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

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.

MAINTENANCE & REMOVAL

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 up in a 45 degree angle
- This creates a conical shape with a leading edge for easy insertion

Hold Folded Cuff
- The index finger should be placed at the upper green corners
- Hold the folded cuff between your thumb and index finger

Flatten Cuff
- Hold the flattened 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 up in a 45 degree angle
- This creates a conical shape with a leading edge for easy insertion

Hold Folded Cuff
- The index finger should be placed at the upper green corners
- Hold the folded cuff between your thumb and index finger

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

INSETION & 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 its original conical shape

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

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MAINTENANCE & REMOVAL

Cuff Irrigation
- Fill the syringe with 45 ml of tap water
- Attach the filled syringe to the green INF (45 ML) port
- Inflating the cuff may indicate the need for the cuff to be re-positioned

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 to the green INF (45 ML) port
- Make sure the flush port remains parallel to the catheter in order to prevent kinking in the tubing

Flush Tubing
- If the catheter tubing becomes obstructed with fecal matter, attach a filled syringe to the purple FLUSH port and depress the plunger
- To remove any remaining stool, attach a syringe to the green INF (45 ML) port
- Perform a digital rectal exam to determine if fecal impaction is present

Bag Replacement
- Grab the piston connector, pull back on the switch until the piston ejects from the collection bag
- 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™ SMS device is intended for fecal management by diverting and collecting liquid or semi-solid stools in patients who cannot accommodate the inflated cuff. It is intended for patients with severe hemorrhoids, or fecal impaction. Not for use on patients with severe rectal or anal fissures, rectal cancer, 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.

CONTRAINDICATIONS
Do not use on patients with any rectal or anal injury, severe rectal or anal structure or stenosis (or 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 severe rectal or anal fissures, rectal cancer, 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.
Contraindications

- Do not use if the catheter has been exposed to extreme temperature or moisture.
- Do not use if the catheter has been damaged, contaminated, or contaminated with any substance that may affect its integrity.
- Do not use if the catheter is not sterile.
- Do not use if the catheter is not available for immediate use.
- Do not use if the catheter is not sterilized.
- Do not use if the catheter is not designed for a specific purpose.
- Do not use if the catheter is not C.R. Bard, Inc.

Inhalation or ingestion of irrigation fluid may be harmful if swallowed. Avoid eye contact. Keep out of reach of children.

Instructions for Use

1. Preparation of Device
   a) Inspect the device for damage and ensure it is not contaminated.

2. Catheter insertion
   a) Place the catheter in the rectum using an appropriate technique for the patient's condition.
   b) Ensure the catheter is connected properly to the collection bag.

3. Preparation of Patient
   a) Ensure the patient is positioned appropriately for catheter insertion.
   b) Perform a digital rectal exam to evaluate for fecal impaction.

4. Insertion of Device
   a) Insert the catheter into the rectum until the retention cuff is beyond the TSZ.

5. Irrigation of the Retention Cuff
   a) Attach the syringe to the clear irrigation port and depress the plunger.

6. Flushing of the Drainage Tube
   a) Attach the syringe to the flush port and flush the tube at a rate of 45 ml/min.

7. Stool Sampling
   a) Insert the catheter into the rectum using a gentle, even pressure.
   b) Perform a digital rectal exam to evaluate for fecal impaction.

8. Removal of the Collection Bag
   a) Grasp the catheter as close to the patient as possible and slowly slide the cuff out of the anus.
   b) Dispose of the device in accordance with institutional protocol for disposal of medical waste.

9. Stool Collection
   a) Remove the catheter from the rectum.

10. System Care, Maintenance, and Sterilization of Device
    a) Dispose of the device in accordance with institutional protocol for disposal of medical waste.
    b) Do not use the device for the purpose of flushing or irrigation.

11. Device Cleaning and Disinfection
    a) Follow the manufacturer's instructions for cleaning and disinfection.
    b) Follow hospital policy and protocols for device cleaning and disinfection.

12. General Guidelines
    a) Follow institutional protocol for disposal of medical waste.
    b) Do not use the device for the purpose of flushing or irrigation.

References

- General Guidelines
  a) General Guidelines
  b) General Guidelines

- Device Cleaning and Disinfection
  a) Follow the manufacturer's instructions for cleaning and disinfection.

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