Non-Storable:
The ActiFlo indwelling bowel catheter is constructed primarily of silicone materials. All system components are latex-free. Single patient use only.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or other healthcare practitioner licensed under state law to order this product.

Refer to the complete ActiFlo indwelling bowel catheter system Instructions for Use supplied by the manufacturer for directions on how to properly use this product.

Intended Use:
The ActiFlo indwelling bowel catheter system is intended for diversion of fecal matter to minimize external contact with the patient’s skin. To facilitate the collection of fecal matter for patients requiring stool management, to provide access for colonic irrigation, and to administer enema/medications.

Contraindications:
- Do not use in patients having known sensitivities or allergies to the materials used in this device.
- Do not use if the patient’s distal rectum cannot accommodate the inflated volume of the stop-flow balloon in an unattended patient. To verify complete deflation of the stop-flow balloon, aspirate air or RFX connector (STOP FLOW 25 mL AIR) pilot balloon to collapse when the syringe is removed from the connector.
- Use only gravity or slow manual irrigation. Do not irrigate patient with compromised intestinal wall integrity.
- Use only slowly or slow manual irrigation. Do not connect irrigation device to catheter irrigation lumen. Do not irrigate patient with compromised intestinal wall integrity.
- Correct catheter should be exchanged in patients in the development of local or systemic infections.
- Do not use the stop-flow balloon in an unattended patient. To verify complete deflation of the stop-flow balloon, aspirate air or RFX connector (STOP FLOW 25 mL AIR).
- Fluids may drain or splatter from the connector when it is disconnected.
- Do not use vigorous aspiration to remove fluid from the retention cuff or to remove air from the stop-flow balloon. Vigorous aspiration may collapse the inflation lumen and/or pilot balloon and may prevent retention cuff or stop-flow balloon deflation.
- Do not allow catheters or lubricating pads/polyurethane (e.g., Hollister® petroleum-based hand/body lotion) to contact the catheter. They may damage the silicone and may compromise the integrity of the device.
- Use only Hollister branded bowel catheter collection bags with the ActiFlo indwelling bowel catheter.
- Feces contain infectious material. Protect from splatter which may occur when disconnecting or emptying the collection bags or during catheter removal.
- After use, this system is a biohazard. Handle and dispose of in accordance with institutional protocol and universal precautions for contaminated waste.

Adverse Events:
The following adverse events may be associated with the use of any rectal device:
- Perforation
- Pressure necrosis
- Loss of sphincter tone
- Obstruction
- Infection
- Excessive leakage of fecal contents

Quick Reference Care Tips

For detailed clinical questions concerning our products: 1.888.740.0999
For orders only: 1.800.323.4060
www.Hollister-ActiFlo.com
Catheter Removal

1. Inflate stop-flow balloon via RED connector with 25 mL of air.

2. Deflate retention cuff by connecting syringe to the BLUE connector and slowly aspirating all water. Disconnect syringe. Verify all water is removed by confirming the BLUE connector pilot balloon is collapsed.

3. Apply water-soluble lubricant to the anal canal. Grasp the catheter at the external retention faceplate, ask patient to bear down (if capable), and apply steady traction to remove the catheter. Repeat step 2 above. Protect caregiver from splatter.

Catheter Maintenance

1. Frequently verify the catheter and collection bag are positioned so the catheter drain tube is not twisted, kinked, or externally compressed. Use a gentle tug and release to seat the retention cuff. Frequently verify that waste is not accumulating in the tube. To correct, strip the drainage away from the patient into the collection bag.

2. Flush the drainage tubing with water using the sampling/tube flushing port at least twice a day. Repeat as needed to help reduce odor.

3. Irrigate as ordered by connecting tubing from irrigation bag (included in kit and available separately) to CLEAR connector. WARNING: Verify connection to correct catheter connector. If appropriate, position patient on left side in slight Trendelenburg position. Allow fluid to drain by gravity into the rectum. Use lukewarm water or saline (as prescribed by physician). Verify retention cuff volume at least every seven days. Connect syringe to BLUE connector, completely aspirating all water. Refill retention cuff via BLUE connector with 35–40 mL of lukewarm water.

Catheter Expulsion

Perform a digital rectal exam to ensure that no stool is present in the distal rectum, and to check for adequate sphincter tone. Rinse the catheter and mimsent, following the ActiFlo indwelling bowel catheter system Instructions for Use package insert with the product. Modify stool consistency as indicated (medications and irrigations as prescribed by physician). If expulsion frequency is excessive, consider discontinuing use of the ActiFlo indwelling bowel catheter system.

Odor Management

Flush the drainage tubing with water using the sampling/tube flushing port at least twice a day. Routinely cleanse any leakage from around the anus. Clean the exposed end of the drainable odor-barrier collection bag and replace it. Change the drainable odor-barrier collection bags every seven days. Hollister collection bags contain a film designed to control odor associated with stool. Catheter removal, stool removal, and reinsertion may be required. Additional stool modification or more frequent irrigation (as prescribed by physician) may be required to prevent recurrence. Regular irrigations can help prevent rectal distention, which is associated with leakage. If leakage is excessive, consider discontinuing use of the ActiFlo indwelling bowel catheter system.

Catheter Insertion

1. Connect end of catheter drain tube to collection bag.

2. Inflate stop-flow balloon via RED connector with 25 mL of air. Disconnect syringe. Make sure the retention cuff is completely deflated (via BLUE connector). Disconnect syringe.

3. Generously apply water-soluble lubricant to the inflated stop-flow balloon, deflated retention cuff, anus, and anal canal. Note: To avoid damage to retention cuff or stop-flow balloon, DO NOT contact either with any sharp edge, including the enclosed lubricating jelly packets.

4. Grasp the lubricated catheter at the distal edge of the retention cuff with catheter connector tubing oriented anteriorly to the patient. Insert the catheter. (Do not cut off.)

5. Fill retention cuff via BLUE connector with 35–40 mL of lukewarm water. Disconnect syringe.

6. Connect the syringe to the RED connector and completely aspirate the 25 mL of air from the stop-flow balloon. Disconnect the syringe and confirm the pilot balloon is fully collapsed. WARNING: Do not leave stop-flow balloon inflated in an unattended patient.

7. Use a gentle tug and release to seat the retention cuff and confirm that the catheter fits tension-free. Confirm patency by irrigating using irrigation bag enclosed with the kit (see Catheter Maintenance, step 3).

8. Apply skin barrier (included in kit) to each buttock to help control odor associated with stool. Catheter removal, stool removal, and reinsertion may be required. Additional stool modification or more frequent irrigation (as prescribed by physician) may be required to prevent recurrence. Regular irrigations can help prevent rectal distention, which is associated with leakage. If leakage is excessive, consider discontinuing use of the ActiFlo indwelling bowel catheter system.

9. Perform a digital rectal exam to ensure that no stool is present in the distal rectum, and to check for adequate sphincter tone. Rinse the catheter and mimsent, following the ActiFlo indwelling bowel catheter system Instructions for Use package insert with the product. Modify stool consistency as indicated (medications and irrigations as prescribed by physician). If expulsion frequency is excessive, consider discontinuing use of the ActiFlo indwelling bowel catheter system.

10. Irrigate as ordered by connecting tubing from irrigation bag (included in kit and available separately) to CLEAR connector. WARNING: Verify connection to correct catheter connector. If appropriate, position patient on left side in slight Trendelenburg position. Allow fluid to drain by gravity into the rectum. Use lukewarm water or saline (as prescribed by physician). Verify retention cuff volume at least every seven days. Connect syringe to BLUE connector, completely aspirating all water. Refill retention cuff via BLUE connector with 35–40 mL of lukewarm water.

Patient Preparation

If appropriate, position patient on left side in knee-chest position. Clear the rectum of stool before catheter insertion. Based on digital exam of the anal canal, select the appropriate catheter length (4 cm length fits most patients; the correct size provides a tension-free fit). Make sure the stop-flow balloon is completely deflated and the retention cuff is inflated. Use a gentle tug and release to seat the retention cuff.

This Quick Reference Care Tips is only intended to highlight select aspects of catheter insertion, maintenance, and removal.*

The ActiFlo indwelling bowel catheter system is intended for the diversion of fecal matter to minimize external contact with the patient’s skin, to facilitate the collection of fecal matter for patients requiring stool management, to provide access for colonic irrigation, and to administer enemas/medications.

*Caution: Prior to using the ActiFlo indwelling bowel catheter system, be sure to read the entire ActiFlo indwelling bowel catheter system Instructions for Use package insert supplied with the product for device Intended Use, Description, Contraindications, Warnings, Precautions, Adverse Events, and Instructions for Use.