

STOOL MANAGEMENT SYSTEM



DIGNISHIELD™

STOOL MANAGEMENT SYSTEM



Protect
What's
Important

BOWEL MANAGEMENT

BAIRD | MEDICAL

PROTECTING SKIN INTEGRITY is essential to patient health. The DIGNISHIELD™ Advance Stool Management System's (SMS) design draws from clinician insight to help mitigate damage to delicate tissue due to leakage, pressure and friction.

IMPROVED CONTAINMENT
 The DIGNISHIELD™ Advance Stool Management System's unique conical cuff **conforms to patient anatomy**, minimizing leakage.



Cuff, Side view

OPTIMIZED DRAINAGE

Area at the opening of the cuff: With BARD® DIGNISHIELD™ Advance SMS's anatomical design, the geometric area at the opening of the cuff is 149% larger while maintaining an external cuff diameter comparable to other commercially available fecal management devices.

DIGNISHIELD™ SMS 2.2 in.	Competitor 1 2.3 in.	Competitor 2 2.1 in.
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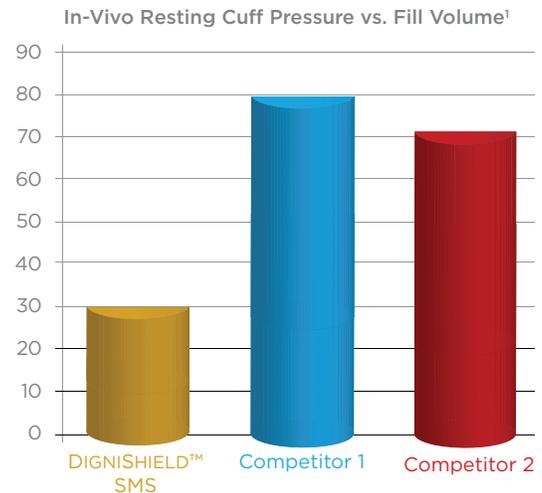
DIGNISHIELD™ SMS Diameter: 1.34 in. = 1.4 in. ² area	Competitor 1 Diameter: .84 in. = .56 in. ² area	Competitor 2 Diameter: .85 in. = .57 in. ² area
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MINIMIZED PRESSURE

Studies suggest that high pressure designs may impact capillary blood flow and cause mucosal tissue trauma.^{1,2,3,4} In simulated bench tests the BARD® DIGNISHIELD™ Advance SMS offers an average of 69% less resting pressure* than other commercially available fecal management devices.* **In a randomized clinical study, retention cuff pressure was at least 2-fold lower for DIGNISHIELD™ ADVANCE SMS than for the other devices.¹**

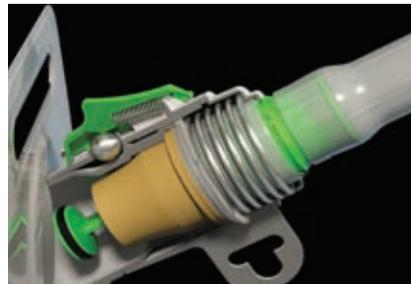
*bench data on file, may not correlate to clinical use



Average retention cuff pressure for subjects in three different positions and at three different elevation angles.

MINIMIZED EXPOSURE

The DIGNISHIELD™ Advance Stool Management System is designed with a unique self-closing mechanism that reduces exposure to harmful microorganisms during bag changes.



1. Disengaged
2. Engaged

RELIABLE SAMPLING

An integrated, easy-to-use sampling port reduces the possibility of contamination when taking specimens.



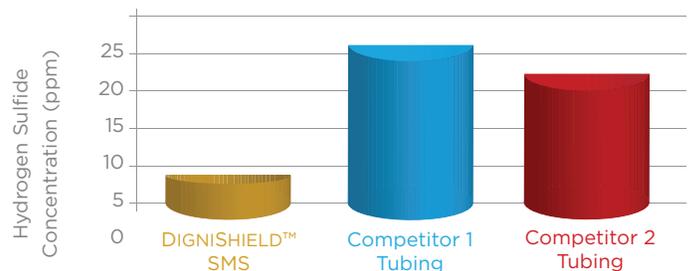
1. Pre-sampling
2. Sampling in progress

PROTECTING AGAINST EXPOSURE means containing odor as well as exposure to harmful microorganisms. Improving containment means improving safety, reducing cleanup and helping patients maintain dignity.

ODOR CONTROL

BARD's proprietary PERMALENE™ polymer technology significantly reduces tubing permeability of compounds that contribute to odor—**more than 76% when compared to silicone tubing.***

Maximum Hydrogen Sulfide detected over 8 hrs.



*bench data on file, may not correlate to clinical use

PRODUCT LABELING WITH A PURPOSE

- Labeling** reminds the clinician of the appropriate indication and use of stool management systems as well as the steps for proper insertion/removal technique and maintenance.
- Orange Chart Label:** Allows documentation of critical information such as confirmation of selection criteria and that no contraindications are present, as well as insertion date and time.
- Patient and Family Education Flyer:** Provides information about stool management systems, device care and when to contact a healthcare professional.
- Extended Care Providers Illustrative Flyer:** Provides information about patient selection criteria, daily care and maintenance as well as directions for use.

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ASSESS PATIENT SELECTION AND SMS CONTRAINDICATIONS BEFORE PROCEEDING

Patient Selection Parameters for SMS Use (Check All That Apply)

- Rectal Tone: Confirmed by Digital Rectal Exam
- Facial Inspection: Absent
- Stool Frequency: ≥ 3 stools in 24 hrs
- Stool Consistency: Semi-solid to Liquid
- Bristol Stool Form Scale: Type 6-7 (diarrhea)
- Stool Culture: Positive for C. difficile
- Briden Scale Score: ≤ 14
- IMD* Risk Level: High Risk to Severe IAD

CONTRAINDICATIONS FOR SMS Use (If Any Box Checked DO NOT PROCEED)

- Rectal injury
- Previous interrupted use of SMS for the past 29 days
- Known sensitivity or allergy to any system components
- Lower leg-level or rectal surgery within last year
- Patient with any rectal or anal injury, stricture, stenosis, tumor, severe hemorrhoids or fecal impaction
- Suspected or confirmed rectal mucosal impairment
- Known rectal or anal device, delivery mechanism or enema in place
- Rectal bleeding precautions

FOR CHART

PATIENT SELECTION CRITERIA FOR STOOL MANAGEMENT SYSTEM (SMS)

Patient Selection Parameters for SMS Use (Check All That Apply)

- Rectal Tone: Confirmed by Digital Rectal Exam
- Facial Inspection: Absent
- Stool Frequency: ≥ 3 Stools in 24 hrs
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Have You?

- Obtained order from physician/nurse
- Received device, supplies, procedures and instructions for use
- Explained procedure to patient/family, member and provided education

FOR DEVICE/BAG CONNECTOR

Insertion

Date: _____
Time: _____
Initials: _____

RIGHT PATIENT

Quality Indicator to confirm selection criteria met and no contraindications are present

Initials: _____
Date: _____

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PATIENT & FAMILY EDUCATION

A few important words about your Stool Management System

Your doctor has ordered an InWelling Stool Management System (SMS) for you or a member of your family. This device is used to collect and control diarrhea in very ill patients who can not control their bowel movements, and/or are unable to get out of bed and use the toilet. The goals are to treat the cause of diarrhea and if possible, prevent any injury to the skin. To accomplish this, the device can be left in place for up to 29 days.

There are many causes for liquid stool or diarrhea. Some medications, illnesses and physical conditions can cause diarrhea. Another cause among patients in the hospital is a stool infection from bacteria such as *Clostridium difficile* (often called "C. diff"). C. diff infection can be caused by antibiotics used to treat other illnesses. In this case the stool often has a strong odor. If you or your family member has a C. diff infection triggered diarrhea, the nurse may ask that you take special care not to spread the infection. This can include proper hand washing with soap and water or wearing gown and gloves. Your doctor may use this device to contain the stool to help prevent the spread of infection to others entering the room.

The SMS is gently inserted into the rectum and a soft cuff is filled with water to help keep it in place. The liquid stool drains through the tubing into a collection bag. To keep the tubing clear, the nurse can attach a water-filled syringe to start a built-in sprinkle system. This helps keep the liquid stool moving into the collection bag when necessary. The collection bags are changed as needed. By holding liquid stool inside the tubing and collection bag it helps to reduce odor and improve patient comfort and patient dignity.

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Directions for Use & Information for Extended Care Providers

When a patient is admitted with an InWelling 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.

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.

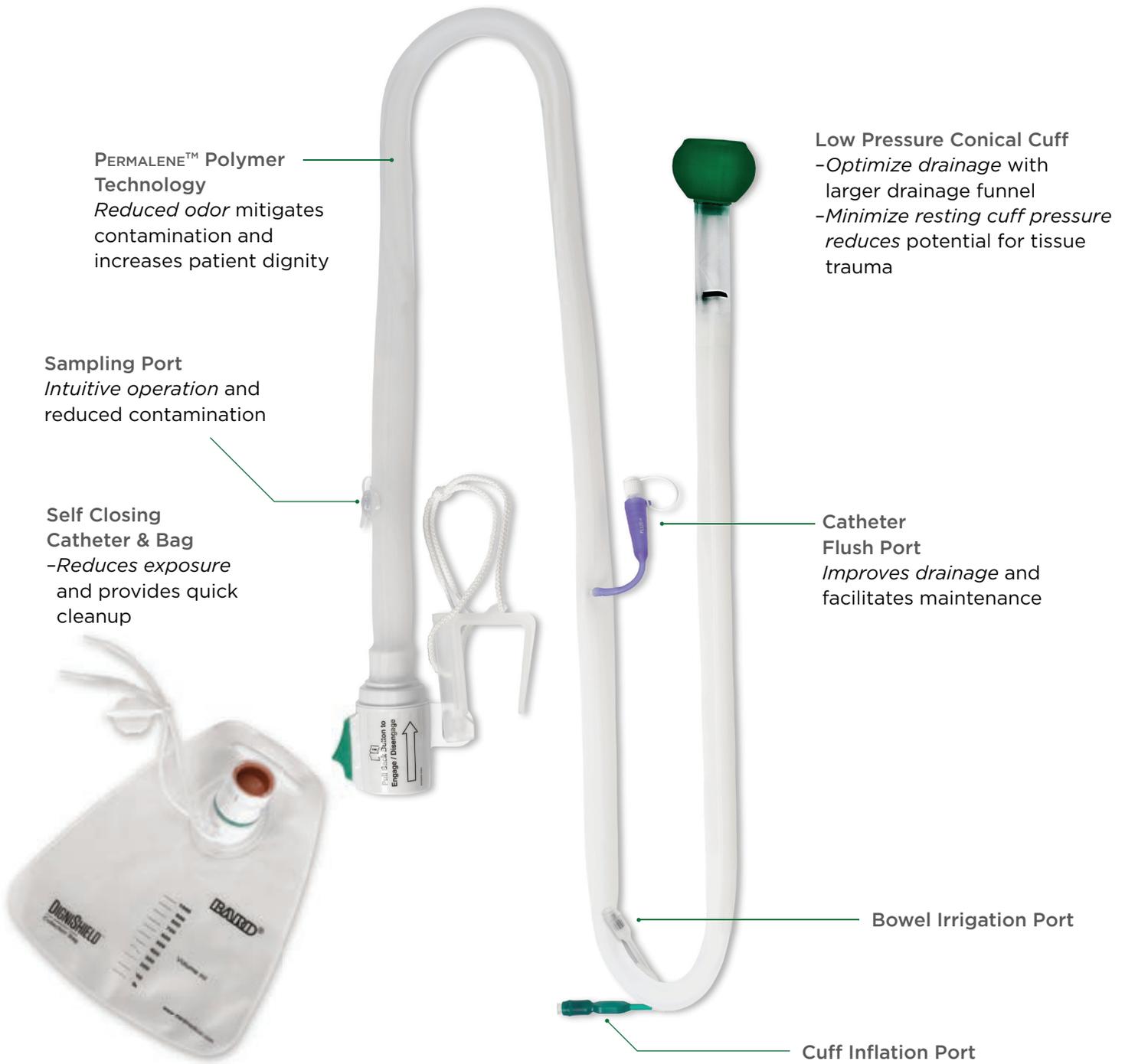
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- Briden Scale Score: ≤ 14
- IMD* Risk Level: High Risk to Severe IAD

Daily care and maintenance of the device includes:

- Check the cuff fill volume periodically to ensure 40-60 mL.
- Inspect cuff with water using Blue H&M* port, as needed to see tubing flow. If leakage occurs, cuff may need to be repositioned and/or procedure reattempted.
- Position tubing to prevent twisting, twisting or kinking.
- Flush outer tubing using purple "FLUSH" port as needed to prevent clogging/obstruction.
- Check collection bag at least once per shift to monitor stool volume. Multiple fills are allowed.
- Place the collection bag below patient hips and off the floor.
- Remove marine site cover to keep site dry and dry.
- Wash hands before and after handling the device.
- Use appropriate protection.

THE DIGNISHIELD™ ADVANCE STOOL MANAGEMENT SYSTEM: Advanced Technology. Advanced Protection.



For more information about the DIGNISHIELD™ Advance Stool Management System and other BARD® products, please contact your sales representative or call 800.526.4455.

	DIGNISHIELD™ Advance Stool Management System	DIGNISHIELD™ SMS Collection Bags
Product Code	SMS002	SMS2B1L
Case Quantity	2	10

References

1. Marchetti, et al. J Wound Ostomy Continence Nurs. 2011; 38(5):1-5
2. Loese, et al. Anest Analg 1979, 57:577-579
3. Seegobin RD, et al. Br Med J 1984, 288:965-968
4. Sparks, et al. Dis Colon Rectum 2010; 53: 346-349

Please consult product inserts and labels for any indications, contraindications, hazards, warnings, cautions and directions for use.

Bard Medical

Leading the way for 70 years

Bard Medical is the global leader in the prevention of serious events in acute care, including some of the most prevalent hospital-acquired infections. Since Bard first introduced the Foley catheter more than 70 years ago, the company has consistently developed and delivered quality healthcare products to improve patient care. These high quality products, backed by the most comprehensive services, uniquely position Bard as an industry leader.



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