Flexi-Seal™
SIGNAL™
FMS

A NEW SOLUTION FROM THE
FLEXI-SEAL™ FMS* FAMILY OF
FAECAL MANAGEMENT SYSTEMS

Seal Their Protection Through Innovation

Introducing NEW

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The seal of innovation™

ConvaTec

* Please see complete Instructions for Use in Package Insert.

The Challenge of Skin Breakdown

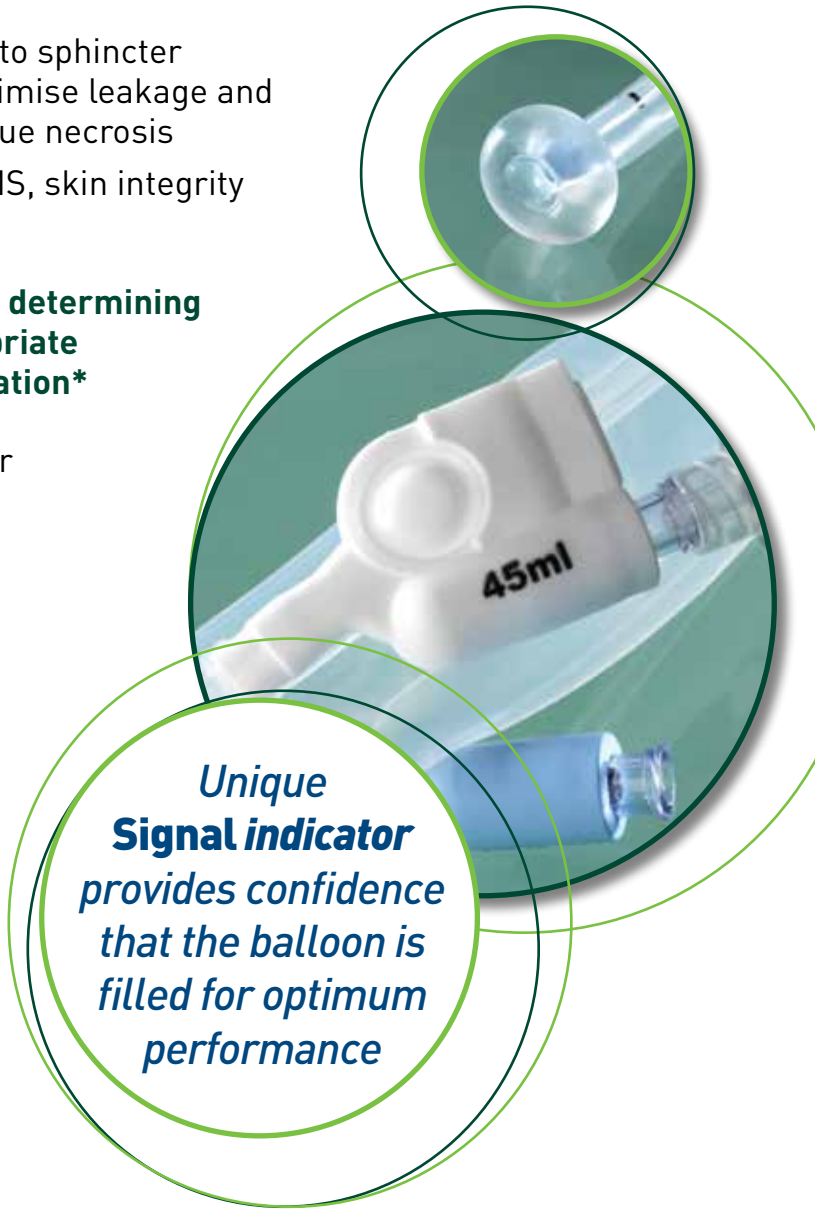
Perianal skin injury can occur within minutes of the onset of faecal incontinence[1]

- **Ulcers and anorectal mucositis** may develop with extended exposure to faeces
- These complications are painful for patients and frustrating for caregivers
- **Faecal incontinence** is a risk factor for pressure ulcer development[2]

Effective faecal containment has the ability to reduce the risk of skin complications.[3]

Flexi-Seal™ SIGNAL™ FMS: Designed to Help Reduce the Risk of Skin Breakdown

- **Soft, flexible retention balloon** conforms to sphincter anatomy to create an effective seal to minimise leakage and is designed to minimise the chance of tissue necrosis
  - In **92%** of patients using Flexi-Seal™ FMS, skin integrity was either maintained or improved[4]
- **Signal indicator pops to guide clinician in determining when retention balloon is filled to appropriate volume (up to 45 ml) to prevent over-inflation***
- Clinical observation has shown that proper inflation minimises the risk of leakage
  - **83%** of caregiver reports indicated minimal or no leakage[4]
  - For patients who had baseline and follow-up endoscopy, rectal mucosa was healthy after Flexi-Seal™ FMS use[4]



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*Signal indicator could pop before 45 ml if the space available for the balloon is smaller than the balloon. Filling should stop when the indicator pops out and stays out. Never add more than 45 ml total.

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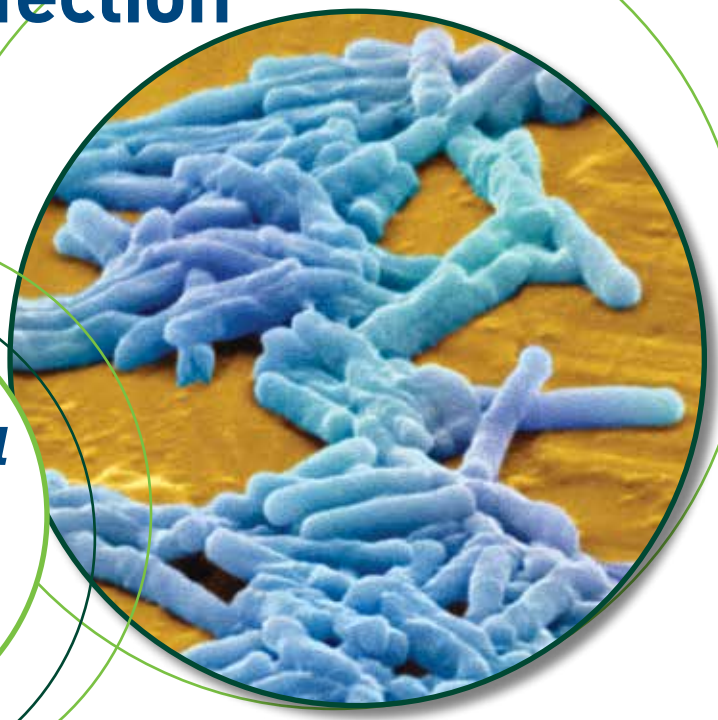
The Challenge of Infection



Infection control *is a priority for patients and caregivers*

- Faecal contamination can result in the spread of a dangerous **nosocomial infection (*C. difficile*)** that puts patients, caregivers, and staff at risk[5]
- Up to **20%** of hospitalised patients can become infected with *C. difficile*[5]
- *C. difficile* infection is associated with **severe diarrhoea**[6]

"Flexi-Seal™ SIGNAL™ FMS is recommended by the Rapid Review Panel (which assesses new and novel equipment , materials and other products that may be of value to the NHS in improving hospital infection control and reducing healthcare associated infections) as being a product where basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols"[7]

—HCAI Technology Innovation Programme
Report Number 5 - The Flexi-Seal Faecal Management System

Flexi-Seal™ SIGNAL™ FMS: Designed to Reduce the Risk of Spread of Infection

- In vitro results revealed that **Flexi-Seal™ FMS**[8]:
  - Effectively contained *C. difficile* and was not associated with environmental *C. difficile* contamination in the vicinity of the collection system
  - **Charcoal-filtered collection bags** provide an effective barrier to *C. difficile* and prevent its leakage and transmission into the wider environment[9]
- **Versatile strap** is designed to securely lock on to an open bed frame, helping to minimise the risk of contamination resulting from spillage

It is critical to contain the fundamental source of cross-contamination[8]

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The Challenges of Total Care Management

Faecal incontinence requires substantial nursing staff time[10]

Faecal incontinence

- Can cause **mental and physical discomfort** in patients
- **Increases total costs** associated with labor and materials[11,12]

"Better management of faecal incontinence can enhance patient comfort and dignity. It can also help reduce mortality and morbidity.

Reducing the number of C. difficile infections and skin problems associated with faecal incontinence, both of which are associated with increased length of stay, will reduce blocked beds which may in turn help with delivery of other trust targets, such as waiting times."[7]

- HCAI Technology Innovation Programme
Report Number 5 - Flexi-Seal Faecal Management System

Flexi-Seal™ SIGNAL™ FMS: Designed to Improve Patient Care and Comfort

Easy to Use

- **Blue finger pocket** is easy to locate and designed for simple single-finger insertion
- The only faecal management system that offers a **syringe precisely labeled to 45 ml** for enhanced ease of use

Patient friendly

- **Soft, flexible retention balloon** conforms to sphincter tone and anatomy for a contoured fit
  - — Single-finger insertion helps ensure proper placement
  - — Balloon-end tubing collapses to an 8mm diameter after deflation to minimise patient discomfort upon removal
- **State-of-the-art charcoal-filtered bags** are designed to contain and lock in odour to create a more pleasant environment for patients and clinicians

83% to 90%
of caregivers reported that Flexi-Seal™ FMS was caregiver and patient friendly, time efficient, and effective.[4]

Cost effective

- The annualised burden of faecal management was **45%** less with Flexi-Seal™ FMS compared with the cost of using traditional methods*[12]
  - — Cost savings largely due to 5,231 hours of reduction in nursing time[12]

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*Cost based on a budget impact model developed within a hospital intensive care unit. Two hundred twenty-three patients met the criteria for Flexi-Seal™ FMS placement during one year.[12]

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Flexi-Seal™ FMS: The Most Widely Used Faecal Management System[13]

Engineered by a company with a heritage of over 30 years experience in wound, ostomy and skin care.

Continuous innovations to Flexi-Seal™ SIGNAL™ FMS *address the needs of patients and caregivers*

Original innovative design *plus* unique Signal indicator

To learn more about the Flexi-Seal™ FMS family of solutions, including the benefits of new Flexi-Seal™ SIGNAL™ FMS, call:

1800 339 412 (Australia)

or **0800 441 763 (New Zealand)**

www.convatec.com

Ordering information

Flexi-Seal™ SIGNAL™ FMS	
Flexi-Seal™ SIGNAL™ FMS Kit* (1 kit/box)	418000
Flexi-Seal™ FMS Collection Bag (10/box)	411102

* Each kit comes with 3 collection bags.

References: 1. Faria DT, Shwayder T, Krull EA. Perineal skin injury: extrinsic environmental factors. *Ostomy Wound Management*. 1996 Aug;42(7):28-30, 32-34. **2.** Keller BP, Wille J, van Ramshorst B, van der Werken C. Pressure ulcers in intensive care patients: a review of risks and prevention. *Intensive Care Med*. 2002;28(10):1379-1388. Epub 2002 Sep 7. **3.** Clinical Evaluation of the Flexi-Seal® FMS Faecal Incontinence Management System. White Paper: Highlights of Clinical Study Data. ConvaTec CC: 0198-03-A695. August 2005. **4.** Padmanabhan A, Stern M, Wishin J, et al. Clinical evaluation of a flexible faecal incontinence management system. *Am J Crit Care*. 2007;16(4):384-393. **5.** Hurley BW, Nguyen CC. The spectrum of pseudomembranous enterocolitis and antibiotic-associated diarrhoea. *Arch Intern Med*. 2002;162(19):2177-2184. **6.** O'Brien JA, Lahue BJ, Caro JJ, Davidson DM. The emerging infectious challenge of *Clostridium difficile*-associated disease in Massachusetts hospitals: clinical and economic consequences. *Infect Control Hosp Epidemiol*. 2007:28(11):1219-1227. **7.** HCAI Technology Innovation Programme. Showcase Hospital Report number 5. The Flexi-Seal® Faecal Management System. 2009. http://www.clean-safe-care.nhs.uk/index.php?pid=84. (accessed 6.01.2010) **8.** Bowler P. *Clostridium difficile*-associated disease (CDAD) infection control and faecal management. Paper presented at: 3rd Annual World Union of Wound Healing Societies and European Wound Management Association Meeting; June 4-8, 2008; Toronto. **9.** Use of filtered faecal collection bags to contain *Clostridium difficile*: an *in vitro* study. WHRI 3274 MA138. September 25, 2009. Data on file, ConvaTec. **10.** ConvaTec Market Research Report: FMS—Knowledge, Attitudes and Practices Study. Data on file, ConvaTec. **11.** Health Industry Distributors Association: 2003 Long Term Care Report; CVT Market Research Report: FMS—Knowledge, Attitudes and Practices Study. Data on file, ConvaTec. **12.** Popovich-Durnal A, Kommala D, Chen Y. Budget impact of adopting a faecal management system in a hospital intensive care unit: a single center experience. Poster presented at 22nd Annual Symposium on Advanced Wound Care; September 16-18, 2009; Washington, DC. **13.** HPIS. Q2 2009. Moving Annual Total (MAT) Faecal Control Category. Data on file, ConvaTec.

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