

Demonstrated Clinical Safety

I like to make informed decisions based on clinical evidence. The findings of a published clinical study demonstrate that Flexi-Seal[®] FMS provides a safe and effective solution for the management of fecal incontinence.¹

- Safety: Rectal mucosa was healthy after Flexi-Seal[®] FMS use for patients who had baseline and follow-up endoscopy.¹
- Leakage: 83% of caregiver reports indicated minimal or no leakage.¹
- Skin Integrity: Skin integrity was either maintained or improved in 92% of patients during use of Flexi-Seal[®] FMS.¹
- **Ease of Use:** 83-90% of caregiver reports indicated that Flexi-Seal[®] FMS was practical, caregiver- and patient-friendly, time efficient, and efficacious.¹

C. difficile Containment

Infection control is a priority in our facility. Patients infected with C. difficile often develop diarrhea. It is critical to contain the fundamental source of cross-contamination. The ConvaTec in vitro data demonstrate that the Flexi-Seal[®] FMS device can effectively contain C. difficile.⁵

According to the APIC's recently published Guide to the Elimination of *C. difficile*:⁶

"Use of a fecal management system that serves to minimize environmental and hand contamination may have a role in preventing transmission of *C. difficile* in healthcare settings."⁶

ConvaTec in vitro study found:5

- Flexi-Seal[®] FMS effectively contained *C. difficile*.
- Flexi-Seal[®] FMS was not associated with environmental contamination with C. difficile in the vicinity of the collection system.
- There was no evidence of transmission of *C. difficile* through the Flexi-Seal[®] FMS device, nor was spore contamination detected in the vicinity of the four devices tested, as monitored by environmental settle plates and air counting techniques.

Reference: 1. Padmanabhan A, Stern M, Wishin J, Mangino M, Richey K, DeSane M. Clinical evaluation of a flexible fecal incontinence management system. *Am J Crit Care.* 2007;16(4):384-393.
2. HPIS. Q1 2008 data. Moving Annual Total (MAT) Fecal Control Category. Data on file, ConvaTec.
3. Cognos. Redistributed YTD Sales through August 2008. Data on file, ConvaTec.
4. Odor reduction in fecal management devices. White Paper. September 3, 2008. Data on file, ConvaTec.
5. Bowler, P. *Clostridium difficile*-associated disease (CDAD) infection control and fecal management. Paper presented at: 3rd Annual World Union of Wound Healing Societies and European Wound Management Association Meeting; June 4-8, 2008; Toronto.
6. Guide to the Elimination of *Clostridium difficile* in Healthcare Settings. Association for Professionals in Infection Control and Epidemiology (APIC). 2008.

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Healthy Rectal Mucosa





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Why I Choose Flexi-Seal[®] FMS

- Clinical Safety Data¹
- Ease of Use
- Dedicated Support
- Continuous Innovation



Why I choose Flexi-Seal[®] FMS

Leadership ------

Flexi-Seal® FMS is the most widely used Fecal Management System.² The device can help dramatically improve patient care, save nursing time and make our nurses' jobs easier and more rewarding.

- The No. 1 brand.²
- Used at over 1800 ICU hospitals.³
- Approximately 500,000 patients have benefited from this device.³



Trusted Expertise

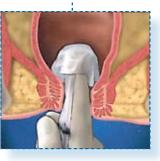
ConvaTec understands my patients' needs and continues to provide me with solutions. I know Flexi-Seal® FMS is a trusted device supported by clinical evidence.1

- They have over 30 years of experience in wound, ostomy and skin care.
- They listen and provide innovations based on my input.
- ConvaTec has experienced clinical experts to provide consulting on products and services.
- Flexi-Seal[®] FMS is supported by clinical evidence.¹
- I trust ConvaTec people and value their commitment to provide quality products and customized services to meet our needs.

Ease of Use ------

Flexi-Seal[®] FMS is very easy to learn and use – that is vital for my nurses. It has some unique features that make our jobs easier.

- Unique finger pocket, designed for easy insertion.
- Simple to attach and detach collection bag; no need for burping with the new charcoal filter.
- Device removal is fast, easy and comfortable.
- Minimal maintenance required.



Patient Comfort ------

Maintaining my patients' dignity and keeping them comfortable is very important to me.

- "One finger" insertion helps ensure patient comfort and proper placement.
- Soft, flexible retention balloon conforms to sphincter anatomy to create an effective seal to minimize leakage.
- Balloon-end tubing collapses to a very small diameter (8mm), making device removal easier and more comfortable.

Support -----

I really appreciate the on-going support ConvaTec offers...it's so valuable to me and my staff. I don't know if other companies would provide this.

- Dedicated clinical in-services provided by registered nurses.
- Continuing education, speaker program events, bedside tips, guidelines, DVDs and other support programs.

Continuous Innovation

I like the product improvements and new solutions ConvaTec provides.

- Precisely labeled syringe to 45 cc.
- Color coded irrigation port for easy identification.

The most recent innovation is Flexi-Seal® FMS Advanced Odor Control, which is designed to help manage odor for patients experiencing increased levels of odor.

- Silicone catheter has a new nylon inner barrier that HOLDS the odor molecules within the catheter to block odor from escaping.⁴
- New collection bag has a charcoal filter to deodorize gas as it is released and reduce ballooning.





