Flexi-Seal Signal Faecal Management System (FMS) Guideline

The flexi-seal signal faecal Management System (FMS) is designed to effectively divert, collect and contain liquid faeces and semi–liquid stool away from the body from immobile or persistently incontinent patients.

Contraindications:

1. This product can be used for maximum 29 consecutive days once inserted. Replace with new FMS only with clinician agreement regarding continued need and risk/ benefit of continued use of device.
2. Not recommended for paediatric patients.
3. Known sensitivity to silicone.
4. Patients have suspected or confirmed rectal mucosa impairment. (e.g. severe or ischemic proctitis, and mucosal ulcerations)
5. Patients who have had large bowel or rectal surgery within the last year.
6. Have any rectal or anal injury.
7. Compromised rectal wall integrity (i.e. have anal or rectal strictures or stenosis; haemorrhoids of significant size)
8. Have a suspected or confirmed rectal/anal tumour.
9. Patients distal rectum is unable to accommodate the inflated volume of the retention cuff (i.e. secondary to tumour, radiation, scarring, inflammatory condition)
10. Have any indwelling, external rectal or anal devices (i.e. thermometer) or need for rectal or anal procedures.(i.e. suppositories, enemas)
11. On DRE (digital rectal examination) the presence of impacted stool, then give an enema.
12. Patients with persistent diarrhoea (see indication 1 below), before using the FMS ensure that the patient is not receiving any medication which may cause diarrhoea. (i.e. too high dose of laxative, use of particular antibiotic.)
13. Patients who are malabsorbing, prior to using the FMS patients should have a change of enteral feed regime. Contact the ICU dietician.

Indications

1. Acute Faecal Incontinence with diarrhoea (>2 episodes of diarrhoea in 24 hours) where all correctable factors have been addressed and a faecal collecting device is either not containing the faeces or is causing/is at risk of causing skin breakdown
2. Reduce risk of spreading infection by containing all diarrhoea that has tested positive (or there is a strong clinical suspicion) for Clostridium difficile; Vancomycin or Gentamicin resistant enterococci within a closed and disposable system.
3. Massive persistent melaena.
4. Protects wound adjacent to or in the sacral area where faecal soiling will inhibit healing (This system can be used in patients without diarrhoea but still at risk of faecal soiling. These patients require a stool modification plan)
5. Those at risk of skin breakdown due to faecal incontinence.
6. Help reduce the cost of managing faecal incontinence.
7. Help improve and maintain patient comfort and dignity.

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Recommendations for insertion of device

1. Where appropriate gain informed consent from the patient for this procedure.
2. Place patient in left lateral position, with knee-chest position if possible
3. Double glove, perform (digital rectal examination) DRE to assess that rectum is empty, confirm presence or absence of rectal tone and there are no other contra-indications to insertion.
4. If the patient is awake or semi-conscious and the skin is intact apply lidocaine gel prior to insertion, this must be prescribed/recorded; occasionally sedative agents may be required, these must be discussed and prescribed by medical staff
5. In addition to the device kit, gloves, apron and lubricant will be required. Open device packet, remove any residual air from the balloon by attaching the syringe to the inflation port and withdrawing the plunger.
6. Expel any air from the syringe. Fill the empty syringe with 45ml sterile water or saline not tap water. Do not overfill beyond 45ml. Attach the syringe to the white inflation port. (the signal is marked with the less/equal to symbol in front of the 45ml)
7. Securely snap the collection bag to the connector at the end of the catheter.
8. Remove any indwelling or anal device prior to insertion of Flexi-Seal Signal (FMS) devise. 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.
9. 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.
10. Inflate the balloon with sterile water or saline by slowly depressing the syringe plunger. (Never inflate the balloon with more than 45ml!)
11. 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 45ml 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.
12. 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 repositioning, 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.
13. 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 rectum floor. Take note of the position indicator line relative to the patient's anal verge. Observe changes in the location of the position black 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.
14. Hang the collection bag below level of patient by the beaded strap, ensuring unobstructed flow, gravity drainage of faeces and ensure tubing not kinked. Do not use the knee bend position as this will cause the device to leak
15. Record insertion, result of DRE, volume in inflation port, note distance between black indicator line and anal verge (usually 1-2 cm) and product lot number in medical notes.
16. The date of insertion should be recorded on the FMS and the date of insertion/bag change recorded on the collection bag.

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Irrigation & Maintenance

1. The catheter should be flushed with at least twice daily with 50-200mls of sterile water. Ensure you are flushing through the irrigation port. Flushing the device may also be necessary if the device is leaking.
2. Total volume of irrigation should be recorded and subtracted from total output in collection bag and documented daily.
3. Daily - with the patient placed in the side lying position hold the FMS in place and deflate the cuff (to check the total volume) replace the fluid in the cuff to a **maximum of 45 mls.**
4. Verify regularly and post patient position changes that FMS tubing is not kinked, twisted or compressed as this will cause leakage and prevent drainage
5. Where appropriate i.e. for patient with wounds at risk of contamination, a stool modification plan should be introduced in patients with a Bristol Stool Chart of 6 or less
6. Should the patient have a cardio-pulmonary arrest while a FMS is inserted the cuff must deflated or device removed.

Removal

1. If the device is no longer required i.e.no longer meets any of the inclusion criteria, then the devise should be removed.
2. Explain procedure to patient.
3. Retention balloon must be deflated. Attach syringe to inflation port and slowly withdraw all water from balloon. Disconnect syringe and discard. (Confirmed by indicator bubble deflated)
4. Hold catheter as close to the patient as possible and slowly slide it out of the anus, ask the patient to try and pass a bowel motion and gently apply traction to catheter, if required lubricate around tubing with water soluble gel

Sampling

1. In preparation for stool sampling, you'll need to obtain a slip tip syringe. (i.e. non luer lock) This is not included in the device packaging.
2. Locate the sample port on the catheter and open the sample port cap.
3. Remove any residual air in the slip tip syringe by depressing the plunger before inserting it into the sample port.
4. Press the tip of the syringe through the slit inside of the sampling port to access the interior of the catheter.
5. Withdraw the syringe plunger to collect the stool sample. Remove the syringe and close the sampling port cap.
6. Transfer the stool sample into a collection devise.

Discharge to the ward

Should a patient continue to require the FMS, please ensure the ward has adequate information and support to use the device safely? Please attached ward information prior to discharge.

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