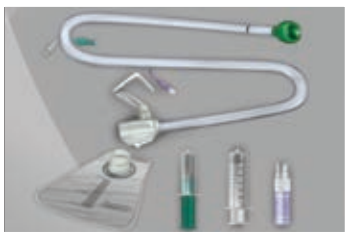
DIGNISHIELD™

STOOL MANAGEMENT SYSTEM (SMS)

ATTENTION: PROPER USAGE IS IMPORTANT

This poster provides a quick reference for the usage of the DigniShield™ Stool Management System. Consult product IFU for further information.

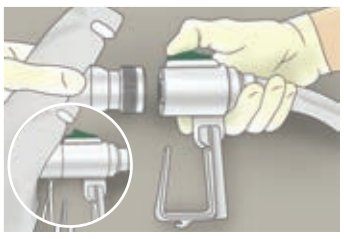
PATIENT & DEVICE PREPARATION



Product Contents

The BARD® DIGNISHIELD™ SMS device consists of the following components:

- catheter tube assembly
- collection bag
- 60 cc syringe
- syringe of lubricating jelly
- Medi-aire® biological odor eliminator

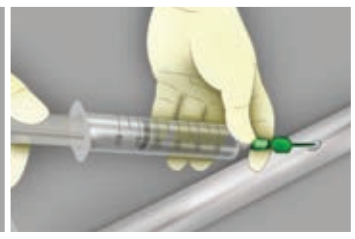


Connect Bag

- Pull back on the green trigger switch and engage piston valve connector onto the collection bag hub
- Ensure that the green ring at the base of the collection bag hub socket is not visible

Deflate Cuff

- Attach the depressed syringe to the green inflation port
- Draw all air from the green retention cuff by pulling back on the syringe plunger



Attach Filled Syringe to Green INF (45 ML) Port

- Fill the syringe with 45 ml of tap water
- Attach the syringe to the green INF (45 ML) port
- Do not inflate at this time

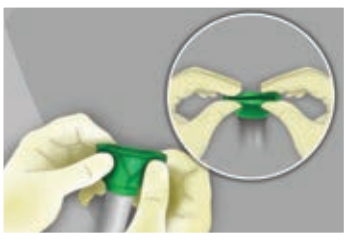
Position Patient

- Place patient in the left knee-chest position
- The goal of patient positioning is to maximize sphincter relaxation to ease catheter insertion
- Perform a digital rectal exam to determine if fecal impaction is present

CUFF FOLDING PROCESS

Hold Deflated Cuff

- Squeeze the retention cuff to ensure all air has been removed



Flatten Cuff

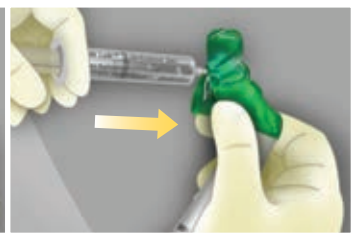
- Flatten the retention cuff between your thumbs and index fingers
- Hold the flattened cuff at upper green corners

Fold Cuff

- Hold the upper left corner of the cuff between your thumb and index finger
- Fold the top right corner of the cuff backward and down to the left in a 45 degree angle
- This creates a conical shape with a leading edge for easy insertion

Hold Folded Cuff

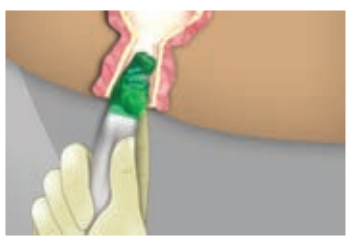
- Hold the folded cuff between your thumb and index finger
- The index finger should be on the side with the folded upper corner



Lubricate

- Generously apply lubricating jelly to the sphincter area
- Lubrication may also be applied to the cuff end of the catheter

INSERTION & SEATING

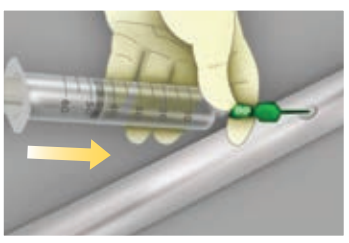


Insert Cuff

- Insert the folded cuff into the patient's sphincter
- As the cuff passes into the patient, slide your thumb away from the cuff
- Use your index finger to push the cuff through the sphincter into the rectal vault

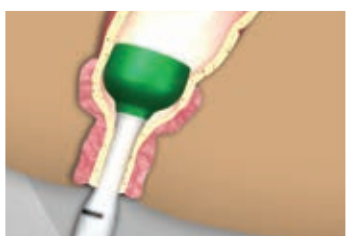
Deploy

- Once inside the rectal vault, the cuff will open to it's original conical shape



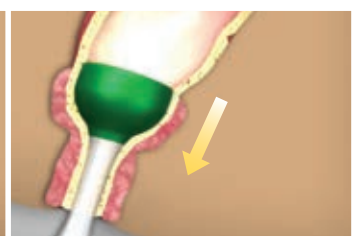
Infuse Water

- Inflate the cuff with 45 ml of tap water by slowly depressing the syringe plunger
- Ensure the inflation port remains parallel to the catheter in order to prevent kinking of the inflation lumen and blockage of injected fluid



Inflate Cuff

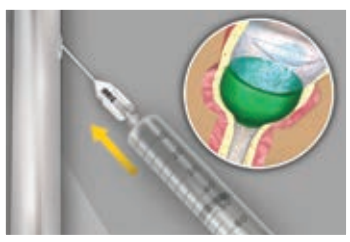
- As water is injected into the inflation port, the cuff will inflate in the rectal vault
- Use the pilot balloon as an inflation guide. If the pilot balloon indicates over or under inflation, withdraw the fluid from the cuff
- Reposition the cuff in the rectal vault and reinflate



Secure Seating

- Remove the syringe from the inflation port and gently pull on the catheter to ensure cuff seating against the rectal floor
- Note the position indicator line relative to the patient's anus
- Changes in the line's position may indicate the need for the cuff to be re-positioned

MAINTENANCE & REMOVAL



Cuff Irrigation

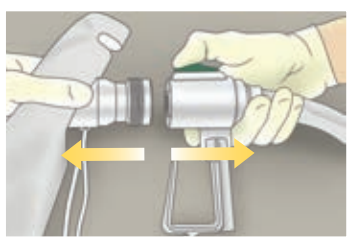
- Fill the syringe with 45 ml of tap water
- Attach the filled syringe to the clear IRRIG port
- Infuse water by depressing the plunger
- Observe the flow of fluid down the catheter tubing
- If leakage occurs, cuff may need to be repositioned and process repeated

Stool Sampling

- Uncap the white sample port
- Gently kink catheter segment between piston valve connector and sample port
- Tilt or milk catheter to collect fecal matter
- Insert a slip-tip syringe into sample port and draw appropriate sample
- Remove syringe and replace the cap on the port

Flush Tubing

- If the catheter tubing becomes obstructed with fecal matter, attach a filled syringe to the purple FLUSH port and depress the plunger
- Make sure the flush port remains parallel to the catheter in order to prevent kinking in the tubing



Bag Replacement

- Grab the piston connector, pull back on the switch until the piston ejects from the collection bag
- Once the bag is removed, insert the bag plug into the collection bag hub
- Dispose of the collection bag in accordance with institutional protocols
- To replace the collection bag, refer to "Connect Bag"

Removal / Disposal

- Attach a depressed syringe to the green INF (45 ML) port and slowly withdraw all water from the cuff
- Once the cuff is deflated, grasp the catheter as close to the patient as possible and slowly slide it out of the anus
- Dispose of the device in accordance with institutional protocols

INDICATIONS FOR USE

The BARD® DIGNISHIELD™ Stool Management System (SMS) is intended for fecal management by diverting and collecting liquid or semi-liquid stools to minimize skin contact in bedridden patients.

CONTRAINDICATIONS

Do not use for more than 29 consecutive days. Do not use on patients known to be sensitive to or allergic to any components within the system. Do not use on patients who had lower large bowel or rectal surgery within the last year.

Do not use on patients with any rectal or anal injury, severe rectal or anal stricture or stenosis (or on any patient if the distal rectum cannot accommodate the inflated cuff) confirmed rectal or anal tumor, severe hemorrhoids, or fecal impaction. Not for use on patients with suspected or confirmed rectal mucosa impairment, i.e. severe proctitis, ischemic proctitis, mucosal ulcerations. Not for use on patients with indwelling rectal or anal device (e.g. thermometer) or delivery mechanism (e.g. suppositories) or enemas in place.

1108-35 R12/11 THP P12/11 5M

BARD | MEDICAL

DigniShield™

STOOL MANAGEMENT SYSTEM

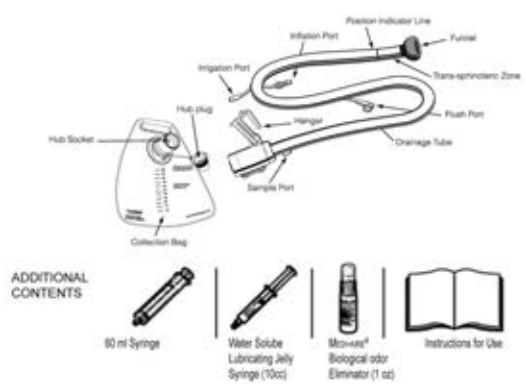
Bard® DigniShield™ Stool Management System SMS002

Indications for Use:
The Bard® DigniShield™ Stool Management System (SMS) is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients.

Adult use only

Device Description:
The Bard® DigniShield™ SMS device consists of a catheter tube assembly, a collection bag (Figure 1), a 60ml syringe, a syringe of lubricating jelly and a biological odor eliminator. The device has no components made of natural rubber latex.

Figure 1 – Catheter Tube Assembly and Collection Bag



Contents:
- Catheter Tube Assembly (Figure 1 Includes collection bag)
- Collection Bag
- 60ml Syringe
- Lubricating Jelly Syringe (10ml)
- Instructions for use
- 1 bottle (1oz) of Medi-aire® (biological odor eliminator)

The Bard® DigniShield™ SMS catheter tube assembly consists of a catheter body and collection bag assembly that is primarily constructed of a proprietary copolymer material called Permalene™, bonded to a low-pressure retention cuff and trans-sphincteric zone (TSZ) primarily contructed of silicone material. The Permalene™ catheter and collection bag material is designed to minimize permeation of gas and water vapor. The low-pressure retention cuff is designed to retain the device in the rectum. The tube opening at the cuff is funnel-shaped to aid in diverting the stool into the drainage tube. The cuff leads to the TSZ segment, which is designed to minimize dilation of the sphincter during use while providing a channel for fecal matter to pass through drainage tube and into the collection bag. Along the drainage tube are three lumens, each with a separate access port. The green inflation port ("INF(45ML)") is used to inflate/deflate the cuff. The clear irrigation port ("IRRIG") is used to infuse water at the end of the retention cuff. The purple flush port ("FLUSH") is used to infuse water through slits or the entire length of the drainage tube to assist drainage of fecal matter. (Figure 2) A sample port on the drainage tube allows for the collection of stool samples through a slip-tip syringe.

A piston valve connector located on the end of the drainage tube of the catheter attaches to the collection bag hub socket. When the collection bag is disengaged from the catheter, the catheter and bag automatically close to prevent spillage. A bag cap is provided to secure the contents of the collection bag when the catheter is removed.:

The 60 ml syringe and lubricating jelly syringe are used in the preparation and use of the catheter. The Medi-aire® biological odor eliminator may be used as an air freshener in the room. Do not spray on patient or device.

Figure 2 – Description of Drainage Tube Ports

The catheter contains four ports.

Label	Port Color	Label Definition
"INF CUFF (45ML)"	Green (matches the cuff color)	Inflation port for retention cuff, specifies recommendended inflation volume and inflation medium
"FLUSH "	Purple	Flushing port
"IRRIG"	Clear	Irrigation port
	White	Sampling port

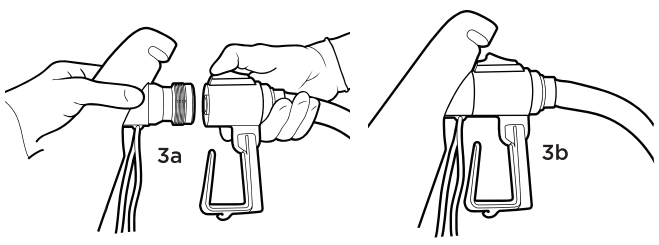
Contraindications
- Do not use for more than 29 consecutive days. The uninterrupted use for this device, including immediate replacement with the same or an identical device, is intended to be 29 days or less.
- Do not use on patients known to be sensitive to or allergic to any components within the system.
- Do not use on patients who had lower large bowel or rectal surgery within the last year.
- Do not use on patients with any rectal or anal injury, severe rectal or anal stricture or stenosis (or on 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 with suspected or confirmed rectal mucosa impairment, i.e. severe proctitis, ischemic proctitis, mucosal ulcerations.
- Do not use on patients with indwelling rectal or anal device (e.g. thermometer) or delivery mechanism (e.g. suppositories) or enemas in place.

Warnings
- Do not use if package is opened or damaged.
- Do not use improper amount or type of fluids for irrigation/flush or cuff inflations. Never use hot liquids.
- Do not over inflate retention cuff.
- Use only gravity or slow manual irrigation. Do not connect mechanical pumping devices to catheter irrigation port. Do not irrigate patient with compromised intestinal wall integrity.
- Rectal bleeding should be investigated to ensure no evidence of pressure necrosis from the device. Discontinuation of use is recommended if pressure necrosis is evident.
- Abdominal distention that occurs while using the device should be investigated.
- Prolonged traction on the catheter may result in the retention cuff migrating into the anal canal which may result in mucosal lesion, temporary or permanent clinical sphincter dysfunction, or catheter expulsion.
- Solid or soft-formed stool cannot pass through the catheter and will obstruct the opening. The use of the device is not indicated for patients with solid or soft formed stool
- As with the use of any rectal device, the following adverse events can occur:
  - Excessive leakage of stool around the device
  - Loss of anal sphincter muscle tone which could lead to temporary or permanent anal sphincter dysfunction
  - Pressure necrosis of rectal or anal mucosa
  - Infection
  - Bowel obstruction
  - Perforation of the bowel
- Single use only. Do not reuse. Reuse and/or packaging may create a risk possibly resulting in patient or user infection. Structural integrity and/or essential material and design characteristics of the device, may be compromised, which may lead to device failure and/or lead to injury, illness or death of the patient.

Precautions
- CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Do not sterilize.
- Close attention should be paid to the use of the device in patients who have inflammatory bowel conditions. The physician should determine the degree and location of inflammation within the colon/rectum prior to considering use of this device in patients with such conditions. Ensure retention cuff and funnel are folded into a low profile form prior to insertion (as shown in Figure 4).
- Patients with very weak sphincter muscles may not be able to retain the device in place and may experience increased leakage of stool.
- If the catheter becomes blocked with solid particles, it may be flushed with water (see Figure 8 - "Flushing of the Catheter"). If obstruction of the catheter is due to solid stool, use of the device should be discontinued.
- To avoid injury to the patient, 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.
- Notify a physician if any of the following occur:
  - Persistent rectal pain
  - Rectal bleeding
  - Abdominal distension
- If the patient's bowel control, consistency and frequency of stool begin to return to normal, discontinue use of the device.

Instructions for Use
1. Preparation of SMS prior to insertion
   a. Verify the retention cuff has been completely deflated. This can be done by squeezing the cuff to ensure there is no residual air inside the device.
      1) If air remains within the cuff, attach the 60 ml syringe to the green inflation port and withdraw all remaining air from the cuff.
   b. After the cuff has been fully deflated, fill the syringe with 45ml of water and set aside.
   c. Using a permanent marker, record the catheter insertion date on the label located on the piston valve connector.
2. Collection bag connection
   A. Attaching the collection bag:
      a) Attach the collection bag to the piston valve connector on the catheter by pulling back on the green trigger switch and engaging the piston valve connector onto the collection bag hub socket (Figure 3-A ,B)
      b) Ensure that the green ring at the base of the collection bag hub socket is not visible. The green ring at the base of the collection bag hub socket will not be visible when the piston valve is properly connected.

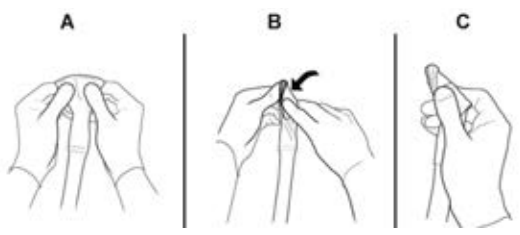
Figure 3 – Attaching the Collection Bag



3. Preparation of Patient
   a) The preferred patient position for catheter insertion is the left lateral knee-chest position, although 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.
   b) Perform a digital rectal exam to evaluate for fecal impaction. If a fecal impaction is present, disimpaction procedure and device insertion may occur at the discretion of the healthcare professional.

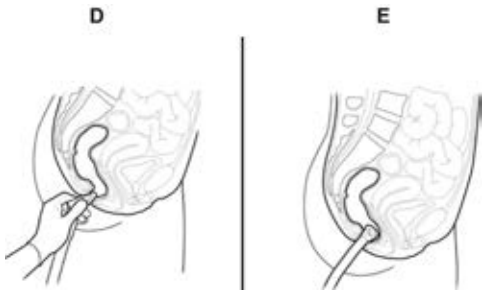
4. Insertion of Device
   a) Unfold the length of the catheter to lay flat on the bed, extending the collection bag towards the foot of the bed.
   b) Attach the 60 ml syringe filled with 45 ml of water to the inflation port, but do not inflate.
   c) Insert the inflation cuff using a four-step process:
      1) As previously stated in Step 1 "Preparation of Device", ensure the retention cuff is completely deflated. (Figure 4A)
      2) Holding the left point of the cuff between the thumb and index finger, fold the top right point of the cuff down and to the left in a 45 degree angle (Figure 4B), in order to create a conical shape with a leading edge for easy insertion. (Figure 4C)
      3) Generously coat the patient's anus with lubricating jelly.
      4) Gently insert the cuff end through the anal sphincter until the cuff is beyond the external orifice and well inside the rectal vault. (Figure 4D and Figure 4E)

Figure 4 (A-C) – Folding the Retention Cuff



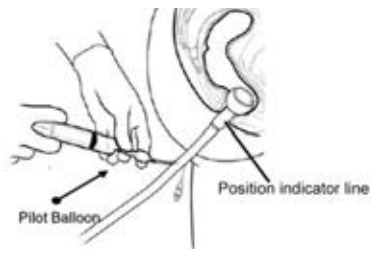
Fold the top right point of the cuff down and to the left in a 45 degree angle, using the left point as a vertex in order to create a conical shape with a leading edge for easy insertion.

Figure 4 (D-E) – Inserting the Device



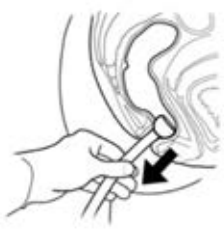
Grasp the catheter and gently insert the cuff end through the anal sphincter until the cuff is beyond the external orifice and well inside the rectal vault.
   d) Inflate the cuff with 45ml of water by slowly depressing the syringe plunger. The green inflation port has an external pilot balloon used as a guide to determine proper inflation; as the cuff inflates, the pilot balloon also inflates. The pilot balloon should be used as a reference to determine proper cuff inflation (Figure 5). If the pilot balloon indicates over-or under inflation, use the syringe to withdraw the fluid from the cuff, reposition the cuff in the rectal vault and reinflate. Ensure the inflation port remains parallel to the catheter in order to prevent kinking of the inflation lumen and blockage of injected fluid.

Figure 5 – Cuff Inflation



Inflate the cuff with 45 ml of water by slowly depressing the syringe plunger. The inflation port has an external pilot balloon as a guide to determine proper inflation; as the cuff inflates, the pilot balloon also inflates. The pilot balloon should be used as a reference to determine proper cuff inflation.
   e) Remove the syringe from the green inflation port and gently pull on the drainage catheter to check that the cuff is securely in the rectum and that it is positioned against the rectal floor. (Figure 6)
   f) Position the length of the flexible drainage tube along the patient's leg, avoiding kinks, obstruction and tension.
      - Take note of the black position indicator line that is printed in the proximal segment of the TSZ. Observe its relative position to the patient's anus. Observe changes in the location of the position indicator band as a means to determine movement of the retention cuff in the patient's rectum. This may indicate the need for the cuff or drainage tube to be repositioned.
   g) Hang the bag using the built-in hanger at a convenient location on the bedside (below the level of the patient's rectum).

Figure 6 – Proper Cuff Placement Against the Rectal Floor



Remove the syringe from the inflation port and gently pull on the drainage tube to check that the cuff is securely in the rectum and that it is positioned against the rectal floor.

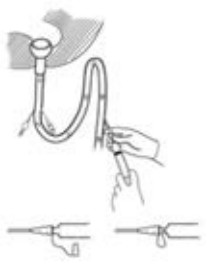
5. Irrigation of the Retention Cuff
   If the retention cuff area becomes obstructed with fecal matter, it may be irrigated by filling a syringe with tap water, attaching the syringe to the clear irrigation port and depressing the plunger (Figure 7). Make sure the irrigation port remains parallel to the catheter in order to prevent kinking in the tubing and blockage of the injected water. Repeat the procedure as often as necessary to maintain proper functioning of the device. Ensure that water drains.

Figure 7 – Irrigation of the Retention Cuff

If the funnel or retention cuff area becomes clogged with solid particles, it may be irrigaged by filling the syringe with water, attaching the syringe to the clear irrigation port and depressing the plunger.

6. Flushing of the Drainage Tube
   If the drainage tube becomes obstructed with fecal matter, flush the tube by filling a syringe with tap water, attaching the syringe to the purple "Flush" port, and depressing the plunger. Make sure the flush port remains parallel to the catheter in order to prevent kinking in the tubing and blockage of the injected water. This is used to maintain an unobstructed flow of stool into the collection bag (Figure 8). If repeated flushing with water does not return the flow of stool through the catheter, the device should be inspected to determine if there is an external obstruction (i.e. pressure from a body part or piece of equipment). If no source of obstruction of the device is detected, use of the device should be discontinued.

Figure 8 – Flushing the Device



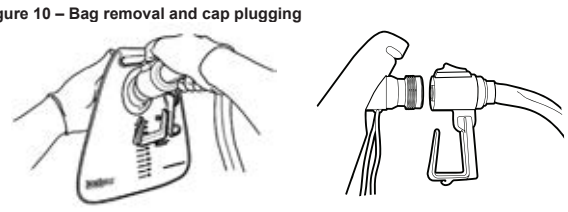
If the drainage tube becomes clogged, flush the device by filling the syringe with tap water, attaching the syringe to the purple "Flush" port, and depressing the plunger.

7. Stool Sampling
   a) Uncap the white sample port (figure 9A).
   b) Gently kink the catheter segment between the piston valve connector and the sample port (Figure 9B).
   c) Tilt or milk the catheter to collect fecal matter around the sample port.
   d) Insert a slip-tip syringe into the sample port valve and draw the appropriate sample of fecal matter into the syringe (figure 9C). Withdraw the syringe.
   e) Secure the white cap back onto the sample port (figure 9D).

Figure 9 – Stool Sampling

8. Removal/Replacement of the Collection Bag
   To remove the collection bag, grab the piston valve connector, gently pull backward on the switch located on the slide of the connector until the piston ejects from the collection bag hub. The piston valve and bag hub should close off automatically in this process. Once the bag is removed, insert the bag cap into the hub connector (Figure 10) and dispose of the collection bag in accordance with institutional protocol for disposal of medical waste. Replace the collection bag by securely snapping a new bag to the connector (reference step 1).
   Collection Bag Reorder # is SMS2B1L.
   A. Collection bag removal / replacement:
      a) Remove the collection bag by pulling back on the green slide and the piston valve until it disengages from the collection bag hub socket (Figure 10A – use figures 3A and 3B here).
      b)Insert the bag cap onto the bag hub socket and dispose of the bag in accordance with hospital policy and protocols Figure 10B).
      c) Collection bag reorder number: SMS2B1L.

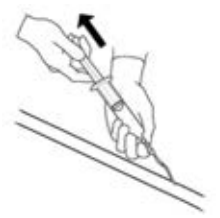
Figure 10 – Bag removal and cap plugging



9. Removal of Device
   To remove the catheter from the rectum, the retention cuff must be deflated.
   A. Attach the 60ml syringe to the green inflation port, and slowly withdraw all water from the retention cuff (Figure 11).

Make sure the inflation port remains parallel to the catheter in order to prevent kinking in the tubing and blockage of fluid. Refer to ideal patient positioning described in step 3 A.
   a) Once you have insured the cuff is fully deflated, disconnect the syringe and discard.
   b) To facilitate removal, you may add an appropriate amount of lubricant to the anal sphincter prior to pulling back on the catheter to remove the cuff
   c) Grasp the catheter as close to the patient as possible and slowly slide the cuff out of the anus. Dispose of the device in accordance with institutional protocol for disposal of medical waste.

Figure 11 – Deflating Retention Cuff



To remove the catheter from the rectum, the retention cuff must be deflated. Attach the syringe to the green inflation port, and slowly withdraw all water from the retention cuff.

10. System Care, Maintenance, and Monitoring of Device
   a) Take note of the black position indicator line that is printed in the proximal segment of the TSZ. Observe its relative position to the patient's anus. Observe changes in the location of the position indicator band as a means to determine movement of the retention cuff in the patient's rectum. This may indicate the need for the cuff or drainage tube to be repositioned.
   b) Change the collection bag as needed.
   c) Secure the bag cap onto each used collection bag and discard according to institutional protocol for disposal of medical waste.
   d) To ensure unobstructed flow of fecal matter from the drainage tube to the collection bag, frequently verify that the catheter and collection bag are positioned so that the catheter is not twisted, kinked, or externally compressed.
   e) Frequently verify that waste is not accumulating in the catheter drainage tube.
   f) Verify patient is not lying on drainage tube or ports in such a manner as to potentially cause discomfort or localized prolonged pressure.
   g) Check the retention cuff volume regularly to ensure proper inflation.

Medi-aire® Biological Odor Eliminator Net contents: 1 fl oz (30 ml)

Medi-aire® spray is a unique, powerful odor eliminator formulated to quickly counteract offensive odors from urine, feces, emesis and even necrotic tissue.

Directions for use: Pump sprayer once or twice. Direct spray away from patient.

Contains: Water, SD alcohol 40, triethylene glycol, benzethonium chloride, D&C color, tetrasodium EDTA.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.

Caution: May be harmful if swallowed. Avoid eye contact. Keep out of reach of children.

General Guidelines

The device may be replaced as needed, to perform patient assessment.

For medical or technical questions, please contact Medical Services and Support 800-227-3357.

If further information or guidelines is needed, please contact Bard Medical, at the address below:

BARD | MEDICAL

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