prescribed for the patient. 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 clampis 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 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 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.

Product Information

Flexi-Seal® SIGNAL® FMS	
Flexi-Seal® SIGNAL® FMS kit (1 kit/box, 3 bags)	418000
Flexi-Seal® FMS Advanced Odor Control	
Flexi-Seal® FMS AOC Kit (1 kit/box, 3 bags)	411104

Flexi-Seal® FMS	
Flexi-Seal® FMS Kit (1 kit/box, 3 bags)	411100
Collection Bag Information	
Collection Bag (10/box)	411101
Charcoal Filter Collection Bag (10/box)	411102

To learn more, call:

1-800-422-8811

M-Fri: 8:30 am - 7:00 pm, EST

www.convatec.com

Non-Sterile | Single Patient Use Only | Does not contain natural rubber latex components

Caution: United States federal law restricts this device to sale by or on the order of a physician or other health care practitioner.

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