STOOL MANAGEMENT SYSTEM

DIGNISHIELD®

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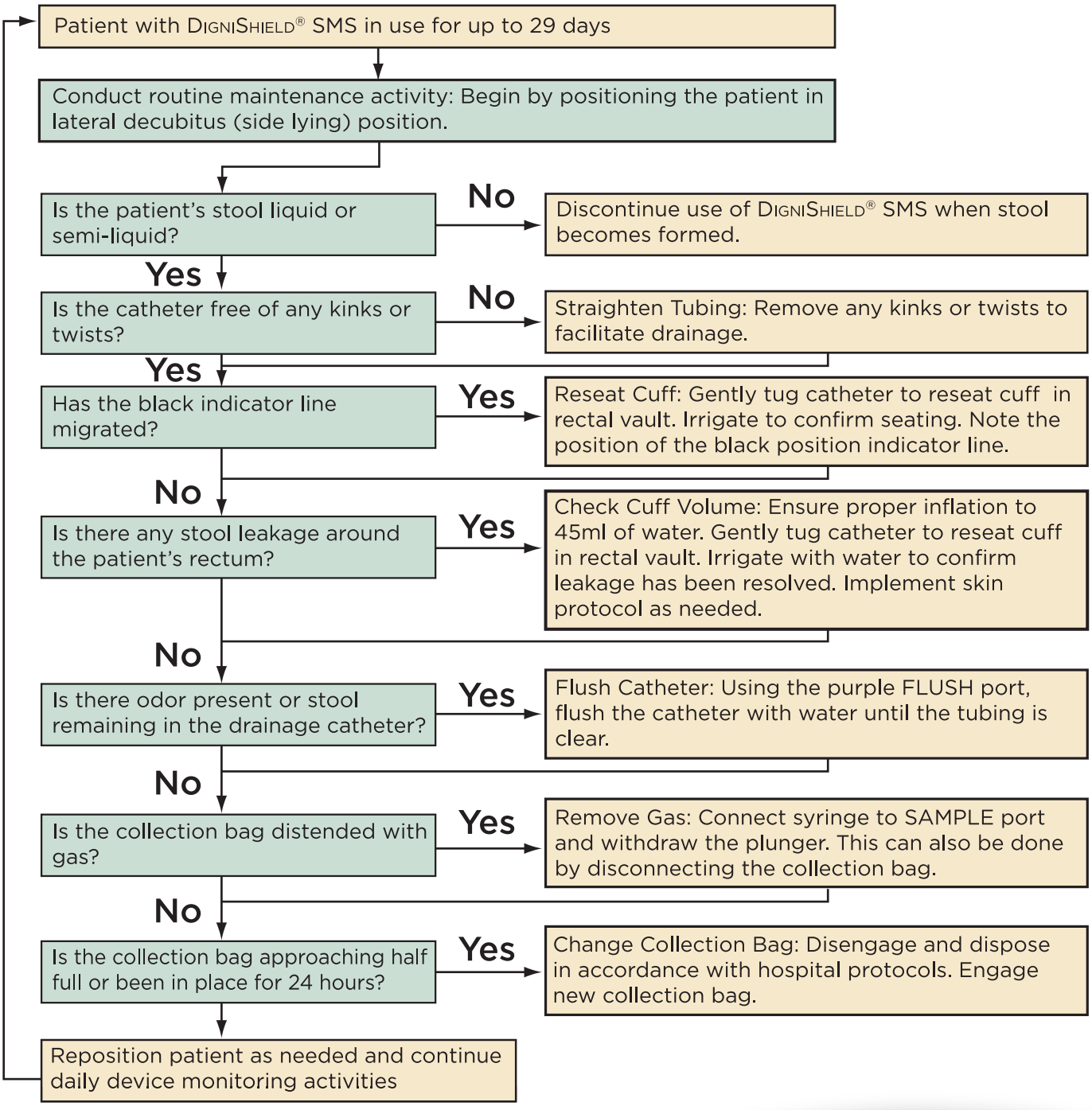
Stool Management System Maintenance Algorithm

This document provides a quick reference of maintenance activities related to the DIGNISHIELD® Stool Management System (SMS). For further information, please consult the product instructions for use.



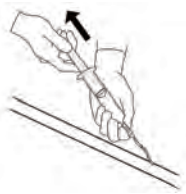
BOWEL MANAGEMENT

BARD | MEDICAL

Directions for use

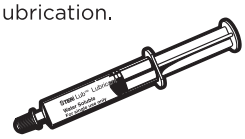
ATTENTION: PROPER INSERTION IS IMPORTANT
This card provides a quick reference for the preparation and insertion of the DIGNISHIELD® SMS Cuff. Consult product IFU for further information on the use of this device.

1 DEFLATE
Remove all air from cuff using syringe.

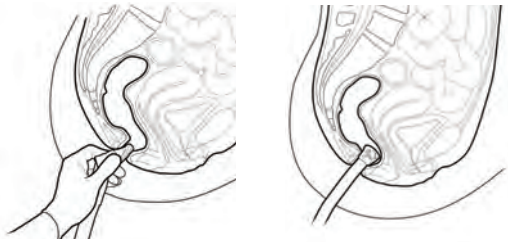


2 FLATTEN/FOLD
Flatten cuff, fold the upper right corner down to the bottom of the cuff in a 45° angle. This creates a leading edge for easy insertion.

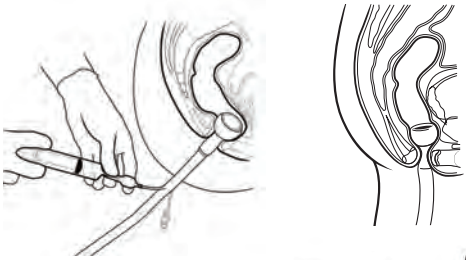
3 LUBRICATE
Apply lubrication.



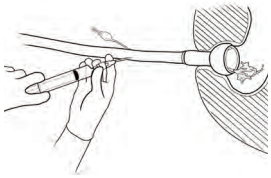
4 INSERT
Insert cuff into rectal vault.



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



6 TEST
Irrigate to verify seating.



The Bard® DigniShield® Stool Management System (SMS) is a single-use device intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in adult, bedridden patients.

Contraindications: The device should not be used for more than 29 consecutive days, on patients with certain medical conditions including rectal or anal injury or abnormalities, on patients with rectal mucosa impairment 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 devices, delivery mechanisms, or enemas in place.

Warnings and Adverse Events: 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.

BARD

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