

Photo © CDC/James Archer



Infection Control



Pressure Ulcer Management



Budget Impact

FlexiSeal[®]
SIGNAL[™]



Unique Product Benefits

Odor Absorbing Technology



Staff & Patient Satisfaction



Six reasons why you should consider the **Fecal Management System** used by more hospitals^{1,2}



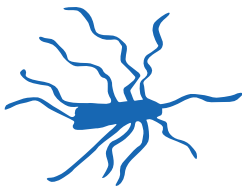
Costly and Growing Problems for Hospitals

The Flexi-Seal™ SIGNAL™ FMS – a closed-end system designed to minimize the spread of infection by containing liquid/semi-liquid stool – has been shown to reduce complications and costs in the hospital setting.³

The Prevalence of *C. difficile* Infection (CDI)

- *C. difficile* infection results in about 3 million cases of diarrhea and colitis in the United States each year.⁴
- In the USA, 1 in 5 patients with a healthcare-associated *C. difficile* Infection experiences a recurrence of the infection.⁵
- National rate of *C. difficile* Infection hospitalization doubled between 2001-2010 in the USA.⁶

C. Difficile Infection



**Nearly
500,000**
infections in the
USA per year⁵



29,000
deaths in
2011 in
the USA⁵



\$4.8 Billion
in excess medical
costs in the USA
per year⁵

Fecal Incontinence and Pressure Ulcer Risk

- Hospitalized adults with fecal incontinence are 22 times more likely to have pressure ulcers than patients without fecal incontinence.³
- The sacrum is the highest risk area for skin breakdown.⁷

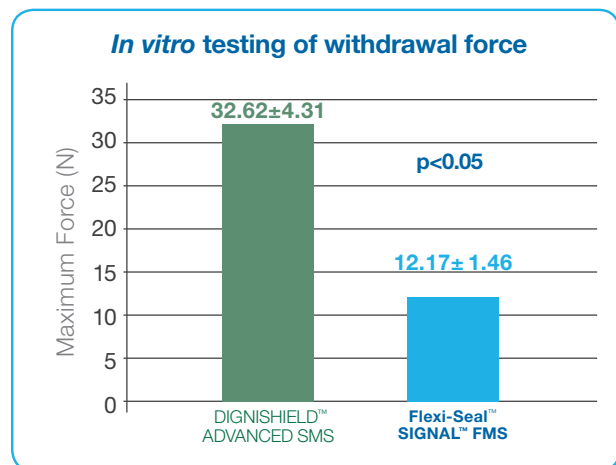
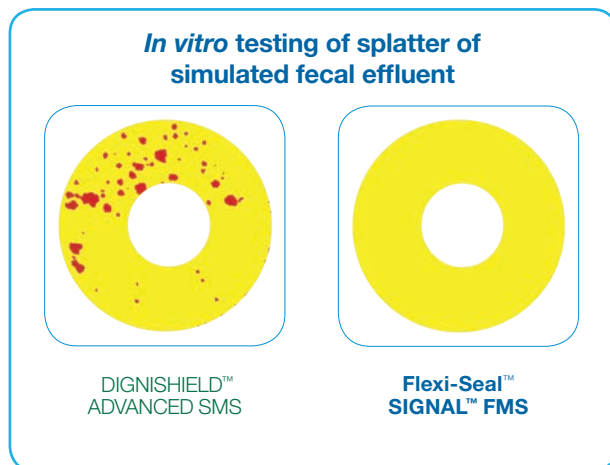
The Cost Impact

- Both *C. difficile* and pressure ulcers are associated with increased length of hospital stay and treatment costs.^{8,9}
- The mean cost per CDI hospital stay in the USA is \$24,400.¹⁰
- In the USA, pressure ulcers are considered a Hospital Acquired Condition (HAC) and associated with an excess cost of \$40,000 per pressure ulcer in stage 3 or 4.¹¹

The Flexi-Seal[™] SIGNAL[™] Difference

Unique Product Benefits (*in vitro* testing)

- Proven *in vitro* to contain the spread of *C. difficile* and prevent *C. difficile* from spreading into the environment.¹²
- Excess gas released through the collection bag filter minimizes the need for frequent bag changes, potentially reducing the aerosolized spread of *C. difficile* spores.^{13,14}
- The filter also eliminates the risk of manually releasing the excess gas from the collection bag.¹⁴
- The SIGNAL[™] indicator is designed to prevent overfilling of the retention balloon.*
- In *in vitro* testing, Flexi-Seal[™] SIGNAL[™] FMS showed no splatter of simulated fecal effluent upon removal compared to more than 25cm³ for DIGNISHIELD[™] ADVANCE SMS.¹⁵
- In *in vitro* testing, Flexi-Seal[™] SIGNAL[™] FMS required nearly 3 times less withdrawal force compared to DIGNISHIELD[™] ADVANCE SMS.¹⁵



Odor Absorbing Technology

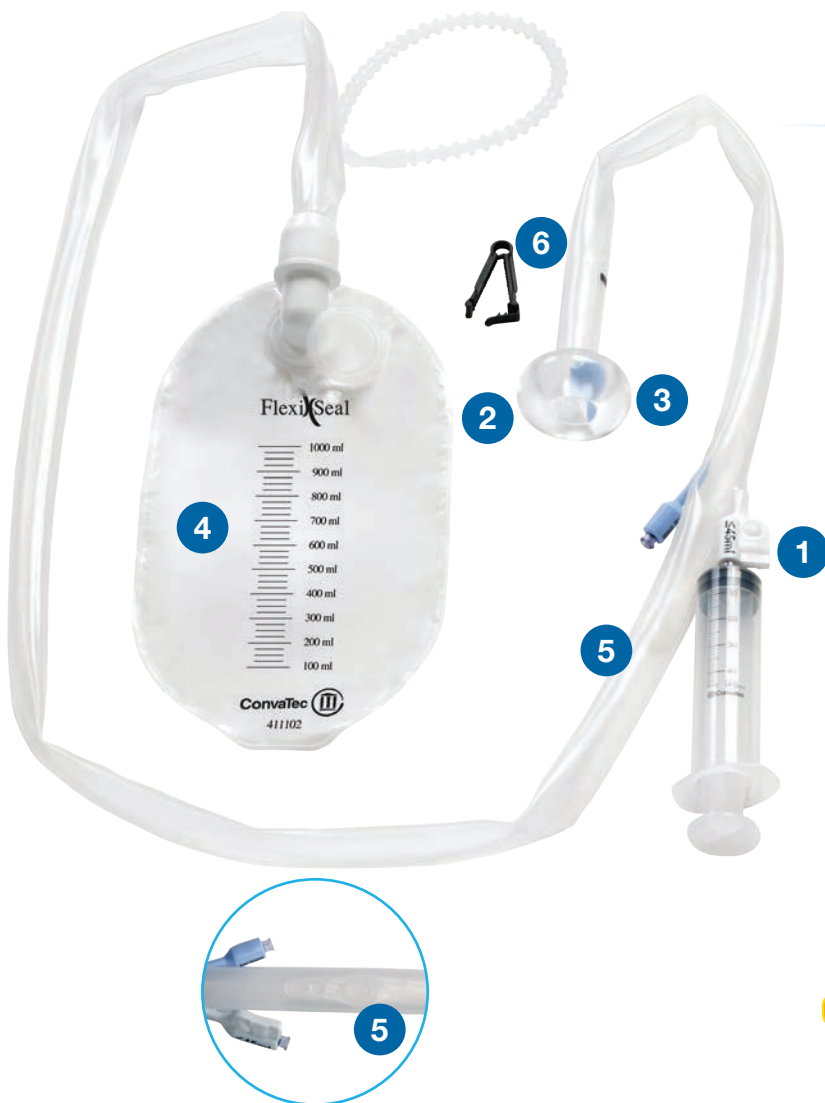
- Odor barrier runs the length of the catheter, providing an end-to-end odor barrier.¹⁶
- Privacy[™] Collection bag with 6x more odor-capturing compared to the charcoal filtered collection bags in *in vitro* testing¹⁷ includes an integrated filter that deodorizes air for a more pleasant, comfortable environment.



Improved Patient Experience

- Opaque Privacy[™] Collection bag hides contents from family and visitors while a clear window allows clinician to monitor stool output and color discreetly without compromising patient privacy.

* Maximum fill volume is ≤ 45 ml. Filling should stop when the SIGNAL[™] indicator pops out and stays out which could happen before 45ml if the rectal space is smaller than maximum balloon size. Never add more than 45ml total.



Product Benefits Overview

- 1 **SIGNAL[™] indicator provides visual indication to help prevent overfilling, which helps indicate optimal fill**
- 2 **Soft retention balloon with catheter**
- 3 **Patented blue finger pocket for ease of insertion**
- 4 **Charcoal-filtered vented bag**
- 5 **Sampling port provides access to the catheter for safe and easy stool collection**
- 6 **Medication delivery via irrigation port**

Product Ordering Codes

Flexi-Seal[™] SIGNAL[™] FMS

Flexi-Seal [™] SIGNAL [™] FMS Kit (1 kit/box, 1 bag)	418000
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Collection Bag Information

Recommended	Privacy [™] Collection Bag with APS Filter (10 bags/box)	411108
	Collection Bag with Filter (10 bags/box)	411102

The Flexi-Seal[®] Fecal Collector with Hydrocolloid Adhesive:

- An alternative when the use of Flexi-Seal[™] SIGNAL[™] FMS is contraindicated
- Skin-friendly hydrocolloid adhesive with tape border
- Tapered pouch with drainage port & deodorizing filter
- Latex-free

Flexi-Seal[™] Fecal Collector

Flexi-Seal [®] Fecal Collector with Hydrocolloid Adhesive (10 Collectors per box)	650078
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We recommend the use of skin barrier products before and during the use of Flexi-Seal[™] SIGNAL[™] FMS or Flexi-Seal[™] Fecal Collectors.

Skin Protectants

Sensi-Care [®] Clear Zinc (24x 2 oz tubes/case) <i>Recommended for intact to red skin</i>	413586
Sensi-Care [®] Protective Barrier (24x 4 oz tubes/case) <i>Adheres to and helps treat denuded skin</i>	324614

REFERENCES: 1. HPSI. Q2 2015 data. Moving Annual Total (MAT) Fecal Control Category. Data on file, ConvaTec.pdf 2. ConvaTec Market Penetration and Potential Assessment.Q1 2015. Data on file, ConvaTec 3. Langill M, Yan S, Kommala D, et al. A Budget Impact Analysis Comparing use of a Modern Fecal Management System to Traditional Fecal Management Methods in Two Canadian Hospitals. *Ostomy Wound Management* 2012; 58(12):25-33. 4. Reference: Schroeder MS. Clostridium difficile-associated diarrhea. *Am Fam Physician*. 2005;71(5):921-928. 5. Lessa FC, Mu Y, Bamberg WM, Beldavs ZG, Dumyati GK, Dunn JR, et al. Burden of Clostridium difficile Infection in the United States. *New England Journal of Medicine*. 2015;372(9):825-34. 6. Steiner C, Barrett M, Terrel L. HCUP projections: *Clostridium difficile* hospitalizations 2011 to 2012. Available from: http://www.hcup-us.ahrq.gov/reports/projections/CDI_Regional_projections_Final.pdf; 2012. Accessed April 25, 2014. 7. VQC State-wide PUPPS 2 Report 2004 *Pressure Ulcer Point Prevalence Survey*, Page 32. 8. Kyne L, Hamel MB, Polavaram R, Kelly CP. Health care costs and mortality associated with nosocomial diarrhea due to *Clostridium difficile*. *Clin Infect Dis*. 2002;34(3):346-353. 9. Bennet G, Dealey C, Posnett J. The cost of pressure ulcers in the UK. *Age and Ageing* 2004; 33(3): 230-235. 10. Lucado J, Gould C, Elixhauser A. Clostridium difficile infections (CDI) in hospital stays, 2009. HCUP Statistical Brief 124. Rockville, MD: Agency for Healthcare Research and Quality. Available at: <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb124.pdf> 11. Jackson M, McKenney T, Drumm J, Merrick B, LeMaster T, VanGilder C. Pressure ulcer prevention in high-risk postoperative cardiovascular patients. *Crit Care Nurse*. 2011;31(4):44-53 12. Jones S, Towers V, Welsby S, et al. *Clostridium difficile* Containment Properties of a Fecal Management System: An In Vitro Investigation. *Ostomy Wound Management* 2011;57(10):38-49. 13. Roberts K, Smith CF, Snelling AM, et al. Aerial dissemination of Clostridium difficile spores. *BMC Infect Dis*. 2008;8:7. 14. Minimizing the spread of *C. difficile* spores from the release of gas. February 19, 2013. Data on file, ConvaTec Inc. 15. Investigation of the Dispersal of Simulated Faecal Effluent during the removal of Faecal Management Catheters Using an in vitro Rectal Cavity Model. WHR13977 MS124. July 28, 2014, Data on File, ConvaTec Inc. 16. Odor Barrier Testing. 130124-001. Data on file, ConvaTec Inc. 17. Flexi-Seal[®] Privacy Bag Filter Evaluation. 121412-001. Data on file, ConvaTec Inc.

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