

**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

2

Continuous and regular product refinements to elevate the level of care

To date **3.5 Million**<sup>13</sup> patients have benefited from Flexi-Seal™



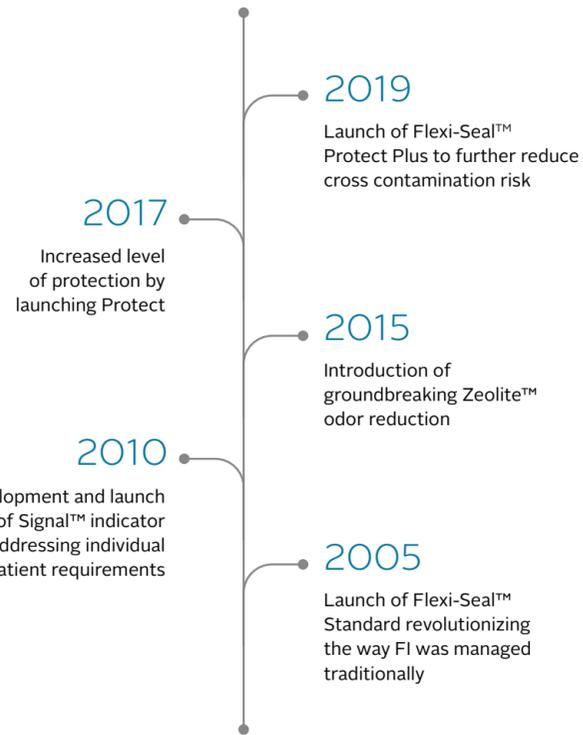
Nationwide dedicated team fully focusing on providing in-house educational support



more than **10,000** hospitals<sup>14</sup> have been supported since the launch of Flexi-Seal™ globally



An estimated **100,000** nurses<sup>15</sup> globally have benefited from our in-service support activities



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

- Training videos<sup>16</sup>
- IFU poster<sup>17</sup>
- Treatment algorithm<sup>18</sup>
- Evaluation form<sup>19</sup>

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.convatec.com](http://www.convatec.com)

1 Bayón García, Cristina & Binks, Rachel & De Luca, Enrico & Dierkes, Christine & Franci, Andrea & Gallart, Elisabet & Niederalt, 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 Damme, Els Claysb, Sofie Verhaeghe, d, Ann Van Heckec, e, Dimitri Beeckmana, 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 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

9 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.

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 Optimizing Fecal Containment Using Individualized Balloon Volumes; Catherine T. Milne APRN, MSN, BC-ANP, CWOCN1; Ann Durnal RN, BSN, CWOCN2; Mary Webb, RN, BSN, MA, CIC3. 1Connecticut Clinical Nursing Associates, LLC, Bristol, Connecticut; 2Ascension Carondelet St Mary's Hospital, Tucson, Arizona; 3San Mateo Medical Center, San Mateo, California

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

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

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

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

16 AP-O20492-MM

17 AP-O19936-MM

18 AP-O19935-MM

19 AP-O19902-MM

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

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

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



**WE MAKE FECAL MANAGEMENT OUR PRIORITY SO IT DOESN'T HAVE TO BE YOURS.**

## The Problem

Up to **30 out of 100** patients admitted to the ICU experience fecal incontinence<sup>1</sup> (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 incontinence<sup>2</sup>.
- Especially ICU patients with FI who smoke, have diabetes and have fever face an increased risk of skin damage and require special attention<sup>3</sup>.

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 item<sup>22</sup>. C. difficile spores can survive for up to five months in the environment<sup>3</sup>.
- In the USA, 1 in 5 patients with a healthcare-associated C. difficile infection experiences a recurrence of the infection<sup>6</sup>.

3

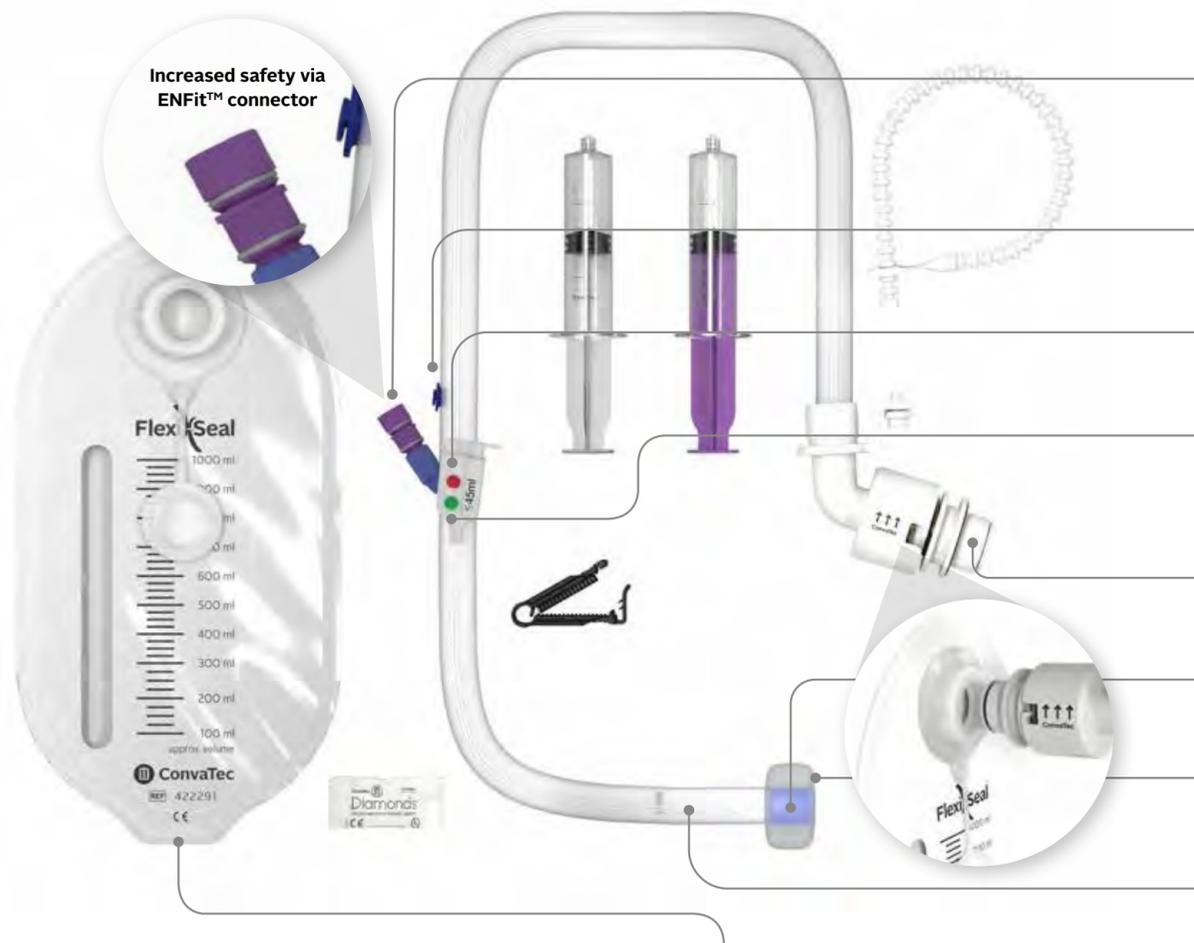
Heavy burden for health system & HCPs



- 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 year<sup>7</sup> representing \$4.8 billion in excess medical costs in the USA annually<sup>8</sup>.
- 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 4<sup>9</sup>.

## 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 setting<sup>2</sup>.



### Product Ordering Codes

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

ENGINEERED WITH UNDERSTANDING

Flexi-Seal™ PROTECT PLUS



Features	Patient Outcomes & Caregiver Experience	Economic Impact
<b>Medication / irrigation port - ENFit™ or Luer connection</b>	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.
<b>Colored sampling port</b>	Designed to facilitate stool sampling and simplify work routine	Reduced nurse effort & provide better user experience
<b>Over inflation warning system</b>	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 <sup>12</sup>
<b>Patient specific inflation indicator</b>	75% of patients require 40ml or less in fill volume for ideal fit and reduced leakage <sup>11</sup> Unique feature that allows for patient specific fill volume to reduce leakage risk <sup>11</sup>	Liquid stool in contact with skin is a major risk driver for pressure ulcers with each estimated to cost 40,000 USD <sup>8</sup>
<b>Self-closing catheter</b>	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 \$24,400.10 <sup>10</sup>
<b>Finger pocket</b>	Designed to provide confidence that balloon is placed correctly	Helps to apply the catheter faster which saves time and worries
<b>Soft balloon</b>	Designed to reduce cross contamination risk by avoiding splatter upon removal compared with competitor products <sup>9</sup>	Helps to reduce the risk of CDI with a mean cost per hospital stay in the USA of \$24,400.10 <sup>10</sup>
<b>Zeolite™ silicone catheter</b>	Improve patient and care giver experience by providing end-to-end odor protection	Increased quality of life by reducing odor in the treatment area
<b>Opaque Flexi-Seal™ Protect Plus Privacy™ collection bag including 4 ConvaTec Diamonds™ gelling and odor control sachets.</b>	Minimize spread of C. difficile spores by releasing air through the active charcoal filter. With 6x more odor-capturing compared to the charcoal filtered collection bags <sup>20</sup> . This filter also eliminates the need of manually releasing the excess gas from the collection bag <sup>21</sup> .	Helps to reduce the risk of CDI with a mean cost per hospital stay in the USA of \$24,400.10 <sup>10</sup>