DIGNISHIELD®
STOOL MANAGEMENT SYSTEM

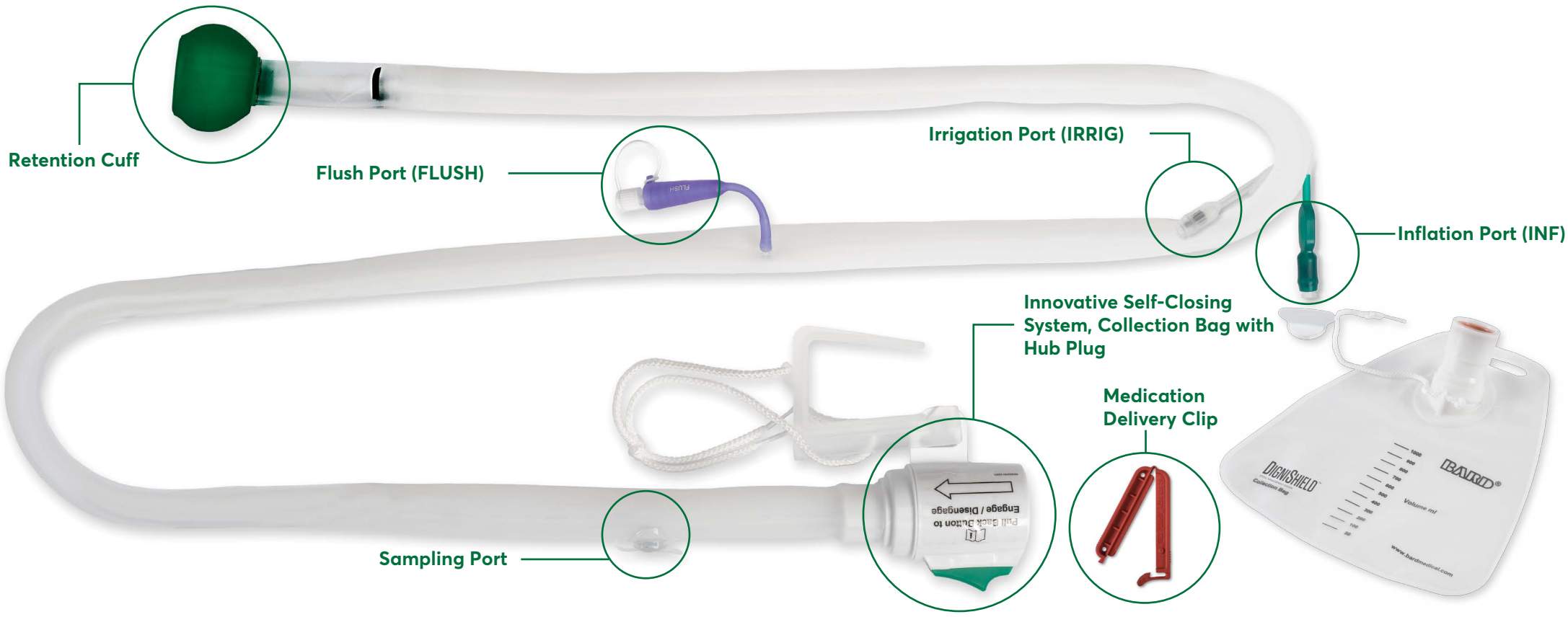
Quick Reference Guide
Daily Patient Assessment

Cuff Placement:
- Assess position of the green transphincteric zone.
- Ensure the cuff has not moved from previous positioning.

Patient Care:
- The device is not intended for use beyond 29 days.
- Do not insert anything into the anal canal while this device is in place (e.g. thermometer, suppositories, etc.). Remove the device prior to insertion of anything into the anal canal.
- Do not use on patients with any rectal or anal injury, severe rectal or anal stricture or stenosis (or any patient if the distal rectum cannot accommodate the inflated cuff), confirmed rectal or anal tumor, severe hemorrhoids or fecal impaction.
- Do not use on patients known to be sensitive to or allergic to any components within the system.
- Perianal care should be performed at routine intervals to ensure the area is clean and dry
- If stool consistency becomes more solid, device use should be discontinued.
- Consult Instructions for Use for further information on the use of this device.

Cuff Volume:
- Ensure cuff has been inflated with 45 ml of water.
- Cuff volume should not exceed 45 ml of water.

Device Maintenance:
- Flush the catheter using the purple FLUSH port as needed to remove residual fecal matter from the tube. Note the amount of fluid infused.
- The patient's bowel can be irrigated using the clear IRRIG port.
- When changing a full collection bag, secure the bag plug and dispose in accordance with hospital protocols.
- Check position of the green transphincteric zone after repositioning patient to ensure the device is seated properly within the rectal vault.
- Check the collection bag at least once per shift to monitor stool volume.
    - o If stool volume decreases significantly, check the catheter for potential kinks / blockages
    - o If stool consistency becomes more solid, device use should be discontinued.



Leakage:
- Assess leakage around the perianal area.
- Ensure the catheter is unobstructed and that there are no kinks or twists in the tubing.

Leakage:
- Ensure catheter is not kinked, twisted or externally compressed. If this has not reduced leakage, go to the next step:
    - o Using a syringe, withdraw water from the green INF port to assess cuff fluid volume.
    - o Reposition the patient and continue to withdraw water from cuff. This ensures all water has been removed.
    - o Fill the syringe with 45 ml of water and re-inflate the cuff using the green INF port. **CUFF VOLUME SHOULD NOT EXCEED 45 ML OF WATER.** This will cause the cuff to become occluded.
    - o Gently pull on the catheter tube to ensure cuff seating in the rectal vault
    - o Irrigate the bowel using the clear IRRIG port to determine if above steps have assisted in minimizing leakage
    - o If leakage persists, deflate the retention cuff and remove the device. Wipe the unit with a disposable towel and re-insert the device following the instructions for use.

Flush System:
- Using the purple FLUSH port, irrigate the catheter regularly to keep the tubing clear and minimize odor.

Odor Control:
- Flush the catheter using the purple FLUSH port at least twice per shift and as needed. Milk the tubing as needed to drain any residual fecal matter into the collection bag.
- Replace collection bag routinely. Secure the bag plug and remove from room. Dispose in accordance with hospital protocols.
- Check position of the green transphincteric zone after repositioning the patient and at regular intervals to ensure the device is seated properly within the rectal vault.
- Irrigate the bowel with water using the clear IRRIG port to ensure proper drainage.

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Indications: The Bard® DigniShield® Stool Management System (SMS) with odor barrier properties is intended for fecal management by diverting and collecting liquid or semi-liquid stool in bedridden patients and to provide access for the administration of medications.

Contraindications: The device should not be used for more than 29 consecutive days, on patients with certain medical conditions including rectal or anal abnormalities, or on patients who have had lower large bowel or rectal surgery within the last year. Do not use on patients with indwelling rectal or anal device, delivery mechanisms, or enemas in place.

Warnings and Adverse Events: There is a potential risk of misconnections with connectors from other healthcare applications. As with the use of any rectal device, adverse events can occur including: leakage of stool, loss of anal sphincter muscle tone, pressure necrosis, infection, bowel obstruction, and perforation of the bowel. Changes to the patient including: rectal bleeding indicating possible pressure necrosis, abdominal distention, cuff migration, and rectal pain should be investigated.

Please consult package insert for more detailed safety information and instructions for use.