

Flexi-Seal™
SIGNAL™
FMS

A LEADING-EDGE SOLUTION FROM THE FLEXI-SEAL™ FMS FAMILY
OF FAECAL MANAGEMENT SYSTEMS

It can hit any hospital.



Flexi-Seal SIGNAL
The seal of innovation™

Contain *C. difficile* before it strikes.



Flexi-Seal™ SIGNAL™ FMS is a
closed system that minimizes exposure
to potentially infectious waste.



In-vitro studies demonstrate that Flexi-Seal™ FMS effectively contains and prevents *C.difficile* from spreading into the environment^{1,2}

Key points:

- Increase in incidence of *C. difficile* and its ability to spread within the healthcare environment highlight the need for more effective measures of bacterial control.
- Flexi-Seal™ FMS has been proven *in-vitro* to contain and prevent the transmission of *C. difficile* into the surrounding environment.
- Flexi-Seal™ FMS may be considered as part of an infection control protocol in the management of patients with *C. difficile* infection.

Method:

Study 1: *In-vitro* assessment of five Flexi-Seal™ FMS devices challenged with a *C. difficile* inoculated medium over 31 days. The device is not intended for use for more than 29 consecutive days.³

A standard, disposable, flat, absorbent underpad, was used as a comparison.

Study 2: *In-vitro* assessment of four Flexi-Seal™ SIGNAL™ FMS devices with charcoal filtered collection bags challenged with *C. difficile* inoculated medium over 11 days.

2 charcoal-filtered collection bags were tested (1.5 and 3 µm pore size)

In both studies:

- Throughout the test period, swab samples were taken daily at various points along the devices.
- Settle plates in the environment were used to assess environmental spread of bacteria.
- A positive control device with pinholes in the catheter and collection bag was used.

Results:

- *C. difficile* was not recovered from any of the test swabs or air samples taken from or around the intact Flexi-Seal™ FMS devices and collection bags. This indicates that the devices and filtered collection bags are capable of effectively containing *C. difficile*.
- *C. difficile* was recovered from many of the test swabs and air samples taken from or around the positive control device. This indicates that the test was capable of detecting *C. difficile*.
- Lateral spread of *C. difficile* was observed along the inner challenged side of the underpad. This suggests that in clinical practice, a soiled underpad may act as a reservoir for *C. difficile* and contaminate bed linen, etc., facilitating the spread of the organism.



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References: **1.** Containment of *Clostridium difficile* by the Flexi-Seal® Fecal Management System: an In Vitro Study. WHR13107 MA106. May 8 2008. Data on file, ConvaTec. **2.** Use of Filtered Fecal Collection Bags to Contain *Clostridium difficile*: an In vitro Study. WHR13274 MA138. 25 September 2009. Data on file, ConvaTec. **3.** Flexi-Seal™ SIGNAL™ FMS Directions for Use, ConvaTec.