

ActiFlo Indwelling Bowel Catheter System
Product Information

NON STERILE:

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 retention cuff or if the distal rectum/anal canal is severely strictured (e.g., secondary to tumor, inflammatory condition, radiation injury, scarring).
- Do not use on patients having impacted stool.
- Do not use on patients with a recent (less than 6 weeks old) rectal anastomosis, or a recent (less than 6 weeks old) anal or sphincter reconstruction.
- Do not use on patients with compromised rectal wall integrity (e.g., ischemic proctitis).
- Do not connect irrigation bag to an IV.
- Do not use irrigation bag for enteral feeding.

WARNINGS (Failure to comply with the following warnings may result in patient injury)

- Do not use if package is open or damaged.
- Do not use improper amount or type of fluids for irrigation or cuff/balloon inflations. NEVER use hot liquids.
- Do not over inflate retention cuff or stop-flow balloon.
- Inflation of the stop-flow balloon causes complete catheter occlusion. Do not leave stop-flow balloon inflated in an unattended patient. To verify complete deflation of the stop-flow balloon, aspirate all air until RED connector (STOP FLOW 25 mL AIR) pilot balloon is collapsed when the syringe is removed from the connector.
- Use only gravity or slow manual irrigation. Do not connect manual pumping devices to catheter irrigation lumen. Do not irrigate patient with compromised intestinal wall integrity.
- Extreme caution should be exercised in patients at risk for the development of toxic megacolon. Occluding the tube by inflating the stop-flow balloon could aggravate this situation.
- Perform irrigations, and enema/medication administrations, via the CLEAR connector (IRRIG/Rx) AND NOT via the BLUE connector (CUFF 35-40 mL H₂O) or RED connector (STOP FLOW 25 mL AIR).
- Blood per rectum should be investigated to ensure no evidence of pressure necrosis from the device. Discontinue use of the device if evident.
- Abdominal distention that occurs while using the device should be investigated.
- Excessive prolonged traction on the catheter, resulting in the retention cuff migrating into the anal canal, could result in temporary or permanent clinical sphincter dysfunction, or catheter expulsion.

PRECAUTIONS

- Do not sterilize.
- The ActiFlo Indwelling Bowel Catheter System is not intended for use longer than 29 days.
- Caution should be exercised in use of this device with patients who may bleed easily due to anticoagulant/antiplatelet therapy or underlying disease conditions. Immediately consult a physician if rectal bleeding is suspected.
- The ActiFlo Indwelling Bowel Catheter System is not recommended for pediatric use.
- To avoid damage to retention cuff or stop-flow balloon, DO NOT contact either with ANY sharp edge including the enclosed lubricating jelly packets.
- The ActiFlo Indwelling Bowel Catheter System may not be effective in individuals who have had their distal rectum significantly altered by surgical resection or reconstruction.
- Patients with very weak sphincter function may expel the catheter under normal use, or may have increased leakage of stool or irrigation fluids compared to patients with normal sphincter function.
- Caution should be observed in patients whose rectum may be altered by stricture due to radiation or affected with radiation proctitis.
- Patients with severe tenesmus, or patients who experience tenesmus or severe pain after insertion of device, may not tolerate the catheter in place.
- Avoid inserting anything (e.g., thermometer, suppository, etc.) into the anal canal with the catheter in place to minimize patient injury or catheter damage.
- Care should be taken when disconnecting syringe from the CLEAR connector (IRRIG/Rx). Fluids may drain or splatter from the connector when it is disconnected.
- Use WATER ONLY to inflate retention cuff. Do not use saline solution, which may adversely affect valve function.
- Use AIR ONLY to inflate the stop-flow balloon. Do not use water or any other fluid.
- 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 ointments or lubricants having a petroleum base (e.g., Vaseline®, 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 contains 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

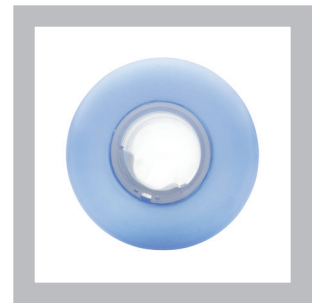


A Hollister Technology



ActiFlo
Indwelling Bowel Catheter System

Quick Reference Care Tips



Sustainable performance.

For detailed clinical questions concerning our products: **1.888.740.8999**
For orders only: **1.800.323.4060**
www.Hollister-ActiFlo.com



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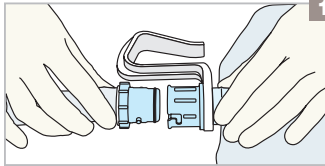
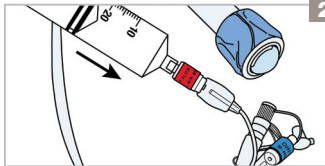

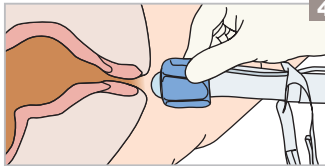
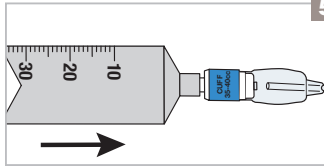
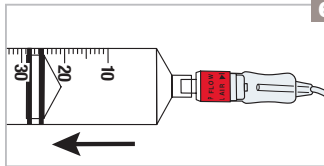
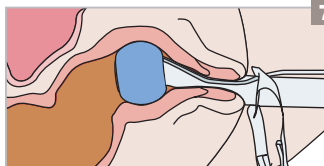
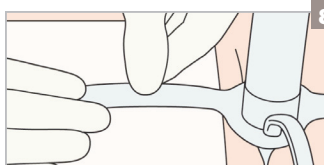
*This Quick Reference Care Tips is only intended to highlight select aspects of catheter insertion, maintenance, and removal.**

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.

Patient Preparation

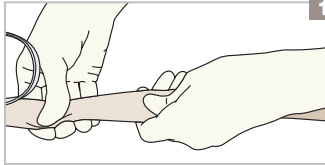
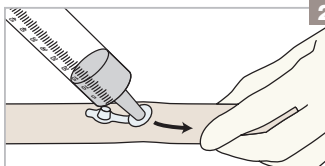
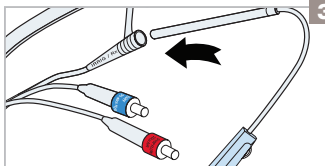
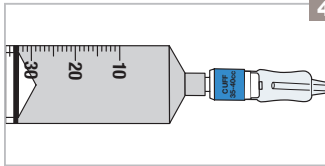
If appropriate, position patient on left side in knee-chest position. Clear the rectum of stool before catheter insertion. Based on digital exam of the anal canal, select the appropriate catheter length (4 cm length fits most patients; the correct size provides a tension-free fit).

Catheter Insertion

-  Connect end of catheter drain tube to collection bag.
-  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.
-  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.
-  Grasp the lubricated catheter at the distal edge of the retention cuff with catheter connector tubing oriented anteriorly to the patient. Insert the catheter.
-  Fill retention cuff via BLUE connector with 35-40 mL of lukewarm water. Disconnect syringe.
-  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.**
-  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).
-  Apply skin barrier (included in kit) to each buttock to help prevent tape injury. Tape the anchor straps to the skin barriers. If unable to use skin barrier or anchor straps, tape anchor straps smoothly to the ActiFlo Indwelling Bowel Catheter. (Do not cut off.)

***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.

Catheter Maintenance

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

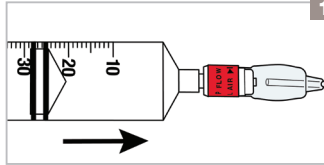
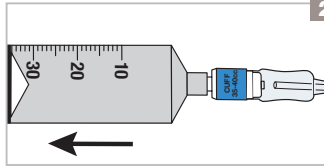
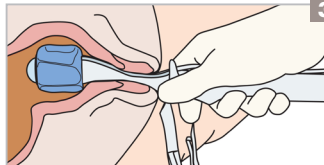
Catheter Expulsion

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 reinsert, following the ActiFlo Indwelling Bowel Catheter System Instructions for Use package insert supplied 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. Cleanse the exposed end of the drainable odor-barrier collection bag spout before capping 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

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

Leakage

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. Be sure the low-impact zone is not twisted, the anchor straps are secured, the tubing is straight and free of stool, and the collection bag is lower than the patient. Placing the patient's bed in a slight reverse Trendelenburg position will facilitate catheter drainage. During irrigation, if tolerated, position the patient's bed in a slight Trendelenburg position. Avoid infusing irrigation too rapidly or using water that is too cool. Excessive leakage during use may be secondary to catheter occlusion 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.