



Non-Sterile
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Non-Sterile



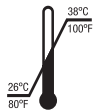
Latex-Free
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Latex-Free



Approximate Volume (mL)
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Not for IV Use
Not for IV Use
Not for IV Use
Not for IV Use



Lukewarm Temperature, 26-38° C (80-100° F)
Lukewarm Temperature, 26-38° C (80-100° F)
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**USA:
Rx Only**

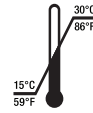
Caution:
Federal (USA) Law Restricts this Device to Sale by or on the Order of a Physician
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Do Not Use if Package is Damaged
Do Not Use if Package is Damaged
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Consult Instructions for Use
Consult Instructions for Use
Consult Instructions for Use



Store at 15-30° C (59-86° F)
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**INSTRUCTIONS FOR USE • INSTRUCTIONS FOR USE 1
INSTRUCTIONS FOR USE 2 • INSTRUCTIONS FOR USE 3**

ActiFlo™

Indwelling Bowel Catheter System

- US** Indwelling Bowel Catheter System

- CA** Indwelling Bowel Catheter System 1

- ES** Indwelling Bowel Catheter System 2

- PT** Indwelling Bowel Catheter System 3



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KIT CONTENTS

CATHETER KITS WITH DRAINABLE COLLECTION BAGS

- 1 Catheter
- 1 Collection Bag with Drain
- 1 Irrigation Bag
- 1 Syringe
- 2 Lubricating Jelly Packets
- 2 Skin Barriers

Stock No	Transsphincteric Zone
32004	4 cm
32005	6 cm

CATHETER KITS WITH CLOSED COLLECTION BAGS

- 1 Catheter
- 2 Collection Bags
- 1 Irrigation Bag
- 1 Syringe
- 2 Lubricating Jelly Packets
- 2 Skin Barriers

Stock No	Transsphincteric Zone
32006	4 cm
32007	6 cm

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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.

1. 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.

2. DEVICE DESCRIPTION

The ActiFlo Indwelling Bowel Catheter System consists of three main parts: the catheter, the collection bag, and the irrigation bag. The insertion end of the catheter contains a retention cuff and an intraluminal balloon, each with its own Luer connector used for inflation and deflation. A third connector provides a way to administer medications into the rectum and provides access for colonic irrigation. The ActiFlo Indwelling Bowel Catheter System allows stool to drain directly from the rectum into a closed or drainable collection bag. Please **See Figure 1** and the following table for configuration and a description of the ActiFlo Indwelling Bowel Catheter.

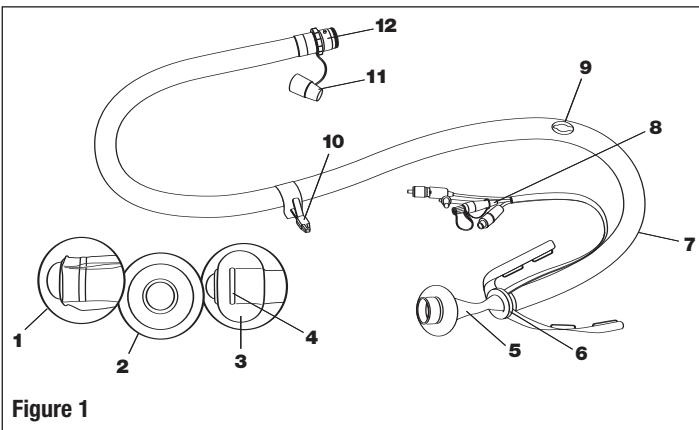


Figure 1

No.	What It Is	What It Does
1	Intraluminal Balloon	<ul style="list-style-type: none"> Inflates for use as an introducer to aid insertion of the catheter through the anal canal Inflates to occlude the inside of the catheter for medication and irrigant retention Deflates to allow the flow of stool
2	Collapse-Resistant Annulus	<ul style="list-style-type: none"> Helps reduce catheter occlusion Designed to help minimize leakage and expulsion
3	Retention Cuff	<ul style="list-style-type: none"> Assists in holding tube in place in the rectal vault
4	Radiopaque Marker	<ul style="list-style-type: none"> Identifies the device under X-ray or fluoroscopy
5	Transsphincteric Zone	<ul style="list-style-type: none"> Soft, collapsible material designed to help avoid impact on rectal sphincter Available in two sizes (4 cm and 6 cm)

6	External Retention Faceplate and Anchor Straps	<ul style="list-style-type: none"> Stabilize catheter to help reduce internal migration Help prevent twisting or inadvertent dislodgement
7	Coated Drain Tube	<ul style="list-style-type: none"> Functions as a conduit to transport waste to collection bag Helps reduce friction, promotes drainage and odor control
8	Catheter Connectors (See below)	<ul style="list-style-type: none"> Color coded and clearly labeled Accept standard Luer tip syringes Pilot balloons indicate the inflation status
9	Flush/Sampling Port	<ul style="list-style-type: none"> Provides easy access to flush the drainage tubing Split septum for convenient sample collection
10	Adjustable Sheet Clip	<ul style="list-style-type: none"> Secures tube in the desired position
11	Drain Cap	<ul style="list-style-type: none"> Caps the tube for bag removal
12	Twist Lock Connector	<ul style="list-style-type: none"> Securely connects to either a drainable or closed collection bag

Catheter Connectors (See Figure 2)

No.	Connector Color and Label	What It Is	What It Does
1	BLUE CUFF 35-40 mL H ₂ O	Retention Cuff Connector	<ul style="list-style-type: none"> Used to inflate with water to fill the retention cuff Recommended volume 35-40 mL water
2	RED STOP FLOW 25 mL AIR	Stop Flow Connector	<ul style="list-style-type: none"> Used to inflate with air to fill the intraluminal balloon Recommended volume 25 mL air
3	CLEAR (IRRIG/RX) with white-capped removable rigid Luer lock fitting and silicone funnel fitting. Both fittings have closure caps.	Irrigation and Medication Connector	<ul style="list-style-type: none"> Allows irrigation or administration of medication

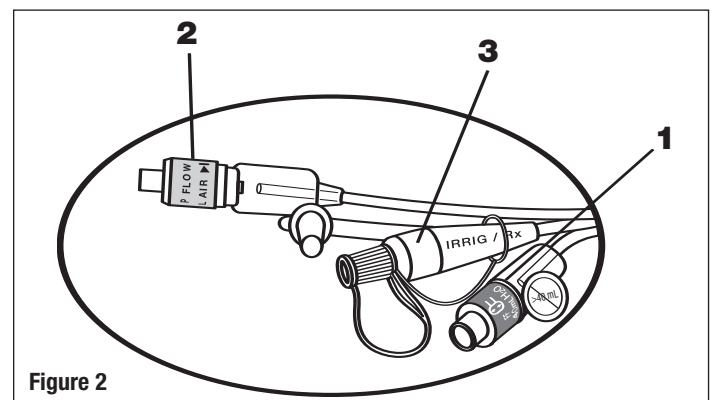


Figure 2

3. 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).

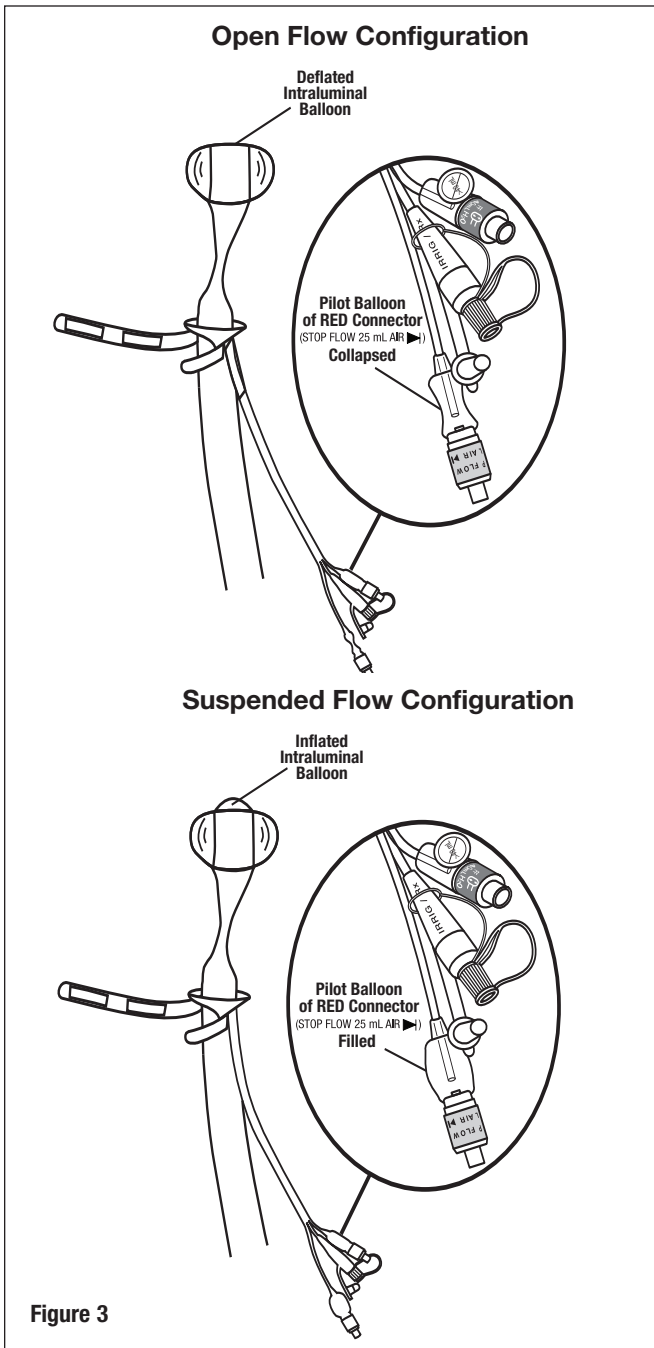
4. WARNINGS

(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 intraluminal balloon.
- Inflation of the intraluminal balloon causes complete catheter occlusion (**See Figure 3**). Do not leave the intraluminal balloon inflated in an unattended patient. To verify complete deflation of the intraluminal balloon, aspirate all air until the RED connector (STOP FLOW 25 mL AIR ►) pilot balloon is collapsed when the syringe is removed from the connector (**See Figure 3**).
- Use only gravity or slow manual irrigation. Do not connect mechanical 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 intraluminal balloon could aggravate this situation.
- Perform irrigations, and enema and medication administrations, via the CLEAR connector (IRRIG/Rx) **AND NOT** via the BLUE connector (CUFF (⊕) = 35-40 mL H₂O) or the RED connector (STOP FLOW 25 mL AIR ►).
- 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.
- The section of the catheter that crosses the anal canal (transsphincteric zone) is made of soft collapsible material designed to help avoid impact on the rectal sphincter. 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.

5. PRECAUTIONS

- Do not sterilize.
- The ActiFlo Indwelling Bowel Catheter is not intended for use longer than 29 days.
- The ActiFlo Indwelling Bowel Catheter is not recommended for pediatric use.
- To avoid damage to the retention cuff or intraluminal balloon, DO NOT contact either with ANY sharp edge, including the enclosed lubrication jelly packets.
- The ActiFlo Indwelling Bowel 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 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 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/Rx). Fluids that are retained in the rectum and colon 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.
- Use AIR ONLY to inflate the intraluminal 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 intraluminal balloon. Vigorous aspiration may collapse the inflation lumen and/or pilot balloon, and may prevent retention cuff or intraluminal 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 compromise the integrity of the device.
- Use only ActiFlo Collection Bags with the ActiFlo Indwelling Bowel Catheter.
- Feces contains infectious material. Protect caregiver and others 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.

6. 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

7. CATHETER INSERTION

Patient Preparation

NOTE: To optimize ActiFlo Indwelling Bowel Catheter System performance, the colon should be evacuated of formed and semi-formed stool prior to use. **In ALL cases, the rectum should be cleared of stool prior to catheter insertion.** Patients who have not had a bowel movement for two or more days should be considered as having FIRM stool and should be given a bowel prep or enema prior to insertion of the catheter.

Regular irrigation and stool modification are recommended (as prescribed by the physician) to optimize stool consistency and to facilitate evacuation through the catheter.

Supplies:

- ActiFlo Indwelling Bowel Catheter System Kit (4 cm or 6 cm) with drainable or closed collection bag
- Container with approximately 100 mL of lukewarm water
- Tape (approximate width: 2 cm)
- Catheter tip syringe, 60 mL

1. The preferred patient position for catheter insertion is the left lateral knee-chest position (the patient's clinical situation may dictate the use of an alternate position). The goal of patient positioning is to maximize sphincter relaxation to ease catheter insertion.
2. Prior to opening the product, examine the rectum and anal canal for fecal impaction, formed and semi-formed stool, and anatomical abnormalities.
3. Disimpact (as prescribed by physician) and/or clear stool as indicated so the rectum is empty prior to catheter insertion. If anatomical abnormalities (mass, lesions, strictures, etc.) are present, consult a physician prior to inserting the catheter.
4. The digital exam will also serve to pre-dilate the anal sphincter and help determine the length of the anal canal (The correct size allows a 1 cm gap between the external retention faceplate and the anal verge).
5. Select the appropriate catheter length. Some patients require the 6 cm catheter to allow for the desired tension-free fit, while others require the 4 cm catheter to prevent excessive catheter movement.
6. Open the product packaging and remove the contents.

Device Preparation

1. Prior to use, verify proper inflation/deflation of the retention cuff and intraluminal balloon and patency of the irrigation lumen as follows. If any product failures are observed in steps a-e below, do not use product.
 - a. Inflate the intraluminal balloon with 25 mL of air using the RED connector (STOP FLOW 25 mL AIR ►). Disconnect the syringe and verify that the pilot balloon indicates inflation of the intraluminal balloon.
 - b. Fill the retention cuff with 35-40 mL of water using the BLUE connector (CUFF Ⓢ= 35-40 mL H₂O). Disconnect the syringe and verify that the pilot balloon indicates inflation of the retention cuff.
 - c. Inspect the retention cuff and intraluminal balloon for proper inflation and the absence of leaks.
 - d. Slowly and completely aspirate ALL fluid from the retention cuff and disconnect the syringe. Withdraw ALL air from the intraluminal balloon, then disconnect the syringe. Verify that the pilot balloons indicate that the retention cuff and the intraluminal balloon are deflated.
 - e. Inject water through the CLEAR connector (IRRIG/Rx) to confirm lumen patency. Disconnect the syringe and close the connector.

Catheter Insertion

1. Connect the end of the catheter drain tube to the collection bag by inserting the catheter twist lock connector into the bag connector. Twist clockwise to lock into place. **WARNING: Prior to use of the ActiFlo Collection Bags read the ActiFlo Collection Bag Instructions including all illustrations on pages 14-16.**
 2. Inflate the intraluminal balloon with 25 mL of air via the RED connector (STOP FLOW 25 mL AIR ►) and then disconnect the syringe.
 3. Withdraw any air or water present in the retention cuff via the BLUE connector (CUFF Ⓢ= 35-40 mL) then disconnect syringe.
 4. Generously apply water-soluble lubricant to the inflated intraluminal balloon, deflated retention cuff, anus and anal canal.
- NOTE: To avoid damage to retention cuff or intraluminal balloon, DO NOT contact either with ANY sharp edge, including the enclosed lubricating jelly packets.

5. Grasp the lubricated catheter at the distal edge of the retention cuff, with the catheter connector tubing oriented anteriorly to the patient (**See Figure 4**).
6. At the time of maximum sphincter relaxation (often associated with end exhalation), insert the balloon end of the catheter into the distal rectum. Maintain anterior orientation of the catheter connector tubing throughout insertion.
7. Fill the retention cuff with 35 mL to 40 mL of lukewarm water via the BLUE connector (CUFF (1) = 35-40 mL H₂O) then disconnect the syringe.
8. Connect the syringe to the RED connector and completely aspirate the 25 mL of air from the intraluminal balloon (STOP FLOW 25 mL AIR ►). Disconnect the syringe and confirm that the pilot balloon is fully collapsed (**See Figure 3**). **WARNING: Do not leave intraluminal balloon inflated in an unattended patient.**
9. Use a gentle tug and release to seat the retention cuff and confirm that the catheter fits tension free (e.g., 1 cm or greater gap between the external retention faceplate and anal verge).
10. Apply skin barrier to each buttock to help prevent tape injury. To apply the skin barriers, open the package, remove the release film, and press the adhesive side to clean, dry, intact skin. Be careful to avoid any oil or soapy residue that could interfere with adhesion. Do not apply to broken skin (product is non-sterile).
11. Ensure that the catheter is not twisted (e.g., the transsphincteric tube is not twisted, the anchor straps are lateral and the catheter connector tubing is anterior).
12. Tape the anchor straps to the skin barrier. Ensure that the anchor straps DO NOT apply tension to the catheter.
13. Hang the collection bag so that the catheter drain tube is not twisted or kinked.
14. Use the sheet clip to secure the drain tube to the sheet.



6. If no noticeable stool is in the fluid draining from the patient, or if the patient has known formed stool, larger stool masses may be present in rectum. To break up large stool pieces, crimp the tubing and repeatedly squeeze and release the ActiFlo Catheter close to the patient. Additional irrigation fluid may be necessary.
7. Proceed with routine irrigation as prescribed by the physician when patency is confirmed (See "Irrigation" section page 10).

8. ROUTINE CARE

Irrigation

WARNING: Prior to use of the ActiFlo Irrigation Bag read the ActiFlo Irrigation Bag Instructions including all illustrations on pages 17-18.

NOTE: Regular irrigation (e.g., every 12 hours) and/or stool modification is recommended (as prescribed by physician) to optimize stool consistency and to facilitate evacuation through the catheter. Patients with very loose or watery stool may require less irrigation.

One method of irrigation, using an irrigation bag and with the intraluminal balloon deflated, is described in steps 1 through 6 and then 10 through 12 below. This is the preferred method for routine irrigation of the catheter, except for patients with thick stool consistency and for scheduled evacuations, when the intraluminal balloon should be inflated.

1. Verify that the collection bag can accommodate additional volume. If not, empty or change the bag before performing irrigation.
2. If appropriate for the patient, position on the left side in a slight Trendelenburg position and fully inflate the air bed (if one is in use).
3. Fill the ActiFlo Irrigation Bag with the prescribed amount (e.g., 300 mL to 500 mL) of lukewarm (26°-38° C, 80°-100° F) water or saline (as prescribed by physician).
4. Hang the irrigation bag from an IV pole 2-3 feet (60 cm to 90 cm) above the patient's anus.
5. Connect the irrigation bag administration tubing to the CLEAR connector (IRRIG/ Rx) after removing the white-capped tethered adapter. **WARNING: Verify connection to correct catheter connector.**
6. Open the roller clamp on the irrigation tubing. Allow the fluid to drain by gravity into the rectum and colon over approximately 10 minutes. If the irrigant will not infuse or infuses slowly, squeeze the gravity bag to clear the occlusion. See additional helpful hints on page 13.

NOTE: If the patient experiences cramping or leakage, it may be related to irrigation volume, irrigation rate or irrigant temperature. These may need to be adjusted for each patient. NEVER use a hot liquid as an irrigant.

Irrigation may also be done with the intraluminal balloon inflated as described in steps 1 through 5 above and then 7 through 12 below. This method works best for patients with thick stool consistency, and for scheduled evacuations.

Confirmation of Patency

WARNING: Prior to use of the ActiFlo Irrigation Bag read the ActiFlo Irrigation Bag Instructions including all illustrations on pages 17-18.

1. Place the patient in a slight head-up position to promote drainage.
2. Fill the ActiFlo Irrigation Bag with 300 mL to 500 mL of lukewarm (26°-38° C, 80°-100° F) water or saline (as prescribed by physician). Hang from an IV pole 2 to 3 feet (60 cm to 90 cm) above the patient's anus.
3. Connect the irrigation bag tubing to the CLEAR connector (IRRIG/Rx) after removing the white-capped tethered adapter. **WARNING: Verify connection to correct catheter connector.**
4. Open the roller clamp on the irrigation bag tubing to allow the fluid to drain by gravity into the rectum and colon.
5. If no irrigant drains from the patient, verify that the RED connector (STOP FLOW 25 mL Air ►) pilot balloon is collapsed (**See Figure 3**). If the pilot balloon is collapsed, verify that the transsphincteric zone is not twisted.

7. To irrigate with the intraluminal balloon inflated, inflate the intraluminal balloon with 25 mL of air via the RED connector (STOP FLOW 25 mL AIR ►) prior to step 6 and then perform step 6.

8. If the irrigation has been done with the intraluminal balloon inflated, connect the syringe to the RED connector (STOP FLOW 25 mL AIR ►) and completely aspirate the 25 mL of air from the intraluminal balloon. **WARNING: Do not leave intraluminal balloon inflated in an unattended patient.**
9. Disconnect the syringe and confirm that the pilot balloon is fully collapsed (See Figure 3).
10. Allow drainage of the fluid and feces out of the rectum and colon. Drainage may be facilitated by positioning the patient in a slight reverse Trendelenburg position to assist gravity.

NOTE: The return may not be complete (e.g., irrigant could be partially absorbed by the patient through the colon) or immediate (e.g., requires colonic response for evacuation).

11. After irrigation is complete close the roller clamp, disconnect the administration set from the CLEAR connector (IRRIG/Rx) and close the connector.
12. Starting near the anus, strip the tubing to push the remaining stool and fluid into the collection bag. Empty or replace the collection bag as needed.

Administration of Enema/Medications

NOTE: The CLEAR connector (IRRIG/Rx) should be flushed with 20 mL of water before and after the administration of enema/medications. Viscous enema/medications may require dilution to facilitate administration through the irrigation lumen.

1. Inflate the intraluminal balloon with 25 mL of air via the RED connector (STOP FLOW 25 mL AIR ►). Disconnect the syringe.
2. Open the CLEAR connector (IRRIG/Rx) and flush the irrigation lumen with 20 mL lukewarm water (26°-38° C, 80°-100° F), then disconnect the syringe and close the connector.
3. Connect the medication syringe or medication bag to the CLEAR connector (IRRIG/Rx) and slowly inject the solution or allow it to flow in by gravity. **WARNING: Do not connect mechanical pumping devices to CLEAR connector (IRRIG/Rx).**
4. Flush the CLEAR connector (IRRIG/Rx) with 20 mL lukewarm water (26°-38° C, 80°-100° F), then disconnect the syringe and close the connector.
5. Allow the enema/medication to dwell for the desired retention time as prescribed by the physician.
6. Using the syringe, completely aspirate the air from the intraluminal balloon via the RED connector (STOP FLOW 25 mL AIR ►). Disconnect the syringe and confirm that the pilot balloon is fully collapsed (See Figure 3). **WARNING: Do not leave intraluminal balloon inflated in an unattended patient.**

Stool Sampling

1. Open the flush/sampling port cap and insert a catheter tip syringe into the flush/sampling port.
2. Draw an appropriate sample of fecal matter into the syringe.
3. Remove the syringe and close the flush/sampling port cap.

Maintenance

1. Whenever the caregiver changes, verify that the intraluminal balloon is deflated; e.g., verify that the RED connector (STOP FLOW 25 mL Air ►) pilot balloon is completely collapsed (See Figure 3). **WARNING: Do not leave intraluminal balloon inflated in an unattended patient.**
2. Frequently verify that the catheter and collection bag are positioned so that the catheter drain tube is not twisted, kinked or externally compressed.
3. Frequently verify that waste is not accumulating in the catheter drain tube. To remove accumulated waste:
 - Hold the catheter near the external retention faceplate with one hand
 - Constrict the drain tube with the other hand
 - Strip the tubing toward the collection bag
4. Make sure that the patient is not lying on the catheter drain tube or catheter connectors. This could cause discomfort or localized pressure.
5. At least twice daily, flush the inside of the catheter drain tube to remove any accumulated fecal matter:
 - Using a catheter tip syringe, inject water into the flush/sampling port
 - Strip the tubing toward the collection bag
6. Using lukewarm (26°-38° C, 80°-100° F) water or saline, irrigate the catheter regularly (e.g., every 12 hours) via the CLEAR connector (IRRIG/Rx) as ordered by a physician (See "Irrigation" section page 10).
7. Small volumes of mucus or feces may leak onto the perianal region and can be managed with routine hygiene and absorbent pads.
8. Drain or replace the collection bag as needed. Handle and dispose of in accordance with institutional protocol and universal precautions for contaminated waste.
9. Verify the retention cuff volume at least every 7 days:
 - Connect the syringe to the BLUE connector (CUFF Ⓢ= 35-40 mL H₂O)
 - Slowly aspirate all fluid from the retention cuff, then disconnect the syringe
 - Verify that the retention cuff is deflated by confirming that the BLUE connector (CUFF Ⓢ= 35-40 mL H₂O) pilot balloon is collapsed
 - Refill the retention cuff via the BLUE connector (CUFF Ⓢ= 35-40 mL H₂O) with 35 mL to 40 mL of lukewarm water, then disconnect the syringe
 - Verify that the BLUE connector (CUFF Ⓢ= 35-40 mL H₂O) pilot balloon indicates that the retention cuff is inflated

9. CATHETER REMOVAL

1. Inflate the intraluminal balloon with 25 mL of air via the RED connector (STOP FLOW 25 mL Air ►). Then, disconnect the syringe.
2. Deflate the retention cuff by connecting the syringe to the BLUE connector (CUFF Ⓢ= 35-40 mL H₂O) and slowly aspirating all water. Then, disconnect the syringe.
3. Verify that the retention cuff is deflated by confirming that the BLUE connector (CUFF Ⓢ= 35-40 mL H₂O) pilot balloon is collapsed.

- Grasp the catheter at the external retention faceplate, ask the patient to bear down (if capable), and apply steady traction to slide the catheter out of the anus during end exhalation (See Figure 5).

The elastic nature of the device may result in abrupt exit of the catheter from the anus. Care should be taken to protect caregiver from splatter.

- If the catheter does not come out relatively easily, apply water-soluble lubricant to the anal canal and repeat steps 3 and 4.



Figure 5

NOTE: After use, handle and dispose of in accordance with institutional protocol and universal precautions for contaminated waste.

10. HELPFUL HINTS

Odor Management

- Flush the tubing with water using the flush/sampling port at least twice a day.
- Cleanse the exposed end of the drainable collection bag spout before capping it.
- Change the drainable collection bags every 7 days.
- Closed collection bags may also be used.
- Routinely cleanse any leakage from around the anus.

Leakage

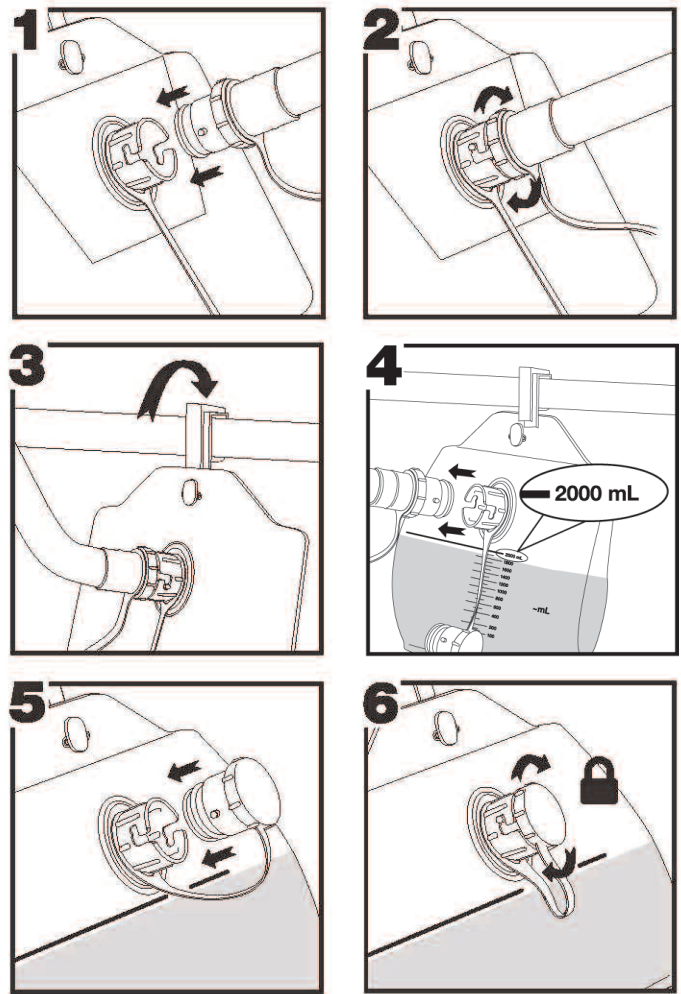
- Make sure the intraluminal balloon is completely deflated and the retention cuff is inflated.
- Apply gentle traction to “seat” the retention cuff.
- Be sure the transsphincteric zone is not twisted, the anchor straps are secured, the tubing is straight and free of stool, and the drainage bag is lower than the patient.
- If tolerated, position the patient in slight Trendelenburg during irrigation.
- 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 distension, which is associated with leakage.
- If leakage is excessive, consider discontinuing use of the ActiFlo system.

Catheter Expulsion

- Perform a digital rectal exam to ensure that no stool is present in the distal rectum.
- Rinse the catheter and reinsert, following the instructions in “Device Preparation” and “Catheter Insertion” pages 8-9.
- Irrigate the patient with the intraluminal balloon deflated to help clear the rectum.
- Modify stool consistency as indicated (medications and irrigations as prescribed by physician).

- 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 ActiFlo system.

11. ActiFlo CLOSED COLLECTION BAG INSTRUCTIONS



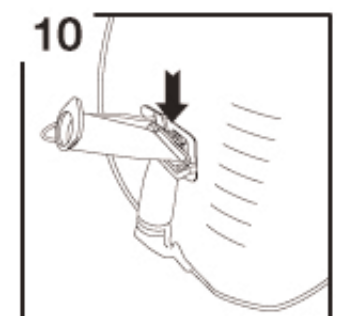
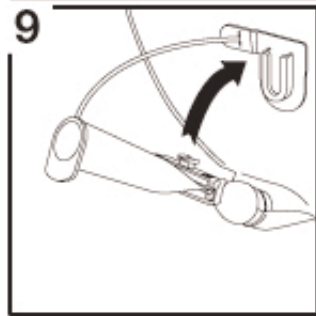
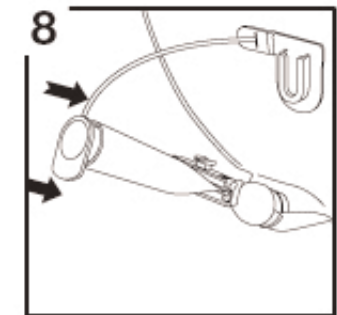
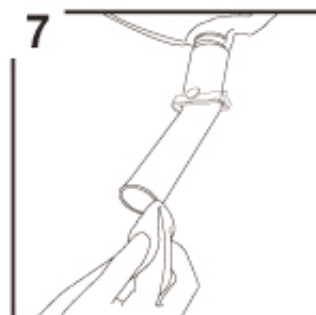
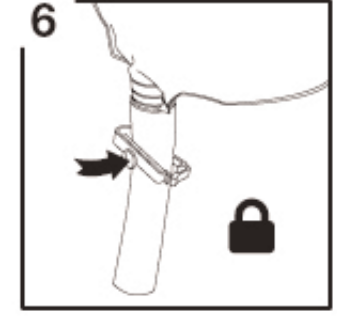
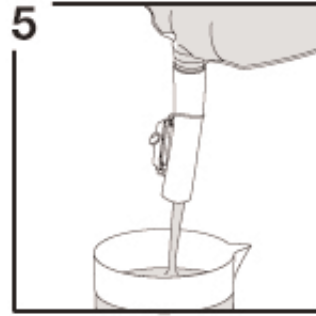
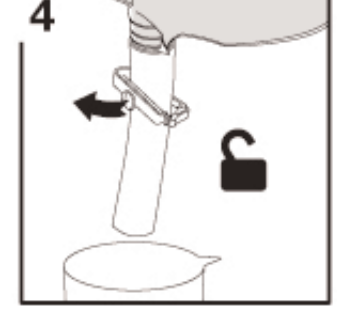
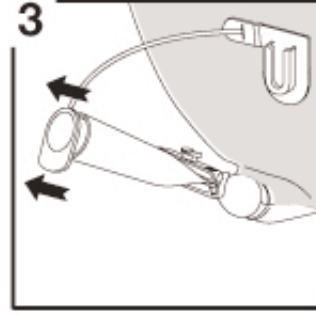
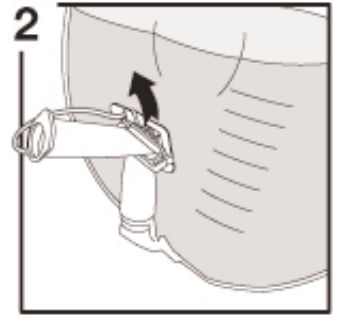
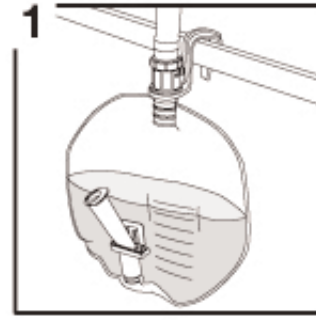
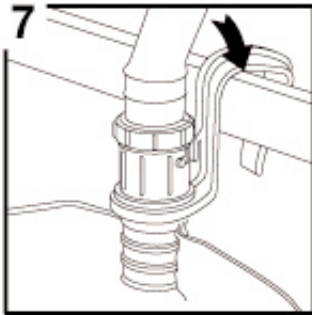
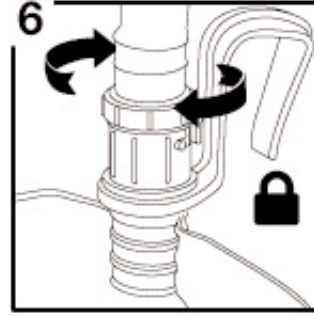
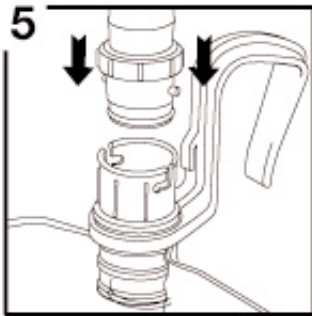
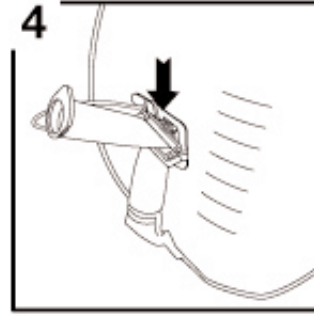
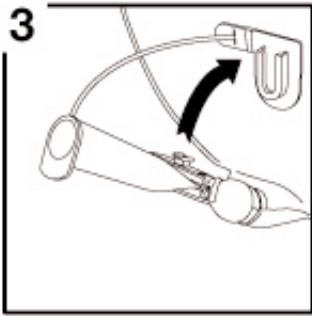
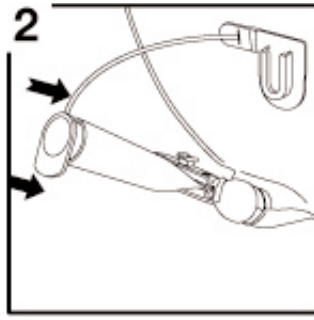
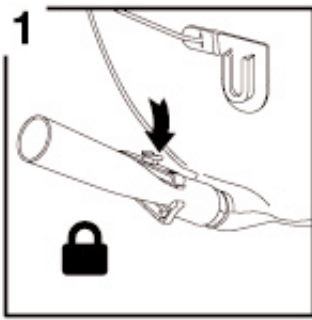
- Non-Sterile
- Latex-Free

WARNINGS AND PRECAUTIONS

- Single patient use only
- For use with ActiFlo Indwelling Bowel Catheter System only
- Do not use if package is open or damaged
- Dispose of contents and used bag in accordance with institutional protocol and universal precautions for contaminated waste

CAUTION: Federal USA Law restricts this device to sale by or on the order of a physician.

12. ActiFlo DRAINABLE COLLECTION BAG INSTRUCTIONS



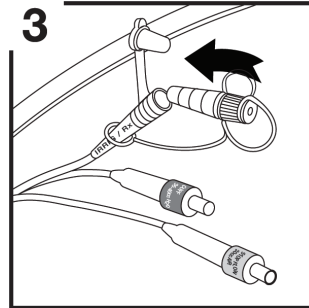
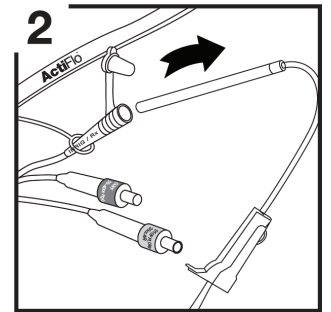
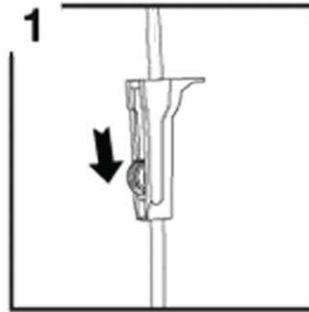
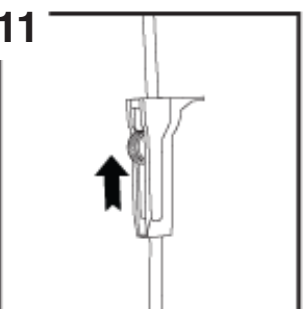
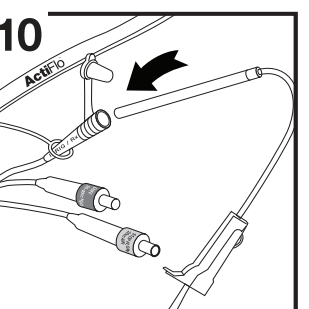
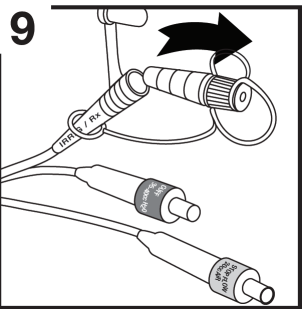
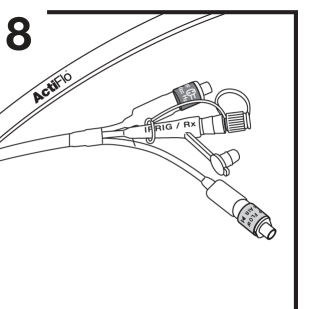
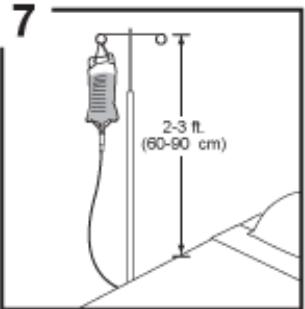
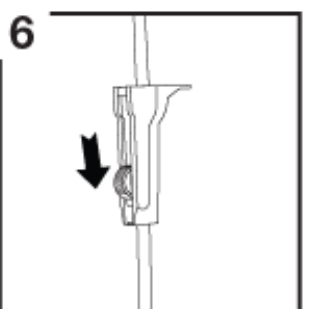
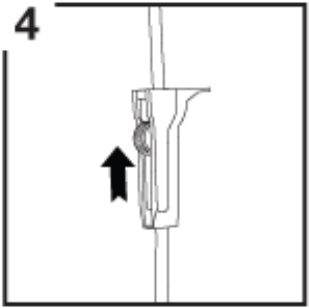
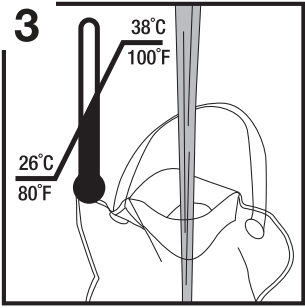
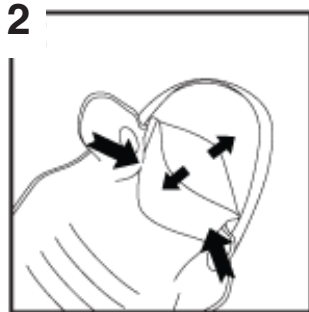
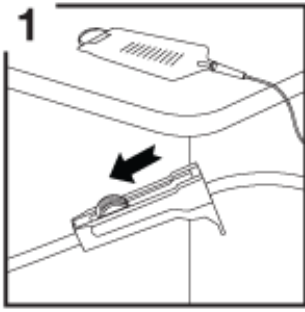
- Non-Sterile
- Latex-Free

WARNINGS AND PRECAUTIONS

- Single patient use only
- Do not use if package is open or damaged
- For use with ActiFlo Indwelling Bowel Catheter System only
- Dispose of contents and used bag in accordance with institutional protocol and universal precautions for contaminated waste

CAUTION: Federal USA Law restricts this device to sale by or on the order of a physician.

13. ActiFlo IRRIGATION BAG INSTRUCTIONS



- Non-Sterile
- Latex-Free

WARNINGS AND PRECAUTIONS

- Single patient use only
- Not for IV use
- Not for enteral feeding
- Replace every 24 hours
- For use with ActiFlo Indwelling Bowel Catheter System only
- Only use lukewarm (26°-38° C, 80°-100° F) temperature water or saline for irrigation (as prescribed by physician)
- Do not use if package is open or damaged

CAUTION: Federal USA Law restricts this device to sale by or on the order of a physician.

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