

DIGNISHIELD[®]



STOOL MANAGEMENT SYSTEM

Directions for Use & Information for Extended Care Providers

When a patient is admitted with an indwelling Stool Management System (SMS) there are many special considerations that external care providers need to be aware of for the benefit of the patient and ongoing effective device use. The patient may have been receiving medication delivery where a clamp is used to occlude the drainage lumen of the device. Ensure there is no clamp in place and stool can flow freely from the patient.

Daily Patient Assessment

The SMS can be used for 29 consecutive days. Patient assessment must confirm proper conditions exist for continued use. Daily care and maintenance of the device is important for optimal outcomes.

Patient Selection Parameters for SMS Use: (Check all that apply)

- Adult use only
- Rectal Tone: Confirmed by Digital Rectal Exam
- Fecal Impaction: Absent
- Stool Frequency: 3-6 Stools in 24 hrs
- Stool Consistency: Semi-Liquid to Liquid
- Stool Culture: Positive for *C. difficile*
- Braden Scale Score: ≤ 14
- IAD* Risk Level: High Risk to Severe IAD

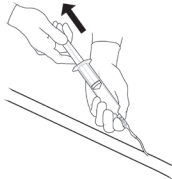
*Incontinence Associated Dermatitis

Daily care and maintenance of the device includes:

- Check the cuff fill volume periodically to ensure 45ml fill
- Irrigate cuff with water, using clear "IRRIG" port, as needed to keep tubing clear. If leakage occurs, cuff may need to be repositioned and irrigation procedure repeated
- Position tubing to prevent kinking, twisting or tugging
- Conduct stool sampling as needed
- Flush catheter tubing using purple "FLUSH" port as needed to prevent catheter obstruction
- Check collection bag at least once per shift to monitor stool volume. Replace as needed
- Keep the collection bag below patient hips and off the floor
- Perform routine skin care to keep skin clean and dry
- Wash hands before and after handling the device
- Wear appropriate protection

Directions for use

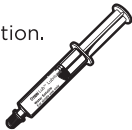
- 1 DEFLATE**
Remove all air from cuff using syringe.



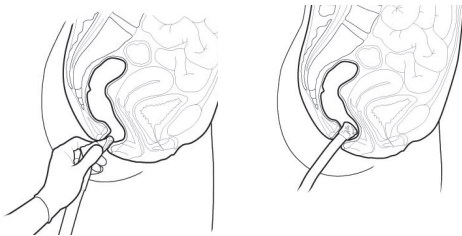
- 2 FLATTEN/FOLD**
Flatten cuff, fold the upper right corner down to the bottom of the cuff in a 45° angle. This creates a leading edge for easy insertion.



- 3 LUBRICATE**
Apply lubrication.



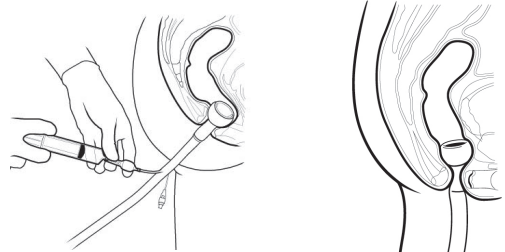
- 4 INSERT**
Insert cuff into rectal vault.



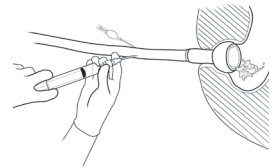
ATTENTION: PROPER INSERTION IS IMPORTANT

This card provides a quick reference for the preparation and insertion of the DigniShield[®] SMS Cuff. Consult product IFU for further information on the use of this device.

- 5 INFLATE (45ml water)**
Inflate cuff with syringe and seat.



- 6 TEST**
Irrigate to verify seating.



Please consult product label and insert for any indications, contraindications, hazards, warnings, cautions and directions for use.

If you have questions or require additional information, please contact your local Bard Sales Representative or call 1-800-526-4455.

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