

**NON STERILE:** The InstaFlo 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 InstaFlo Bowel Catheter System Instructions for Use that is packaged with the InstaFlo Bowel Catheter System Kit for directions on how to properly use this product.

**INTENDED USE**

The InstaFlo Bowel Catheter System is intended for the diversion of liquid or semi-liquid stool to facilitate the collection of fecal matter in patients with little or no bowel control.

**CONTRAINDICATIONS**

- Do not use in patients with 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, mucosal ulcerations).

**WARNINGS**

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

- Do not use if package has been opened or damaged.
- Do not use improper amount or type of fluids for irrigation or retention cuff inflation. NEVER use hot liquids.
- Do not overinflate retention cuff.
- Use only gravity or slow manual irrigation. Do not connect mechanical pumping devices to catheter irrigation connector (IRRIG).
- Perform irrigations via the CLEAR connector (IRRIG) AND NOT via the BLUE connector (CUFF 35-40 mL H<sub>2</sub>O).
- Blood per rectum should be investigated to ensure there is 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 migration into the anal canal, could result in temporary or permanent clinical sphincter dysfunction or catheter expulsion.

**PRECAUTIONS**

- Do not sterilize.
- The InstaFlo Catheter 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 InstaFlo Catheter is not recommended for pediatric use.
- To avoid damage to retention cuff, DO NOT contact with ANY sharp edge.
- The InstaFlo Catheter 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 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 the 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 the chance of patient injury or catheter damage.
- Care should be taken when disconnecting the syringe from the CLEAR connector (IRRIG). Fluids may drain or splatter from the connector when it is disconnected.
- Use WATER ONLY to inflate the retention cuff. Do not use saline solution, which may adversely affect valve function.
- Do not use vigorous aspiration to remove fluid from the retention cuff. Vigorous aspiration may collapse the inflation lumen and/or pilot balloon, and may prevent 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 compromise the integrity of the device.
- Use only Hollister branded bowel catheter collection bags with the InstaFlo Catheter.
- Feces contain infectious material. Protect from splatter which may occur when disconnecting 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.

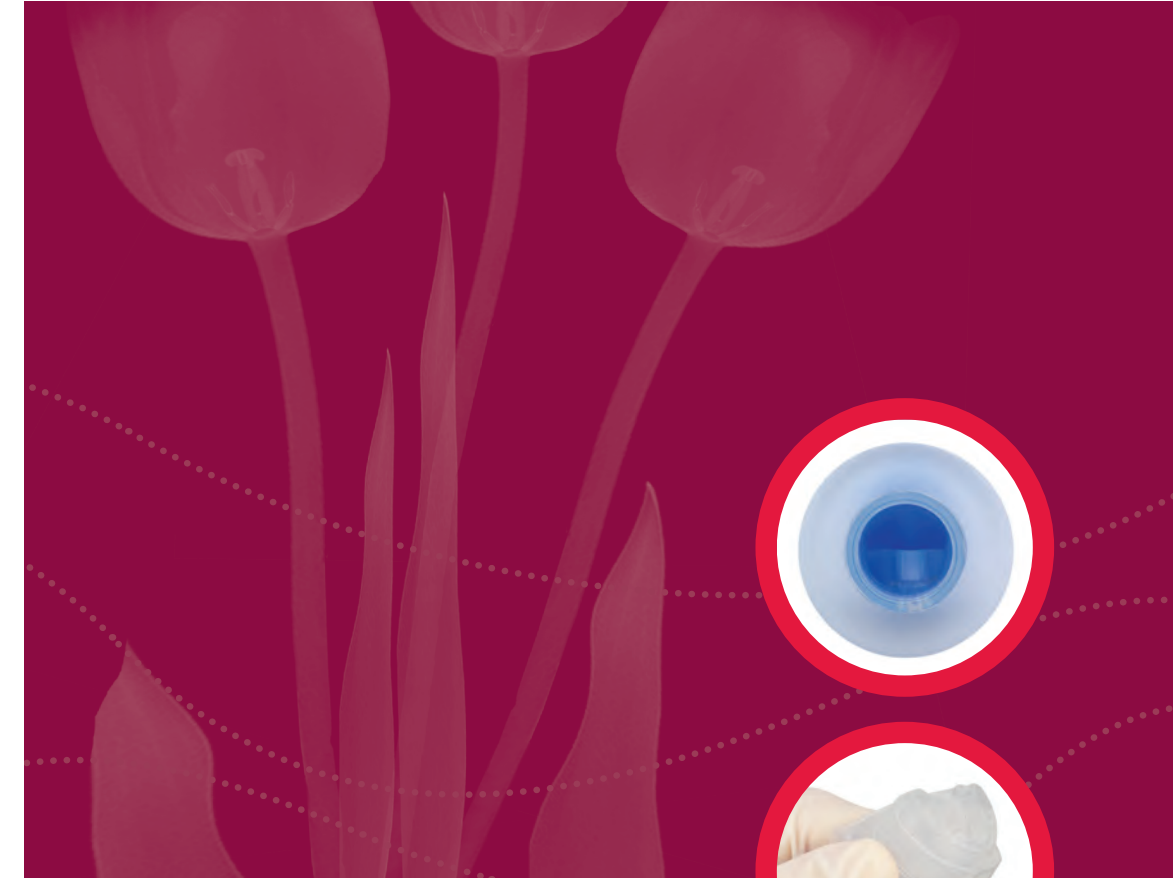
**ADVERSE EVENTS**

The following adverse events may be associated with the use of any rectal device:

- |                          |                                       |
|--------------------------|---------------------------------------|
| • Perforation            | • Obstruction                         |
| • Pressure necrosis      | • Infection                           |
| • Loss of sphincter tone | • Excessive leakage of fecal contents |



**Quick Reference Care Tips**



*Advanced simplicity.*

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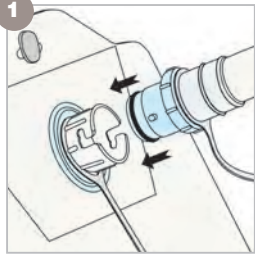
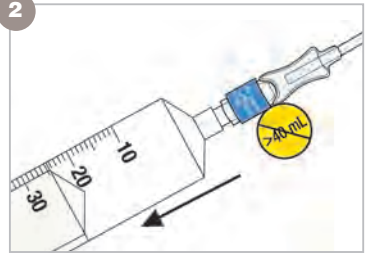
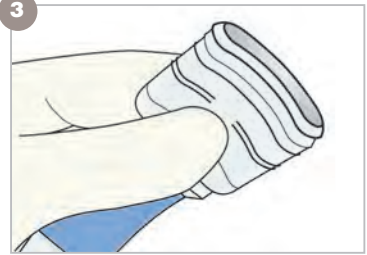
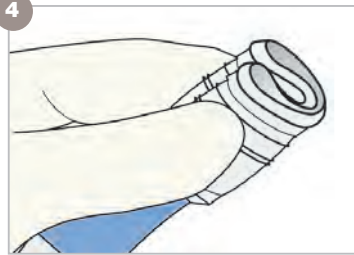

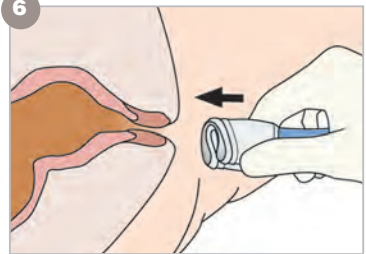
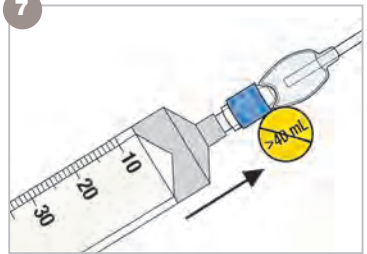
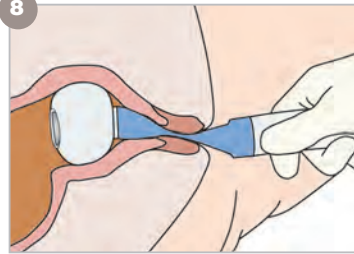
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This is a Quick Reference Guide which is only intended to highlight select aspects of catheter insertion, removal, and routine care.\*

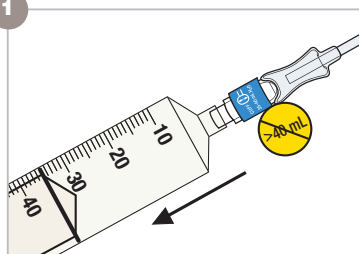
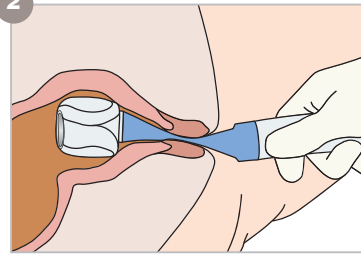
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## Catheter Insertion

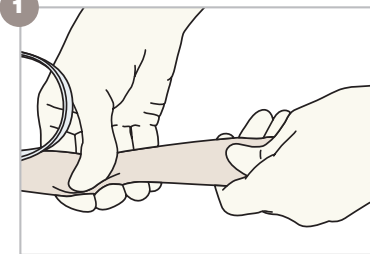
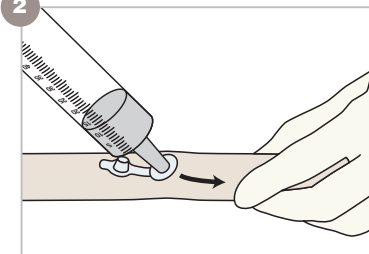
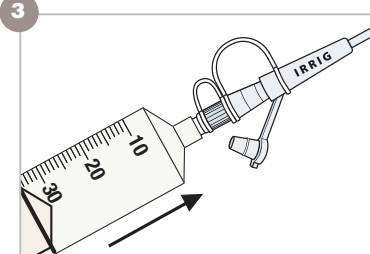
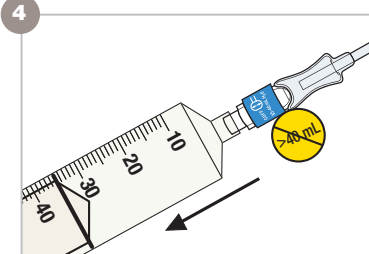
- 1  **Connect tube to bag**
- 2  **Withdraw all air from cuff via BLUE connector**
- 3  **Squeeze cuff flat**
- 4  **Fold cuff in half**
- 5  **Generously lubricate catheter end**
- 6  **Insert cuff into distal rectum**
- 7  **Fill cuff with 35-40 mL water via BLUE connector**
- 8  **Gently tug and release to seat the cuff**

## Catheter Removal

When the patient's stool consistency is no longer liquid or semi-liquid, remove the InstaFlo Bowel Catheter.

- 1  **Deflate retention cuff by connecting the Luer syringe to the BLUE connector and slowly aspirate all water. Disconnect syringe. Verify all water is removed by confirming the BLUE connector pilot balloon is collapsed.**
- 2  **Apply water-soluble lubricant to the anal canal. Grasp the catheter as close to the anus as possible, ask the patient to bear down (if capable), and apply steady traction to remove the catheter. Protect caregiver from splatter.**

## Routine Care

- 1  **Frequently verify the catheter and collection bag are positioned so the catheter drain tube is not twisted, kinked, or externally compressed. Frequently verify that waste is not accumulating in the drain tube. To correct, strip the tubing toward the collection bag.**
- 2  **Flush the drain tube with water using the sampling/tube flushing port at least twice a day. Repeat as needed to help reduce odor.**
- 3  **If stool is not flowing into the catheter, irrigate the catheter. Fill the Luer syringe with water, connect the syringe to the CLEAR connector (IRRIG), and slowly depress the plunger. **WARNING: Verify connection to correct catheter connector****
- 4  **Verify retention cuff volume at least every seven days. Connect the Luer syringe to BLUE connector, slowly aspirating all fluid. Refill retention cuff via BLUE connector with 35-40 mL of water**

## Helpful Hints

### Odor Management

- Flush the tubing with water using the sampling/tube flushing port at least twice a day
- Routinely cleanse any leakage from around the anus

### Leakage

- Make sure the retention cuff is inflated
- Use a gentle tug and release to seat the retention cuff (e.g., approximately 1 cm of the blue tubing should be visible)
- Be sure the low impact zone is not twisted, the tubing is straight and free of stool, and the drainage bag is lower than the patient
- Excessive leakage during use may be secondary to catheter occlusion with stool. If leakage is excessive, consider discontinuing use of the InstaFlo Bowel Catheter System

### Catheter Expulsion

- Verify that no stool is present in the distal rectum
- Rinse the catheter and reinsert, following the instructions for "Catheter Insertion"
- Verify that the catheter and collection bag are positioned so that the catheter drain tube is not twisted, kinked, or externally compressed
- If expulsion frequency is excessive, consider discontinuing use of the InstaFlo Bowel Catheter System