



Flexi-Seal™ PROTECT PLUS

The Flexi-Seal™ PROTECT PLUS Fecal Management System is an indwelling fecal management catheter intended for use to manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications. The device is intended for use in adult patients.

- Remove any indwelling or anal device prior to insertion of the Flexi-Seal™ PROTECT PLUS device.
- Perform a digital rectal exam to evaluate suitability for insertion of device.



ATTENTION: Please refer to the instructions for use for full information on device.

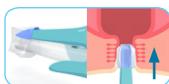
1. Insert the ConvaTec Diamonds™ sachets, one at a time, into the bag opening. Attach the collection bag to the catheter connector with arrows pointing upwards.



2. Connect a syringe to the white inflation port and remove all air.



3. Lubricate a gloved finger and insert the gloved finger into the blue finger pocket on the balloon and lubricate the balloon. Gently insert the balloon into the rectal vault.



4. Connect the syringe to the white inflation port and start inflating approx. with 10 ml water or saline into the balloon before removing your finger. Inflate the balloon until the green indicator pops. **Do not fill with more than 45ml of fluid.**



5. The red dome will indicate if the balloon is overfilled. If the red dome is triggered, fully deflate the balloon. Repeat the balloon inflation process and stop inflation once the green dome has signalled optimal fill.



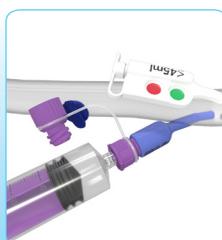
6. Gently pull on the soft catheter to check the secure placement against the rectal floor.



The Flexi-Seal™ PROTECT PLUS Fecal Management System is available with ENFit™ or Luer connection.

The purple ENFit™ connector in the blue housing, marked "IRRIG. /Rx" is used to flush the device if needed and administer medication, if prescribed.

ENFit™ helps to further reduce the risk of balloon over inflation by avoiding misconnection of medication to the inflation port.



Product Ordering Codes	
Flexi-Seal™ Protect Plus FMS kit LUER (1kit/box, 1bag)	422303
Flexi-Seal™ Protect Plus FMS kit ENFit™ (1kit/box, 1bag)	421703
Flexi-Seal™ Protect Plus Privacy™ Collection Bag with APS Filter (5/box)	422291

Maintenance

- Observe the device frequently for obstructions from kinks, solid fecal particles or external pressure.
- Gently pull on the soft catheter to check that the balloon is securely in the rectum and that it is positioned against the rectal floor.
- Observe changes in the location of the position indicator line to determine movement of the retention balloon in the patient's rectum.
- Change the collection bag as required.
- A dark blue sampling port is present if stool samples are required to be taken by the clinician.



Irrigation

- To irrigate the device, fill a syringe with water at room temperature, attach the syringe to the connector in the blue irrigation/medication housing (marked "IRRIG./Rx") and slowly depress the plunger. **Do not irrigate through the white inflation port (marked " $\leq 45\text{ml}$ ").**



- It is recommended to repeat the process twice a day, **unless otherwise stated in your protocol or if patient's condition does not allow.**

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. If no source of obstruction of the device is detected, use of the device should be discontinued.

Troubleshooting

In the event of expulsion of the device, deflate the balloon fully; rinse the balloon end of the catheter and reinsert following the instructions for 'Device Insertion'. A rectal exam should be conducted prior to re-insertion to verify that no stool is present. If expulsion continues for more than three episodes, discontinuation of the device should be considered.

In the event of stool leakage, correct the position of the retention balloon and irrigate the device. If leakage persists, deflate the balloon fully and remove the device. Rinse the balloon end of the catheter and reinsert following the instructions for 'Device Insertion'. A rectal exam should be conducted prior to re-insertion to verify that no stool is present.

IFU Training Videos



**WE MAKE FECAL MANAGEMENT OUR PRIORITY
SO IT DOESN'T HAVE TO BE YOURS.**

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