ENFit™ Compatible Stool Management System (SMS) FAQ

How does SMS relate to other enteral feeding devices?

- Enteral devices are used for instilling fluids into or withdrawing fluid from the digestive tract
- The BARD® DIGNISHEILD® SMS falls within the same FDA classification as other enteral devices such as but not limited to:
  - Nasogastric tubes
  - Enteral feeding tubes
  - Gastrojejunal tubes

Why would we want an ENFit™ compatible Stool Management System? We do not feed the patient via the rectal route.

- The changes affecting your hospital are aimed at reducing enteral device misconnections
- Indwelling stool management systems have small-bore access ports for medication delivery and bowel irrigation
- Rectal medication delivery and irrigation have the same risk of misconnections as feeding

But the standard excludes rectal devices from the scope?

- Currently, there is an exclusion that generically removes “all” rectal devices from the scope
- The exclusion is based on feedback regarding large-bore rectal tubes
- Large-bore connectors are inherently excluded as this only pertains to small-bore connectors
- BARD has proposed that the exclusion be removed
- Additional clarity also proposed to be added into the scope for indwelling rectal devices
- BARD’s proposal is within the ISO committee with support from both the U.S. Food and Drug Administration (FDA) and the Association for the Advancement of Medical Instrumentation (AAMI)
Indications: The Bard® DigniShield® Stool Management System (SMS) with ENFit™ Connector and odor barrier properties is intended for fecal management by diverting and collecting liquid or semi-liquid stool in bedridden patients and 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 on patients with indwelling rectal or anal device, delivery mechanisms, or enemas in place.

Warnings and Adverse Events: There is a potential risk of misconnections with connectors from other healthcare applications. 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.