

ConvaTec Announces U.S. FDA 510(k) Clearance and Launch of Flexi-Seal™ PROTECT Fecal Management System

- *Continued innovation for market-leading range of fecal management systems for critical care*
- *Designed to protect patients and clinicians against over-inflation risk, while helping to reduce risks of skin breakdown and spread of *C. difficile* infection associated with acute fecal incontinence*

READING, UNITED KINGDOM (2 May 2017) — ConvaTec Group Plc (“ConvaTec”), a leading global medical technology company, today announced the U.S. launch of the Flexi-Seal™ PROTECT Fecal Management System (FMS), following receipt of 510(k) clearance from the U.S. Food and Drug Administration (FDA).

Flexi-Seal™ PROTECT FMS is the latest addition to the company’s market-leading range of advanced systems developed to manage acute fecal incontinence, and help to reduce the associated risks of skin breakdown and spread of *C. difficile* infection. The new product is designed to provide protection for both patients and clinicians in a number of innovative ways:

- **Fill Protection** – the only system that senses when the retention balloon is correctly filled and visually indicates over-inflation.
- **Patient Protection** – the blue finger pocket allows easy and accurate placement of the soft silicone retention balloon.
- **Privacy and Odour Protection** – the privacy bag lets clinicians monitor volume without compromising patient privacy; and the odour barrier runs the full length of the catheter providing an end-to-end odour barrier.¹

Acute fecal incontinence is a significant issue for hospitals and presents numerous management challenges for clinicians and patients, including an increased risk of pressure injury (pressure ulcer) development as well as the risk of infection spread associated with *C. difficile*-related diarrhea.

ConvaTec developed Flexi-Seal™ PROTECT FMS to help clinicians address these many challenges. A temporary containment device indicated for incontinent patients with liquid or semi-liquid stool, Flexi-Seal™ PROTECT FMS is designed to effectively contain and divert fecal matter, and has been proven, *in vitro*, to contain *C. difficile* and its spread into the environment.² The easy-to-use system provides an excellent alternative to traditional methods of managing fecal incontinence such as pads, diapers, fecal pouches and rectal tubes.

“Flexi-Seal™ PROTECT FMS demonstrates our continuing commitment to innovation in critical care, responding to and addressing the needs of customers and patients,” said Mads Haugaard, Vice President and General Manager, Continence and Critical Care, ConvaTec. “Our goal is to help protect these critically ill patients by minimizing the risks of complications such as skin breakdown and infection spread as well as to help ensure its safe and effective use by the critical care team.”

The U.S. launch of Flexi-Seal™ PROTECT FMS follows the launch of ConvaTec’s Sensi-Care® Skin Protectant Incontinence Wipes last month, adding to the company’s comprehensive range of

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products to help healthcare professionals protect patients' skin and lessen associated risks such as pressure injury development and infection.

Flexi-Seal™ PROTECT FMS is an indwelling fecal management catheter intended for use to manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications. Following U.S. launch, Flexi-Seal™ PROTECT FMS will be rolled out in additional markets throughout 2017.

For more information, visit www.convatec.com or contact ConvaTec customer service at 1 (800) 422-8811.

About ConvaTec

ConvaTec is a global medical products and technologies company focused on therapies for the management of chronic conditions. The Company is listed on the London Stock Exchange (stock symbol: CTEC) and has leading market positions in advanced wound care, ostomy care, continence and critical care, and infusion devices. ConvaTec's products provide a range of clinical and economic benefits, including infection prevention, protection of at-risk skin, improved patient outcomes and reduced total cost of care. www.convatecgroup.com

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1. Odor Barrier Testing. 130124-001. Data on file, ConvaTec Inc.
2. 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.