

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

ActiFlo

Indwelling Bowel Catheter System

Frequently Asked Questions

These Frequently Asked Questions are only intended to highlight select aspects of catheter insertion, maintenance, and removal.*

Product Information

1. *What makes the ActiFlo Indwelling Bowel Catheter System different from other commercially available products?*

The ActiFlo System is the only bowel catheter system capable of proactively managing various stool consistencies, thereby maximizing indwell time. It is a total system that is designed to help enhance overall performance, help control costs, and help improve patient outcomes.

2. *Does the ActiFlo Indwelling Bowel Catheter System require a physician's order?*

Yes. 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.

3. *What are the most common situations in which the ActiFlo Indwelling Bowel Catheter System may be used?*

- Bowel incontinence, 2-3 loose/diarrhea stools a day
- Bedridden patients unable to use a bedpan or commode
- Patients who require rectally-administered medications
- Burns or donor sites likely to be contaminated
- Infectious diarrhea
- Prolonged sedation, mechanical ventilation, and/or paralysis
- Wounds in or near the sacral or perianal area
- Patients unable to tolerate frequent repositioning
- Patients with a urinary catheter or other lines at risk from fecal contamination
- NOT recommended for pediatric use
- NOT intended for use longer than 29 days

4. *Can the ActiFlo Indwelling Bowel Catheter System be used in patients with complex medical conditions?*

Decisions about clinical appropriateness for this device are up to the prescribing physician.

5. *Does this product contain latex?*

No, the specifications for ActiFlo Indwelling Bowel Catheter System products and packaging do not include natural rubber latex as a component, and our component suppliers do not add natural rubber as part of their production process.

***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.

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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How to Use

1. How long can the ActiFlo Indwelling Bowel Catheter System be used?

The ActiFlo Indwelling Bowel Catheter System is intended for use up to 29 days.

2. Why use a stop-flow balloon?

This feature allows the clinician to create a smooth tip for catheter insertion. The stop-flow balloon is the feature that permits the clinician to temporarily stop flow through the catheter so rectally-administered medications can dwell in the rectum for the prescribed amount of time.

3. What do the anchor straps do?

The anchor straps help prevent inadvertent dislodgement and inward migration of the catheter. This helps avoid obstructed catheter flow, leakage, or expulsion.

4. Why is gravity irrigation used?

This allows water to flow more slowly and with lower pressure than when a syringe is used to irrigate. Gravity irrigation helps prevent leakage, odor, and catheter expulsion.

5. What is the appropriate size catheter to use?

The ActiFlo Indwelling Bowel Catheter System is available in two sizes, 4 cm and 6 cm. The 4 cm length fits most patients; the correct size provides a tension-free fit.

6. Will the ActiFlo Indwelling Bowel Catheter System lead to rectal tissue damage?

In a study of 32 patients treated with this system, there were no anal mucosal abnormalities observed.¹ In a separate study of 20 patients, proctoscopic exams were normal after tube removal in all cases.² The physician prescribing the ActiFlo Indwelling Bowel Catheter System must evaluate the risks and benefits of using the device for each individual patient.

7. What is the recommended retention cuff volume for patients with low sphincter tone?

Use 35-40 mL in the retention cuff in all cases (see Instructions for Use).

8. If the ActiFlo Indwelling Bowel Catheter is expelled, can it be reinserted?

Yes. According to the Instructions for Use, as long as it's still within 29 days of the initial insertion, the catheter can be washed off, checked for product integrity, and reinserted. It is important to investigate why the device was expelled. Check for retained stool in the rectum or other problems that may have contributed to catheter expulsion and resolve these issues.

9. How can we reduce odor?

The collection bags available with the ActiFlo System contain a film which is designed to control odor associated with stool. Other helpful hints to help control odor:

- Flush the drainage tubing with tap water using the sampling/tube flushing port at least twice a day
- Routinely cleanse any leakage from around the anus
- If using the drainable collection bags, cleanse the exposed end of the drainable collection bag spout before capping it
- Change the drainable collection bags every seven days

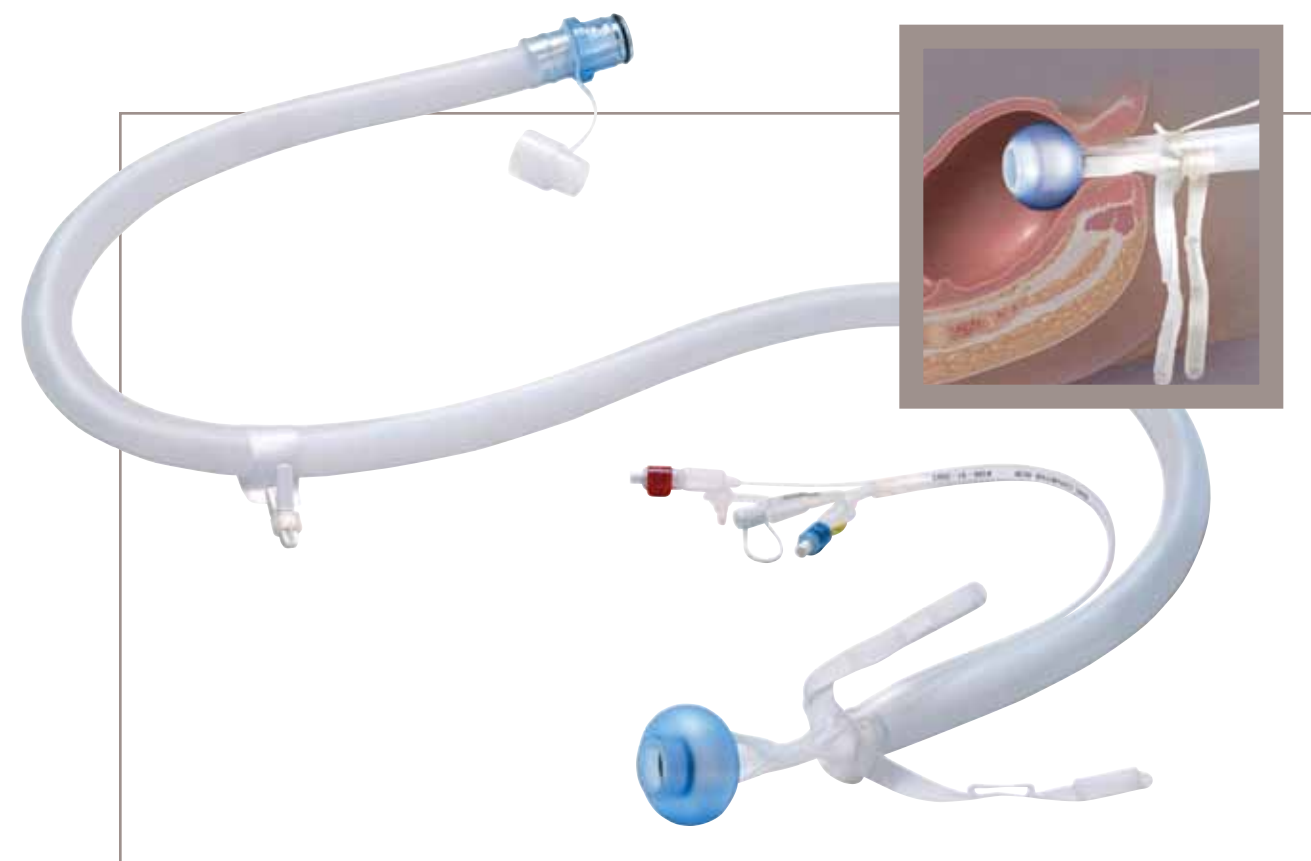
10. How can leakage be reduced?

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 System.

11. How often should the retention cuff be deflated, and why?

The retention cuff volume should be verified at least every seven days. This allows you to adjust for any loss of fluid from the retention cuff.



1. Kim J, et al. Clinical application of continent anal plug in bedridden patients with intractable diarrhea. *Dis Colon Rectum* 2001; 44:1162-1167.

2. Keshava A, Renwick A, Stewart P, Pilley A. A nonsurgical means of fecal diversion: the Zassi Bowel Management System. *Dis Colon Rectum* 2007; 50:1017-1022.