

Directions for Use

Preparation of Device & Patient



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



- Securely attach the collection bag to the catheter flange collar



- Position the patient in left side lying position; if unable to tolerate, position the patient so access to the rectum is possible
- Remove any indwelling or anal device prior to insertion of the Flexi-Seal® CONTROL™ device
- Perform a digital rectal exam to evaluate for contraindications
- Wearing the gloves, unfold the length of the catheter to lay it flat on the bed, extending the collection bag towards the foot of the bed

Insertion of Device



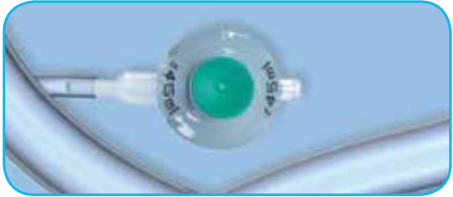
- Using the syringe provided, remove the air that is in the balloon by attaching the syringe to the grey inflation port (marked "≤45ml") and withdrawing the plunger
- Remove the supplied syringe and fill it with 45ml of water or saline and connect the syringe to the grey inflation port of the catheter



- Insert a lubricated gloved finger into the blue finger pocket for digital guidance during device insertion
- Coat the balloon end of the catheter with lubricant



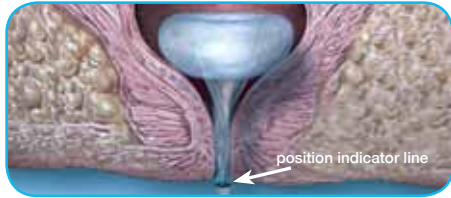
- Grasp the catheter and gently insert the balloon end through the anal sphincter until the balloon is beyond the external orifice and well inside the rectal vault
- The finger may be removed or remain in place in the rectum during initial balloon inflation



- Inflate the balloon with up to 45ml of fluid by slowly depressing the syringe plunger
- With the insertion finger removed, the green SIGNAL™ indicator will expand once the balloon has reached the optimal fill level for the anatomy
- There may be cases where the SIGNAL™ indicator will not expand if the space in the rectum is large
- Never fill with >45ml of fluid



- The Auto-Valve™ fill line will close when the appropriate volume has been introduced
- If the green SIGNAL™ indicator expands at less than 30ml of fluid, withdraw the fluid and reposition the balloon in the rectal vault
- After repositioning, fill the balloon as described above. The Auto-Valve™ fill line will close when the appropriate volume has been introduced



- Remove the syringe from the inflation port
- 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
- Note the distance of position indicator line relative to the patient's anus



- Position the length of the silicone catheter along the patient's leg, avoiding kinks and obstruction



- Hang the collection bag by the bead strap on the bedside at a position lower than that of the patient
- Record the insertion date
- Regularly check for changes in the location of the position indicator line to determine if there is a need to reposition the balloon or device and assess if risks have changed

Irrigation, Maintenance & Removal of Device



- To irrigate the device, fill the syringe with water at room temperature, attach the syringe to the blue irrigation port (marked "IRRIG.") and slowly depress the plunger
- Do not irrigate through the grey inflation port (marked "≤45ml")
- Record the volume of introduced irrigation water



- Repeat irrigation procedure as often as necessary to maintain proper functioning of 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 (e.g., pressure from body part or piece of equipment, or resolution of diarrhoea)
- If no source of obstruction of the device is detected, use of the device should be discontinued



- Change collection bag as needed
- Observe the device frequently for obstructions from kinks, solid faecal particles or external pressure
- Discard used collection bags according to institutional protocol for disposal of medical waste



- To remove the catheter from the rectum, the retention balloon must first be deflated
- Attach the syringe to the grey inflation port (marked "≤45ml") and slowly withdraw all fluid from the retention balloon
- Disconnect the syringe and discard
- Grasp the catheter as close to the patient as possible and slowly remove from the anus

Medication Administration (Dosage prescribed by physician)



- Prepare the device for the administration of medication, by flushing the irrigation line with 10mls of room temperature water
- Remove the black 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
- 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, as prescribed by the physician. Dosage needs to be controlled by the physician
- Connect the medication syringe to the blue irrigation port (marked "IRRIG."). Depress the syringe plunger to administer the medication, as prescribed by the physician
- 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 clamp is 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



- To collect a sample from the catheter, open the blue sample port cap
- Press the tip of a catheter syringe through the slit inside of the sampling port to access the interior of the catheter
- Withdraw the syringe plunger to collect the sample
- Withdraw the syringe and close the sampling port cap

PRODUCT DESCRIPTION

The Flexi-Seal® CONTROL™ Faecal Management System contains:

- 1 soft catheter tube assembly,
- 1 Flexi-Seal Privacy™ collection bag with APS filter,
- 1 Luer-Lock Syringe, and
- 1 cinch clamp

The soft 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.

INDICATIONS

For use to manage faecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications as prescribed by a physician.

CONTRAINDICATIONS

- This product is not intended for use
 - for more than 29 consecutive days
 - for paediatric patients [patients under 18 years of age]
- The Flexi-Seal® CONTROL™ Faecal Management System should not be used on individuals who:
 - have suspected or confirmed rectal mucosal impairment, i.e., severe proctitis, ischemic proctitis, mucosal ulcerations
 - have had rectal surgery within the last year
 - have any rectal or anal injury
 - have haemorrhoids of significant size and/or symptoms
 - have a rectal or anal stricture or stenosis
 - have a suspected or confirmed rectal/anal tumor
 - have any in-dwelling rectal or anal device (e.g. thermometer) or delivery mechanism (e.g. suppositories or enemas) in place
 - are sensitive to or who have had an allergic reaction to any component within the system

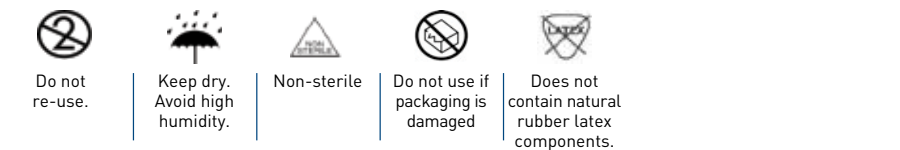
PRECAUTIONS AND OBSERVATIONS

- 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 anti-coagulant / antiplatelet therapy or underlying disease. If signs of rectal bleeding occur, remove the device immediately and notify a physician. Remove any indwelling or anal device prior to insertion of the Flexi-Seal® CONTROL™ FMS.
- 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 for 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 a minimum, the skin should be kept clean, dry and protected with a moisture barrier product.
- If the catheter becomes blocked with faeces, it can be rinsed with water using the irrigation port only (see Directions for Use "Irrigation of the Device"). Do not use the ≤45ml grey 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
- This device is for single use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination. Physical properties of the device may no longer be optimal for intended use.

GENERAL GUIDELINES

The device may be changed as needed to perform normal patient assessment. The device is not intended for use for more than 29 consecutive days.

If the product package is damaged, do not use.



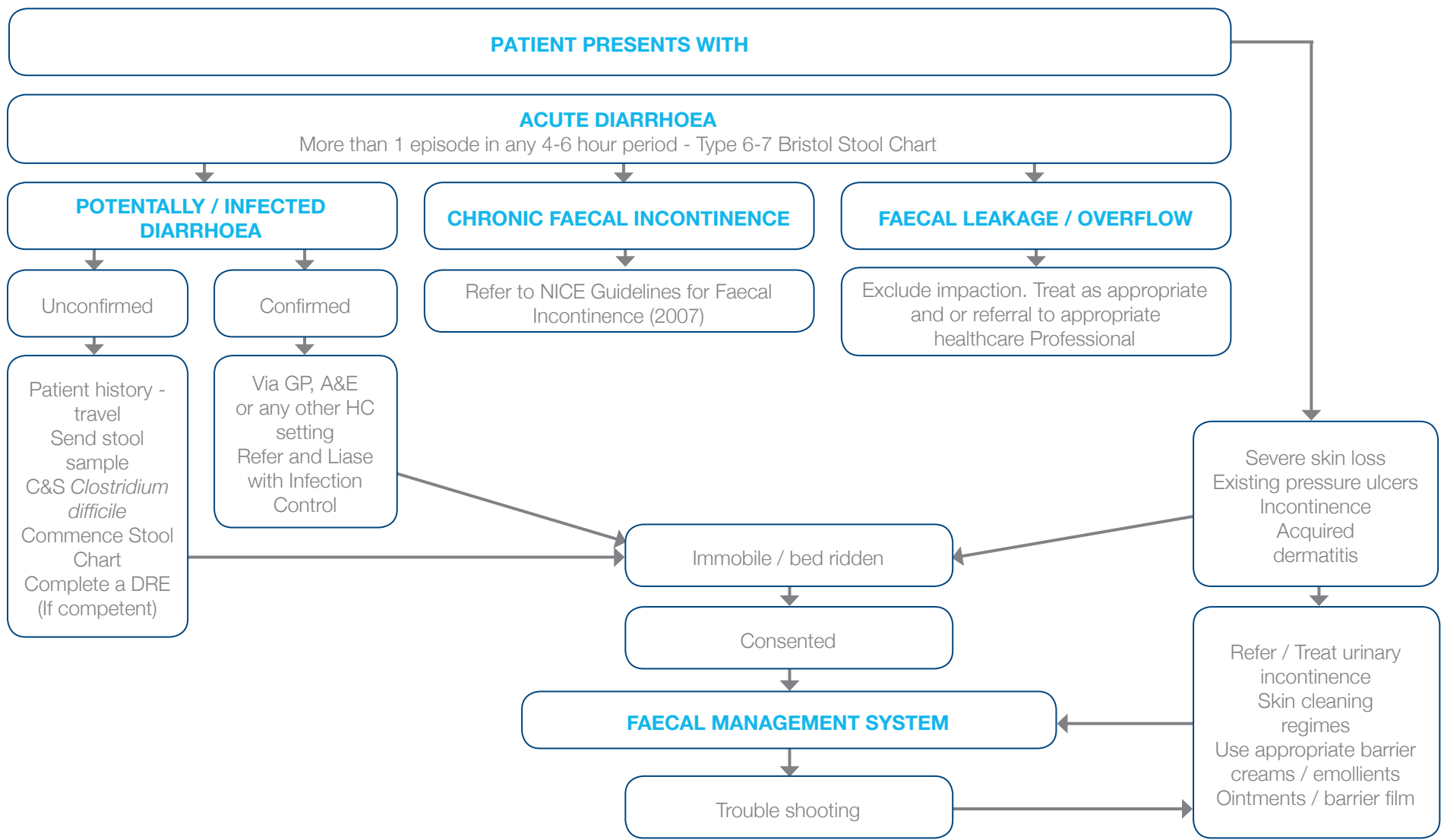
Product Ordering Codes

Flexi-Seal® CONTROL™ FMS	NHS Code	
Flexi-Seal® CONTROL™ FMS Kit (1 kit/box, 1 bag)	411107	FWN101
Flexi-Seal® SIGNAL™ FMS		
Flexi-Seal® SIGNAL™ FMS Kit* (1 kit/box)	418000	FWN086
Charcoal Filter Collection Bag (10/box)	411102	

Collection Bag Information

Privacy™ Collection Bag with APS Filter	411108	FWN102
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QUICK REFERENCE GUIDE FOR THE USE OF CONTROL



To learn more, call:

0800 289 738 (UK)

1800 946 938 (ROI)

Mon-Fri, 8:30 AM TO 7:00 PM

www.convatec.com

