Frequently Asked Questions For Flexiseal

1. Does the retention balloon need to be periodically deflated?

No, it does not. The retention balloon on Flexi-Seal® FMS represents an innovative technology that enables it to inflate with minimal pressure. For that reason, the Flexi-Seal® FMS balloon does not have to be periodically deflated and reinflated.

2. Does inflating the Flexi-Seal® FMS retention balloon with 45 mL vs 30 mL, used with Foley catheters, increase the risk of damaging rectal tissue?

In the Flexi-Seal® FMS clinical trial, the retention balloon was inflated with 45 ml, and there were no adverse events related to its use. No changes of the rectal mucosa, assessed by endoscopic exams before and after its use, were reported.

3. For how long can Flexi-Seal® FMS be used?

Flexi-Seal® FMS is designed for managing acute fecal incontinence and can be used for up to 29 days.

4. What if a patient requires fecal diversion for longer than 29 days?

Flexi-Seal® FMS is designed for managing acute fecal incontinence and is not indicated for chronic incontinence.

When fecal incontinence with liquid stool is present, the patient will receive anti-diarrhoea therapy. As the stool becomes more solid, the use of Flexi-Seal® FMS will have to be discontinued, because it is indicated only for management of liquid and semiliquid stool. It is expected that, in most cases, this will occur in less than 29 days.
If a patient requires fecal diversion for longer than 29 days, upon removal of Flexi-Seal® FMS, a clinician will need to decide which alternative fecal management method to use.

5. How can Flexi-Seal® FMS be used in a long-term care setting, if it can be used only for 29 days?

Residents of long-term care facilities may have episodes of acute fecal incontinence with liquid or semiliquid stool. Flexi-Seal® FMS can be used as a safe and effective tool to manage such acute situations in a long-term care setting.

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6. Is sedation or analgesia required for insertion of the device?

When carried out according to the Directions for Use (refer to the package insert), the insertion of Flexi-Seal® FMS is designed to not cause pain and therefore does not require sedation or analgesia.

7. Is there a risk that Flexi-Seal® FMS may leak?

Small amounts of moisture or seepage around the catheter is anticipated. For this reason, we recommend using a bed pad at all times, in case of spotting. Sometimes during the course of using Flexi-Seal® FMS, the retention balloon may
slide deeper inside the rectum and no longer provide an effective seal, thus letting feces leak around the catheter.

Alternatively, in a patient with a weak rectal sphincter, the balloon may slide out and also lead to leakage. Please see below how to prevent these situations.

8. How can leakage be prevented?

The best way to prevent leakage is to ensure that the retention balloon is adequately inflated and properly positioned in the rectum at all times during the use of Flexi-Seal® FMS.

Review carefully the "Insertion of device" section of the Directions for Use and make sure that all the instructions for proper insertion are followed. After ensuring that the balloon is properly positioned, 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 balloon in the rectum.

If the position indicator line moves up, i.e., closer to the anus, this may indicate that there is a need for gently pulling the catheter to bring the balloon where it should be.

If the position indicator line moves down, i.e., away from the anus, this may indicate that the device may expel. In such cases, the balloon should be deflated, removed and reinserted as described in the "Insertion of Device" section of the Directions for Use.

9. How can expulsion of the device be prevented?

Proper positioning, and maintenance of proper positioning, of the retention balloon are keys to prevention of expulsion. Maintenance of proper positioning can be achieved by observing changes in the location of the position indicator line to determine movement of the balloon in the rectum. If the position indicator line moves down, i.e., away from the anus, this may indicate that the device may expel. In such cases, the balloon should be deflated, removed and reinserted.
Patients with very weak sphincter muscles may not be able to hold the device in place.

In the clinical trial, Flexi-Seal® FMS was retained in all subjects but one, who had poor sphincter tone prior to entering the study.

10. Does the device need to be sterile?

The anorectal area is not sterile, therefore there are no sterility requirements for Flexi-Seal® FMS.

11. How can odor be prevented?

Prevent leakage (see the answer to "How to prevent leakage" above).

Ensure unobstructed flow of stool through the catheter into the collection bag. If the catheter becomes blocked with solid particles, it can be rinsed with water (see the "Maintenance of device" section of the Directions for Use.). Periodically, "milk" the catheter to facilitate the flow.

Change the collection bag frequently, or before it becomes too full (maximum capacity is one litre; however, we recommend changing the bag between 600 ml and 800 ml).

12. Can Flexi-Seal® FMS be used for formed stool?

No, it cannot. Formed stool cannot pass through the catheter and will obstruct the opening. The use of the device is indicated only for liquid or semiliquid stool. When a patient's stool becomes formed, the use of Flexi-Seal® FMS should be discontinued.
13. How can occlusion of the catheter be prevented?

Periodically, "milk" the catheter to facilitate the flow.

If the catheter becomes blocked with solid particles, it can be rinsed with water (see the "Maintenance of device" section of the Directions for Use.).

14. Is a stool modification programme required to use Flexi-Seal® FMS?

No stool modification program is required to use Flexi-Seal® FMS, as it is indicated only for liquid or semiliquid stool. If the stool is not of such consistency, the use of Flexi-Seal® FMS is not recommended.

15. Since Flexi-Seal® FMS is a closed system, can it allow for obtaining stool samples?

Stool samples can be obtained by disconnecting the collection bag from the catheter and getting the necessary amount of sample through the catheter's opening.

16. Does it require a MD or RN to insert the device?

Flexi-Seal® FMS was designed to help nurses to manage fecal incontinence. A nurse can insert the device on the order of a physician or other health care professional authorised to prescribe.

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

17. What is the pressure when the balloon is inflated?
The pounds per square inch (PSI) are less than one. In the research conducted to date, the pressure of the mucosal tissue is greater than that of the Flexi-Seal® FMS retention balloon. The result of this PSI difference is that the mucosal tissue takes the shape of the retention balloon. This minimises the chance of tissue necrosis.

18. Why does the balloon on Flexi-Seal® FMS have to be filled with water or saline vs. just inflating with air... like an ordinary balloon?

Silicone is permeable to air so the balloon would deflate to some degree after several hours if it were filled with air. This is true of non-medical balloons too.

19. If the retention balloon has been partially inflated with air, should the air be removed before use?

Yes, the air should be removed/deflated from the balloon. Simply use the syringe to remove air from the balloon.

20. Will Flexi-Seal® FMS stay in place with patients who have had either a prostatectomy or a hysterectomy?

Some patients who have had a prostatectomy or a hysterectomy may have a problem with device retention if there was pelvic nerve damage postoperatively that affected the internal and external rectal sphincter muscles. However, even if the external (voluntary) sphincter was weakened, if the internal (involuntary) sphincter was neurologically intact, the device retention and function should not be affected.