Flexi-Seal® FMS

Directions for Use

1 Step One: Patient Selection Criteria

Patient with temporary faecal incontinence → **No** → Not a candidate for Flexi-Seal® FMS

Yes

Does the patient have any of the following **contraindications***?

- Paediatric patients (under 18)
- Allergies to product components
- Lower large bowel or rectal surgeries within the last 12 months
- Rectal or anal injuries
- Severe rectal or anal stenosis or stricture
- Suspected or confirmed rectal mucosa impairment
- Confirmed rectal or anal tumors
- Severe haemorrhoids
- Faecal impaction

→ **Yes** → Not a candidate for Flexi-Seal® FMS

No

Is the patient bedridden? → **No** → Not a candidate for Flexi-Seal® FMS

Yes

Is the stool liquid or semi liquid? → **No** → Not a candidate for Flexi-Seal® FMS

Yes

Healthcare professional to perform digital rectal examination 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® FMS

Yes

Does the digital rectal exam show signs of stool impaction? → **Yes** →

- At healthcare professional discretion process to disimpaction procedure
- Reassess use of Flexi-Seal® FMS

→ Does patient meet Flexi-Seal® FMS criteria? → **Yes** → Insert Flexi-Seal® FMS per directions for use in package insert

Does patient meet Flexi-Seal® FMS criteria? → **No** → Not a candidate for Flexi-Seal® FMS

Completely latex free. LATEX

* Please see Flexi-Seal® FMS package insert for complete instructions

2 Step Two: Preparation of Device and Patient

In addition to the device kit, gloves and lubricant will be required.

Fill the syringe with 45 ml tap water or saline at room temperature (please ensure that the balloon is entirely deflated before use of product). Attach the syringe to the inflation port.

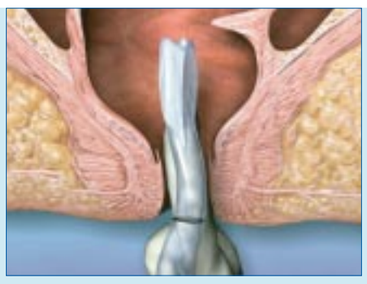
Securely snap the collection bag to the connector at the end of the catheter.

Position the patient in the left side-lying position; if unable to tolerate, position the patient so access to the rectum is possible.

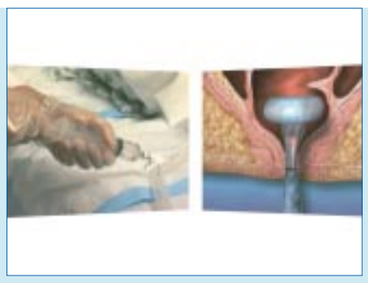
3 Step Three: Insertion of Device

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 retention balloon cuff finger pocket for digital guidance during device insertion.

Coat the balloon end of the catheter with lubricating jelly.

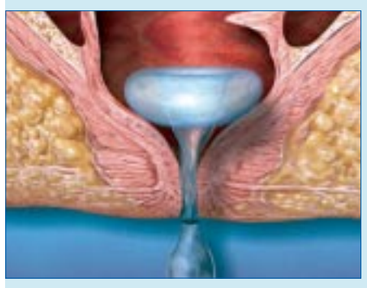


Grasp the catheter and gently insert the balloon end through the anal sphincter until the balloon is inside the rectal vault.

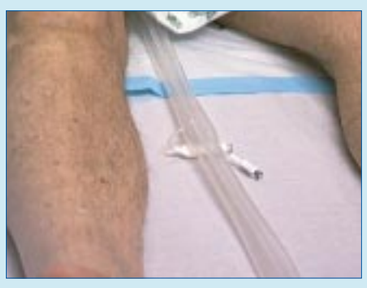


Inflate the balloon with 45 ml of water or saline by slowly depressing the syringe plunger.

The oval inflation indication chamber on the inflation port will expand as fluid is injected. This normal expansion should subside once the plunger stops. If the inflation indication chamber remains excessively expanded after the plunger stops, the balloon is not properly inflating. This is likely the result of improper balloon positioning in the rectal vault. In this case, use the syringe to withdraw the fluid from the balloon, reposition the balloon in the rectal vault and re-inflate the balloon.



Remove the syringe from the inflation port, and gently pull on the soft silicone catheter to check that the balloon is securely in the rectum and that it is positioned against the rectal floor.



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

Take note of the position indicator line relative to the patient's anus. 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.

Hang the bag by the strap at a convenient location on the bedside.

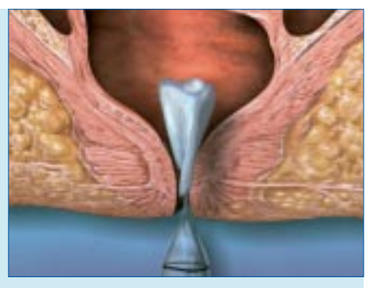
4 Step Four: Maintenance and Removal of Device

If the silicone catheter becomes blocked with solid particles, it can be rinsed by filling the syringe with tap water at room temperature, attaching the syringe to the irrigation port and depressing the plunger.

Repeat the procedure as often as necessary to maintain proper functioning of the device. Flushing the device as described above is an optional procedure for use only when needed to maintain the unobstructed flow of stool into the collection bag. 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 or piece of equipment). If no source of obstruction of the device is detected, use of the device should be discontinued.

Change the collection bag as needed. Snap the cap onto each used bag and discard 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 be deflated. Attach the syringe to the inflation port, and slowly withdraw all water from the retention balloon. Disconnect the syringe and discard.

Grasp the catheter as close to the patient as possible and slowly slide it out of the anus.

Dispose of the device in accordance with institutional protocol for disposal of medical waste.

Product Description

The Flexi-Seal® Faecal Management System contains 1 soft silicone catheter tube assembly, 1 syringe, and 3 collection bags.

The soft silicone 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 one end and a connector for attaching the collection bag at the other end.

Two small tubes are attached to the silicone catheter. One tube, with "45 ml" printed on it, is used to inflate the retention balloon after the device has been inserted into the patient's rectum. Another tube, with "IRRIG." printed on it, is used to flush the device if needed.

Indications

For the faecal management of patients with little or no bowel control and liquid or semi-liquid stool.

Precautions and Observations

1. Close attention should be exercised with the use of the device in patients who have inflammatory bowel conditions. The physician should determine the degree and location of inflammation within the colon/rectum prior to considering use of this device in patients with such conditions.
2. 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 very weak sphincter muscles may not be able to hold the device in place and may experience increased leakage of stool.
3. 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.
4. If the catheter becomes blocked with solid particles, it can be rinsed with water (see "Irrigation of the device"). If obstruction of the catheter is due to solid stool, use of the device should be discontinued.
5. To avoid injury to the patient, do not insert anything into the anal canal while this device is in place (e.g. thermometer, suppositories etc). Remove the device prior to insertion of anything into the anal canal.
6. Notify a physician if any of the following occur:
   - persistent rectal pain
   - rectal bleeding
   - abdominal distension
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:

- Excessive leakage of stool around the device
- Pressure necrosis of rectal or anal mucosa
- Bowel obstruction
- Loss of anal sphincter muscle tone could lead to temporary anal sphincter dysfunction
- Infection
- Perforation of the bowel

General Guidelines

The device may be changed as needed to perform normal patient assessment.

The device is not intended for use beyond 29 days.

ConvaTec Wound Therapeutics™ Helpline Freephone 0800 289 738 (UK) or 1800 946 938 (ROI)

ConvaTec Ltd, Harrington House, Milton Road, Ickenham, Middlesex, UB10 8PU.
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