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
• 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

Deflate Cuff
• Attach the depressed syringe to the green inflation port
• Draw all air from the green inflation port
• Ensure the inflation port remains parallel to the catheter in order to prevent kinking of the inflation lumen and blockage of injected fluid

Attach Filled Syringe to Green INF (45 ML) Port
• Fill the syringe with 45 ml of tap water
• Use the pilot balloon as an inflation guide. If the pilot balloon indicates over or under inflation, withdraw the fluid from the cuff

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

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

Hold Folded Cuff
• 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

Cuff Irrigation
• Fill the syringe with 45 ml of tap water
• Attach the filled syringe to the clear IRR port
• Inflase 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
• Fill 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

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 is seated 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

Infuse Water
• 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

MainteNance & Removal

Cuff Irrigation
• Fill the syringe with 45 ml of tap water
• Attach the filled syringe to the clear IRR port
• Influse 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
• Fill 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 snaps 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

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

Stool Sampling
• Uncap the white sample port
• Gently kink catheter segment between piston valve connector and sample port
• Fill 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

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 is seated 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

Observations
• Slight Abrams/Griswold is normal
• If fluid remains in the line, patient may have blockage of injected fluid

DISCLOSURES
• The DigniShield® SMS System is intended for fecal management by diverting and collecting liquid or semi-liquid stool in bedridden patients and is 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 in patients with indwelling rectal or anorectal device, delivery mechanisms, or in place.

MISCONCEPTIONS
• The DigniShield® SMS System should not be used in patients who have had lower large bowel or rectal surgery within the last year. Do not use in patients with indwelling rectal or anorectal device, delivery mechanisms, or in place.

ATTENTION: PROPER USAGE IS IMPORTANT
This poster provides a quick reference for the usage of the DigniShield® SMS Stool Management System. Consult product IFU for further information.
Indications for Use: 
• 1 bottle (1 oz) of 60 ml Syringe Contents:

Administration of medication.

Collection bag assembly that is primarily constructed of a proprietary copolymer material.

A piston valve connector located on the end of the drainage tube of the catheter attaches to the collection bag hub. The collection bag is bagged in a self-sealing plastic pouch, which is attached to the piston valve connector. The catheter bag and the collection bag assembly are primarily constructed of a proprietary polyurethane material. A piston valve connector located on the end of the drainage tube of the catheter attaches to the collection bag hub. The collection bag is bagged in a self-sealing plastic pouch, which is attached to the piston valve connector. The catheter bag and the collection bag assembly are primarily constructed of a proprietary polyurethane material.

Bard® DigniShield® CAMS catheter bag assembly consists of a catheter body and collection bag assembly that is primarily constructed of a proprietary copolymer material. The catheter bag is a bagged collection bag assembly that is primarily constructed of a proprietary copolymer material. The catheter bag is attached to the piston valve connector by an external pilot balloon as a guide to ensure unobstructed flow of fecal matter from the drainage tube to the collection bag. The piston valve connector is connected to the external pilot balloon by a Luer lock syringe that is used to deliver medication. The catheter bag is a bagged collection bag assembly that is primarily constructed of a proprietary copolymer material. The catheter bag is attached to the piston valve connector by an external pilot balloon as a guide to ensure unobstructed flow of fecal matter from the drainage tube to the collection bag. The piston valve connector is connected to the external pilot balloon by a Luer lock syringe that is used to deliver medication.

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