

InstaFlo Bowel Catheter System
Product Information

The approved labeling for this device states it is not intended for use longer than 29 days.
NON STERILE: The InstaFlo Bowel Catheter System 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.
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.

PRECAUTIONS

- Do not sterilize.
- The InstaFlo Catheter is not intended for use longer than 29 days.
- Caution should be exercised in the 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 the 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.

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 the 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 H₂O).
- 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.

ADVERSE EVENTS (The following adverse events may be associated with the use of any rectal device.)

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

Advanced simplicity.

Simple
Convenient
Effective



Hollister and logo, Hollister, and InstaFlo are trademarks of Hollister Incorporated. Covered under one or more of the following patents: US Patents 7147627, 7722583, Australia Patents 2003207608, 2007201015, Canada Patent 2462570, and Japan Patent 4260107, and other patents pending.
 © 2011 Hollister Incorporated. Printed in USA. 911317-511

Hollister Incorporated
Libertyville, IL USA

For detailed clinical questions concerning our products:
1.888.740.8999
For orders only: 1.800.323.4060

Distributed by Hollister Limited
Aurora, Ontario
1.800.263.7400

www.hollister.com



The InstaFlo Bowel Catheter System is designed to be easy to learn and use, and to help minimize the need for clinician intervention and maintenance. It is the only diarrhea management system to combine a collapse-resistant ring, a low-pressure retention cuff, and a sampling port.

Product features

Collapse-Resistant Ring

- designed to help minimize catheter expulsion
- helps guard against leakage

Low-Pressure Retention Cuff

- assists with holding tube in place

Sampling/Tube Flushing Port

- facilitates stool sampling while system remains in place
- enables tube flushing

Low-Impact Zone

- designed to help minimize impact on anal sphincter

Catheter Connectors

- color-coded and labeled for easy identification
- indicate retention cuff inflation status via pilot balloon
- accept standard Luer tip syringes

Disposable Odor-Barrier Collection Bag

- helps diminish odor

Coated Drain Tube

- low friction helps promote easy handling

Twist Lock Fitting

- connects securely to disposable odor-barrier collection bag

3 simple steps for insertion*

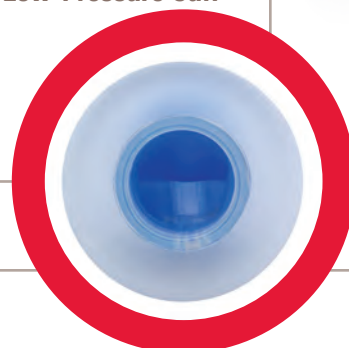
1 connect

2 prep

3 place



Collapse-Resistant Ring and Low-Pressure Cuff



Folded Cuff for Insertion



Sampling/Tube Flushing Port



Stock No	Catheter Kit includes
33005	Catheter
	2000 mL Disposable Odor-Barrier Collection Bag
	60 mL Luer Syringe
	Instruction Booklet
	Quick Reference Insertion Guide

Stock No	Box of 5
31008	2000 mL Disposable Odor-Barrier Collection Bag



*Caution: Prior to use of the InstaFlo Bowel Catheter System, be sure to read the entire InstaFlo 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.