




The Problem

Up to **30 out of 100** patients admitted to the ICU experience fecal incontinence¹ (FI) during their hospital stay making FI a significant challenge for hospitals to tackle.

Especially as FI leads to:


1



Additional patient suffering

- In addition to the prevailing condition that brought them to the ICU, patients could have an undignified experience if FI is not taken care of effectively.
- Hospitalized adults with fecal incontinence are 22 times more likely to have pressure ulcers than patients without fecal incontinence².**
- Especially ICU patients with FI who smoke, have diabetes and have fever face an increased risk of skin damage and require special attention³.


2



Increased cross contamination risk

- C. difficile* is shed in feces and can be transferred to patients mainly via the hands of healthcare personnel who have touched a contaminated surface or item²³. *C. difficile* spores can survive for up to five months in the environment⁵.
- In the USA, 1 in 5 patients with a healthcare-associated *C. difficile* infection experiences a recurrence of the infection⁶.**

3

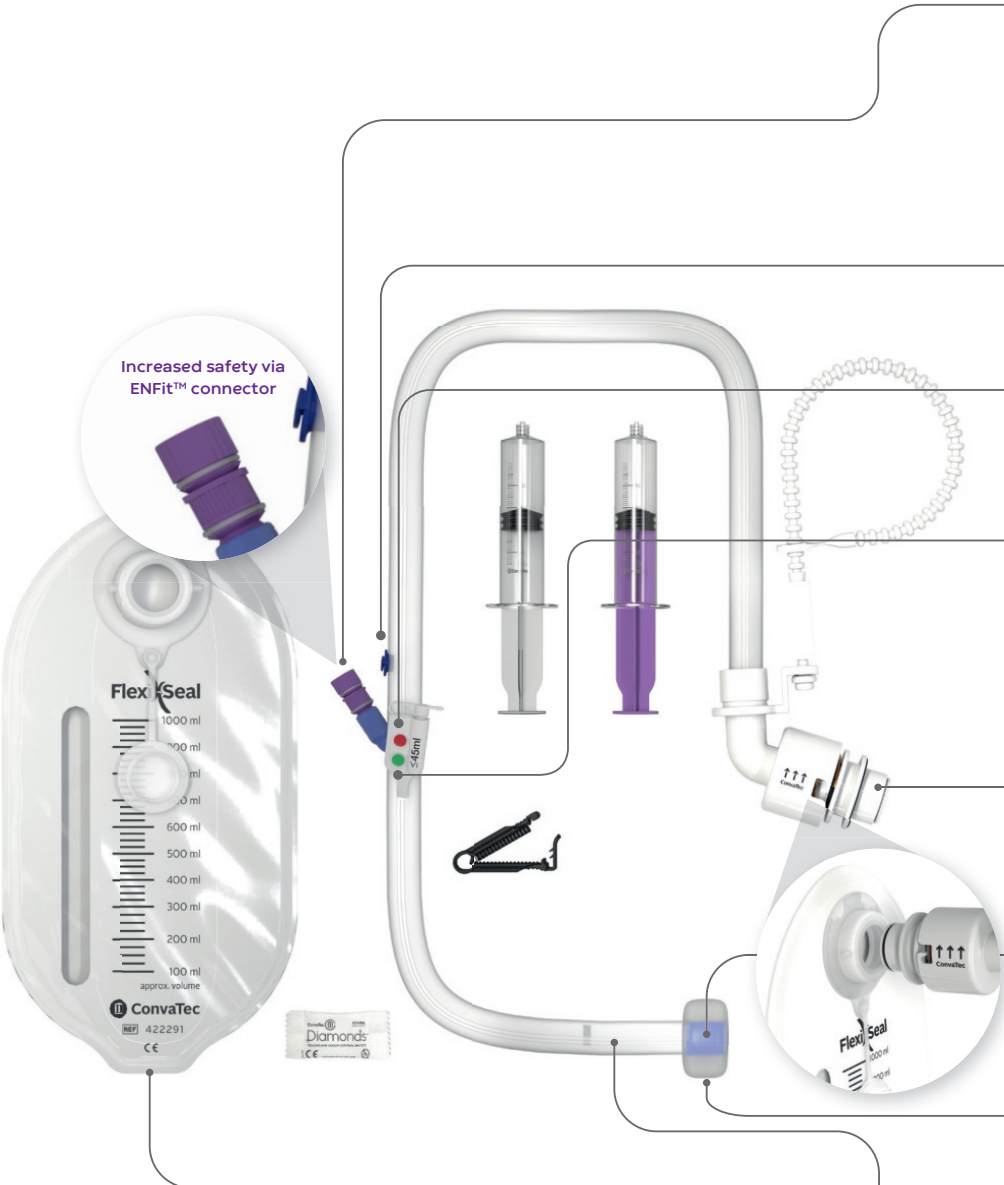


Heavy burden for health system & HCPs

- FI negatively impacts the treatment outcome binding significant resources and leading to prolonged patient suffering. If FI is not managed effectively additional and non-reimbursable cost can skyrocket.
- C. difficile* infections result in about 3 million cases of diarrhea and colitis in the United States each year⁷ representing \$6.3 billion in excess medical costs in the USA annually⁸.
- In the USA, pressure ulcers are considered a Hospital Acquired Condition (HAC) and are associated with an excess cost of \$40,000 per pressure ulcer in stage 3 or 4⁹.

The Solution

Flexi-Seal™ which is designed to help improve outcomes of patients suffering from FI has been shown to **reduce complications and costs** associated with FI in the hospital setting².



Features	Patient Outcomes & Caregiver Experience	Economic Impact
Medication / irrigation port - ENFit™ or Luer connection	Deliver medication effectively via a secondary route. Available as ENFit™ or Luer connection	Increased efficiency for HCP by administering medication rectally. ENFit™ helps to further reduce the risk of balloon over inflation by avoiding misconnection of medication to the inflation port.
Colored sampling port	Designed to facilitate stool sampling and simplify work routine	Reduced nurse effort & provide better user experience
Over inflation warning system	Unique feature that indicates balloon over inflation helping to reduce risk of rectal tissue damage	Over inflation can lead to severe rectal tissue damage that requires prolonged treatment & hospitalization ¹⁵
Patient specific inflation indicator	75% of patients require 40ml or less in fill volume for ideal fit and reduced leakage ¹² Unique feature that allows for patient specific fill volume to reduce leakage risk ¹²	Liquid stool in contact with skin is a major risk driver for pressure ulcers with each estimated to cost 40,000 USD ⁹
Self-closing catheter	Designed to reduce the risk of cross-contamination during bag change as well as increase caregiver confidence	Helps to reduce the risk of CDI with a mean cost per hospital stay in the USA of \$24,400 ¹¹
Finger pocket	Designed to provide confidence that balloon is placed correctly	Helps to apply the catheter faster which saves time and worries
Soft balloon	Designed to reduce cross contamination risk by avoiding splatter upon removal compared with competitor products ¹⁰	Helps to reduce the risk of CDI with a mean cost per hospital stay in the USA of \$24,400 ¹¹
Zeolite™ silicone catheter	Improve patient and care giver experience by providing end-to-end odor protection	Increased quality of life by reducing odor in the treatment area
Opaque Flexi-Seal™ Protect Plus Privacy™ collection bag including 4 ConvaTec Diamonds™ gelling and odor control sachets.	Minimize spread of <i>C. difficile</i> spores by releasing air through the active charcoal filter. With 6x more odor-capturing compared to the charcoal filtered collection bags ²¹ . This filter also eliminates the need of manually releasing the excess gas from the collection bag ²²	Helps to reduce the risk of CDI with a mean cost per hospital stay in the USA of \$24,400 ¹¹

Our Commitment



We make fecal management our priority so it doesn't have to be yours by providing you with:

1

Sustained in-servicing support to give you a helping hand



Nationwide dedicated team fully focusing on providing in-house educational support



more than **10,000** hospitals¹⁵ have been supported since the launch of Flexi-Seal™ globally

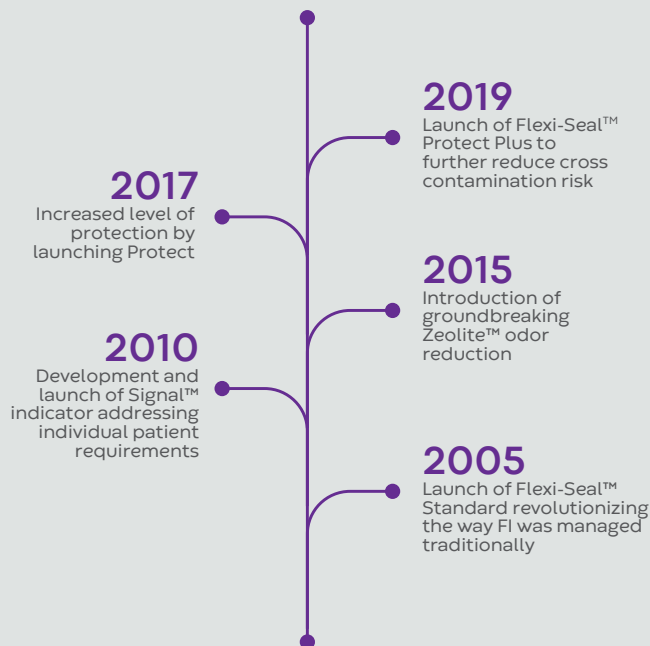


An estimated **100,000** nurses¹⁶ globally have benefited from our in-service support activities

2

Continuous and regular product refinements to elevate the level of care

To date **3.5 Million¹⁴** patients have benefited from Flexi-Seal™



3

State of the art educational materials to ensure you feel confident using Flexi-Seal™ - reach out to our sales team or customer service to receive your copy

Resources:

1 Bayón García, Cristina & Binks, Rachel & De Luca, Enrico & Dierkes, Christine & Franci, Andrea & Gallart, Elisabet & Niedera, Georg & Wyncoll, Duncan. (2012). Prevalence, management and clinical challenges associated with acute faecal incontinence in the ICU and critical care settings: The FIRST™ cross-sectional descriptive survey. Intensive & critical care nursing : the official journal of the British Association of Critical Care Nurses. 28. 242-50.

2 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.

3 Independent risk factors for the development of incontinence-associated dermatitis (category 2) in critically ill patients with fecal incontinence: A cross-sectional observational study in 48 ICU units; Nele Van Dammea, Els Claysb, Sofie Verhaeghec, d, Ann Van Hecke, e, Dimitri Beekmana, f, g. * International Journal of Nursing Studies 81 (2018) 30-39

4 Guide to the elimination of Clostridium difficile in Healthcare settings. Association for Professionals in Infection Control and Epidemiology (APIC) 2008.

5 Clostridium difficile: a sometimes-fatal complication of antibiotic use. PA PSRS Patient Saf Advis 2005 Jun;2(2):1-8.

6 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.

7 Schroeder MS. Clostridium difficile-associated diarrhea. Am Fam Physician. 2005;71(5):921-928.

8 Zhang S, Palazuelos-Munoz S, Balsells E M, Nair H, Kyaw M H. Cost of hospital management of Clostridium difficile infection in United States—a meta-analysis and modelling study. BMC Infect Dis. 2016; 16(1): 447.

9 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.

10 Metcalf et al. Contamination Risk During Fecal Management Device Removal: An In vitro, Simulated Clinical Use Study. Wound Manage Prev 2019; 65(3): 30-37.

11 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>

12 Optimizing Fecal Containment Using Individualized Balloon Volumes: Catherine T. Milne APRN, MSN, BC-ANP, CWOCN; Ann Durnal RN, BSN, CWOCN2; Mary Webb, RN, BSN, MA, CIC3, IConnecticut Clinical Nursing Associates, LLC, Bristol, Connecticut; 2Ascension Carondelet St Mary's Hospital, Tucson, Arizona; 3San Mateo Medical Center, San Mateo, California

13 MAUDE FDA Data Analysis - Accessed during January 2019 - Data on file, ConvaTec

14 ConvaTec Estimate - based on global unit sales - Data on file

15 ConvaTec Estimate - based on sales force statistics - Data on file

16 ConvaTec Estimate - based on sales force statistics - Data on file

17 AP-020492-MM

18 AP-019936-MM

19 AP-019935-MM

20 AP-019902-MM

21 Flexi-Seal® Privacy Bag Filter Evaluation. 121412-001. Data on file, ConvaTec Inc.

22 Minimizing the spread of C. difficile spores from the release of gas. February 19, 2013. Data on file, ConvaTec Inc.

23 CDC FAQ on C. difficile. Available at: <http://www.cdc.gov/cdiff/index.html>, Accessed 25th of October 2019

Product Ordering Codes

Flexi-Seal™ Protect Plus FMS kit LUER (1kit/box, 1bag)	422303
Flexi-Seal™ Protect Plus FMS kit ENFit™ (1kit/box, 1bag)	421703
Flexi-Seal™ Protect Plus Privacy™ Collection Bag with APS Filter (5/box)	422291

Reach out and learn more how we can best support you to achieve improved patient outcomes together.

To learn more, call: 1-800-422-8811

Mon-Fri, 8:30am - 7:00pm

www.flexi-seal.convatec.com

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