**Frequently Asked Questions**

These Frequently Asked Questions are only intended to highlight 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 indwelling time. It is a total system that is designed to 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

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.
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. In a separate study of 20 patients, proctoscopic exams were normal after tube removal in all cases. 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.

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