

ConvaTec & You

Working Together to Improve Fecal Incontinence Management

© 2007 E.R. Squibb & Sons, L.L.C.
US-07-492



[Text on slide.]

Fecal Incontinence

A Serious Problem

- **Managing incontinent patients demands considerable nursing time**
- **Wounds can become contaminated**
- **Increases risk for spread of infection**
- **According to a study published in *JAMA*, patients with hospital-acquired infections:**
 - Increase their stay by nearly 10 days¹
 - Incur more than \$38,000 in excess charges¹

¹Zhan C, Miller M. *The Journal of American Medical Association*. 2003 Oct; 290:1868-1874.



[The slide should be presented as scripted.]

Full JAMA reference: Zhan C, Miller M. Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization. *The Journal of the American Medical Association*, Oct 8, 2003; volume 290(14); pages 1868-1874

Flexi-Seal® Fecal Management System *A Serious Solution*

- **Flexi-Seal® FMS is designed to improve fecal management of incontinent patients with liquid or semi-liquid stool by:**
 - Helping to reduce the risk of skin breakdown...
 - Helping to reduce the risk of infection...
 - Helping to protect wounds from contamination...
 - Helping to reduce cost of managing fecal incontinence...
 - Helping to improve patient comfort & patient dignity ...

Flexi-Seal is a registered trademark of E.R. Squibb & Sons, L.L.C.

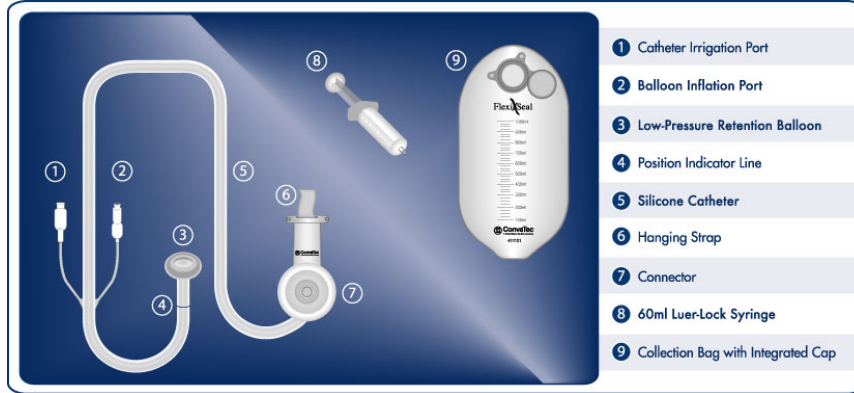


Stress that Flexi-Seal® FMS is indicated for only semi-liquid to liquid stool.

Flexi-Seal® Fecal Management System

Product Overview

The Flexi-Seal® FMS kit consists of:

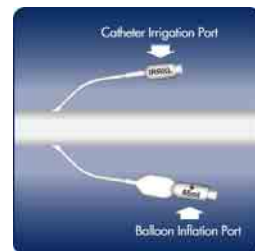


Slide is self explanatory. Catheter and collection bag details are on the next two pages.

Flexi-Seal® Fecal Management System

Catheter Details

- Molded to shape silicone retention balloon
- Thin silicone collapsible wall cannula
- Insertion pocket under the balloon
- Irrigation line to rinse system
- Luer lock valves on both inflation and irrigation lines
- Strap for convenient hanging at bedside



 **ConvaTec**
A Bristol-Myers Squibb Company

Text on slide.

Key points:

Catheter is 22mm in diameter. It is capable of “collapsing” to 8mm in diameter. Thus, it conforms to the sphincter anatomy to help preserve sphincter tone and function. The soft, low pressure balloon is filled with water or saline and gently conforms to the rectal vault, helping to reduce the risk of necrosis. System is completely latex free.

Flexi-Seal® Fecal Management System Collection System

- Waste is collected in a disposable bag at the bedside end of the catheter
- The bag snaps on with a watertight flange coupling
- A sealing cap is attached to the bag flange
- The bag has a clear side with gradations
- The bag is constructed by normal ostomy pouch processes



 **ConvaTec**
A Bristol-Myers Squibb Company

Key Points: Closed-end collection bag eliminates contact with feces to help prevent spread of infection.

The collection bags can hold up to 1 liter of feces.

Flexi-Seal® Fecal Management System

ICU Nurse Response¹

- **Flexi-Seal® FMS was concept tested among:**
 - 257 ICU nurses / nurse managers via an internet study
 - 30 materials managers via phone survey
- **Product concept was favorable with study participants**

¹Fecal Incontinence Management System Forecasting Study. Synovate Healthcare, 2004.



Flexi-Seal® FMS was evaluated through a 42 patient clinical trial across 7 study sites. The objective of the clinical trial was to evaluate the safety and performance of FMS in subjects with diarrhea and incontinence.

The mean age of subjects at baseline was 60.7 years.

Most subjects (61.9%) were female.

The study initially enrolled patients only from the ICU; the protocol was later modified to allow enrollment of subjects from non-ICU inpatient, acute-care, hospitalized settings. Consequently, most patients (79%) were from ICU settings.

Additional information that can be shared:

Many subjects had altered mental and physical status at baseline:

Only 40.5% of subjects were alert and responsive; and

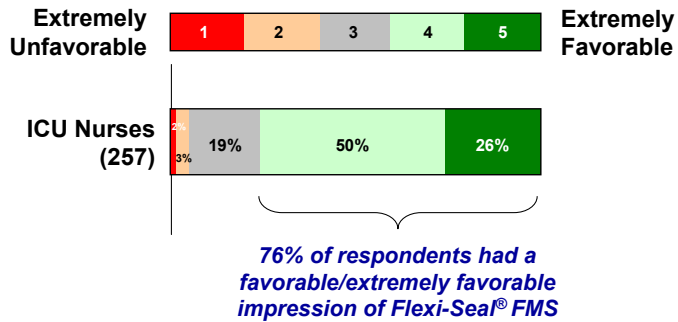
Only 54.8% of subjects were responsive to touch.

Flexi-Seal® Fecal Management System

ICU Nurse Response¹

Customer's Overall Impression

This product concept was viewed favorably by ICU Nurses



¹Fecal Incontinence Management System Forecasting Study. Synovate Healthcare, 2004.

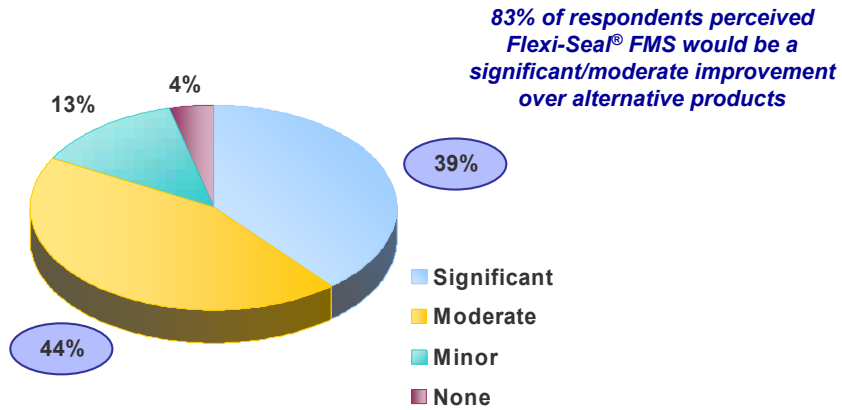


Text on slides.

REFERENCES: Synovate Study 2004

Flexi-Seal® Fecal Management System ICU Nurse Response¹

Perceived Improvement vs. Alternatives



¹Fecal Incontinence Management System Forecasting Study. Synovate Healthcare, 2004.

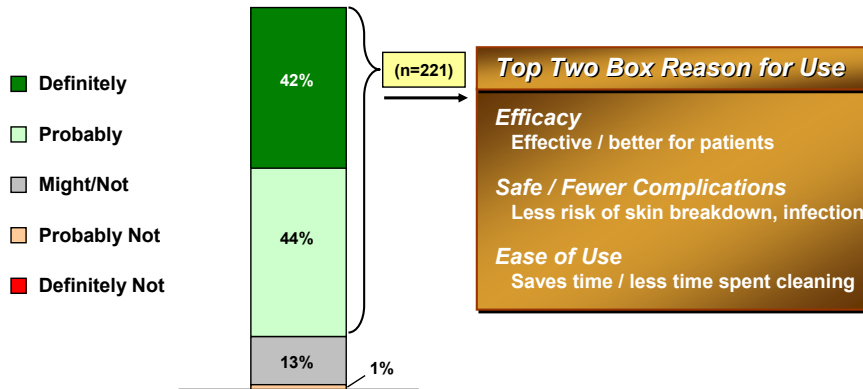


83% of respondents perceived Flexi-Seal® FMS as a significant/moderate improvement over alternative products

REFERENCES: Synovate Study 2004

Flexi-Seal® Fecal Management System ICU Nurse Response¹

Likelihood to Use



¹Fecal Incontinence Management System Forecasting Study. Synovate Healthcare, 2004.



REFERENCES: Synovate Study 2004

Flexi-Seal® Fecal Management System

Clinical Evaluation¹

- **Objective:**
 - To evaluate the safety and performance of the Flexi-Seal® Fecal Management System in subjects with diarrhea and incontinence
- **Study Details**
 - 42 patients across 7 study sites
 - Mean age: 61 years
 - 16 males, 26 females
 - 33 ICU patients, 9 non-ICU patients

¹Clinical Evaluation of The Flexi-Seal® FMS Incontinence Management System. ConvaTec CC:0198-03-A695. Highlights of clinical study data. August 2005. Data on File, ConvaTec.



Flexi-Seal® FMS was evaluated through a 42 patient clinical trial across 7 study sites. The objective of the clinical trial was to evaluate the safety and performance of FMS in subjects with diarrhea and incontinence.

The mean age of subjects at baseline was 60.7 years.

Most subjects (61.9%) were female.

The study initially enrolled patients only from the ICU; the protocol was later modified to allow enrollment of subjects from non-ICU inpatient, acute-care, hospitalized settings. Consequently, most patients (79%) were from ICU settings.

Additional information that can be shared:

Many subjects had altered mental and physical status at baseline:

Only 40.5% of subjects were alert and responsive; and

Only 54.8% of subjects were responsive to touch.

Flexi-Seal® Fecal Management System

Clinical Evaluation: Study Design¹

- Baseline**
- Digital rectal exam (all subjects) and disimpaction (as required)
 - Baseline endoscopic proctoscopy (initial 10 subjects)
 - Insertion of device

- Daily assessments**
- Reports of adverse events
 - Investigator assessment of use and performance
 - Caregiver (nurse) assessment of ease of use and performance

- Final assessments**
- Device removal (within 29 days)
 - Final endoscopic proctoscopy (initial 10 subjects)

¹Clinical Evaluation of The Flexi-Seal® FMS Incontinence Management System. ConvaTec CC:0198-03-A695. Highlights of clinical study data. August 2005. Data on File, ConvaTec.



A digital rectal exam was performed to determine the absence of fecal impaction.

If fecal impaction was detected, disimpaction occurred and enrollment into the study continued at the discretion of the investigator.

Baseline (and final) endoscopic proctoscopy was to be performed in the first 10 enrolled subjects; thereafter, safety was to be monitored without endoscopic proctoscopy by the nature and number of adverse events.

Once the device was inserted, the study coordinator and primary investigator assured all direct caregivers for the subject had been adequately instructed on management of the device.

A daily diary was maintained to record relevant information for each study subject. The study coordinator and/or investigator made daily visits to review the Daily Device Assessment Diary and discussed any concerns with caregivers.

Each subject could remain in the study for a maximum of 29 days or until the device was no longer clinically indicated, whichever came first.

Flexi-Seal® Fecal Management System

Clinical Evaluation Results: Endoscopic Proctoscopy¹

- 11 subjects had baseline proctoscopy



Baseline
(Before Flexi-Seal® FMS)

Results from
Subject #2



Final Visit
(After Flexi-Seal® FMS)

- Flexi-Seal® Fecal Management System did not cause necrosis or other mucosal abnormalities

¹Clinical Evaluation of The Flexi-Seal® FMS Incontinence Management System. ConvaTec CC:0198-03-A695. Highlights of clinical study data. August 2005. Data on File, ConvaTec.



Endoscopic proctoscopy performed in this study showed that the use of Flexi-Seal® did not cause necrosis or other mucosal abnormalities.

Eleven subjects had endoscopic proctoscopy at baseline; 10 were required to have baseline proctoscopy per protocol, and the 11th subject underwent proctoscopy (per protocol) before the requirement was discontinued according to a protocol amendment.

Final proctoscopy was available for 8 of these subjects—the final assessment indicated healthy mucosa in each subject; and

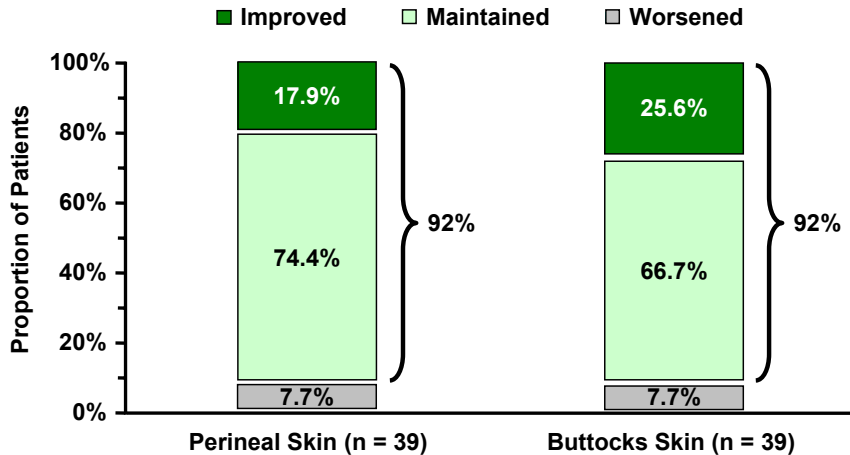
Three subjects did not have final proctoscopy performed; 2 died and 1 had endoscopy deferred due to the patient's status at the end of study.

One additional subject had a post-device endoscopy for evaluation of a gastrointestinal bleed (see “Adverse Events” on Slide 15), but per protocol did not have a pre-device endoscopy.

Flexi-Seal® Fecal Management System

Clinical Evaluation Results: Skin Condition Changes¹

- Skin condition was maintained or improved in 92% of subjects³



¹Clinical Evaluation of The Flexi-Seal® FMS Incontinence Management System. ConvaTec CC:0198-03-A695. Highlights of clinical study data. August 2005. Data on File, ConvaTec.



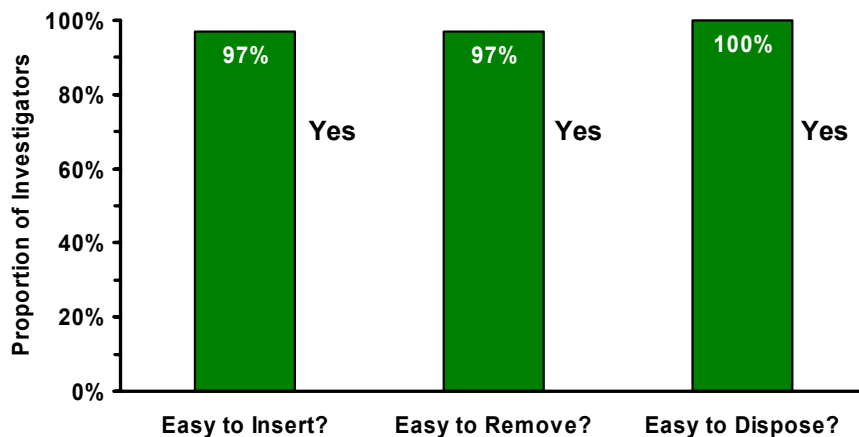
Skin condition at the final visit (normal skin, patchy redness, extensive redness without breakdown, red blistering without open areas, or redness with open areas) was compared to the skin condition at baseline for each subject to determine whether skin condition had improved, worsened, or been maintained.

By the final visit, skin condition was maintained or improved in 92% of subjects at the buttocks and perineal area in this setting of diarrhea and incontinence.

Flexi-Seal® Fecal Management System

Clinical Evaluation Results: Investigator Ratings Ease-of-Use¹

- Flexi-Seal® FMS was highly favorable with investigators³



¹Clinical Evaluation of The Flexi-Seal® FMS Incontinence Management System. ConvaTec CC:0198-03-A695. Highlights of clinical study data. August 2005. Data on File, ConvaTec.



Investigators were asked to answer yes or no to questions about ease of insertion at baseline and ease of removal and disposal at the final visit.

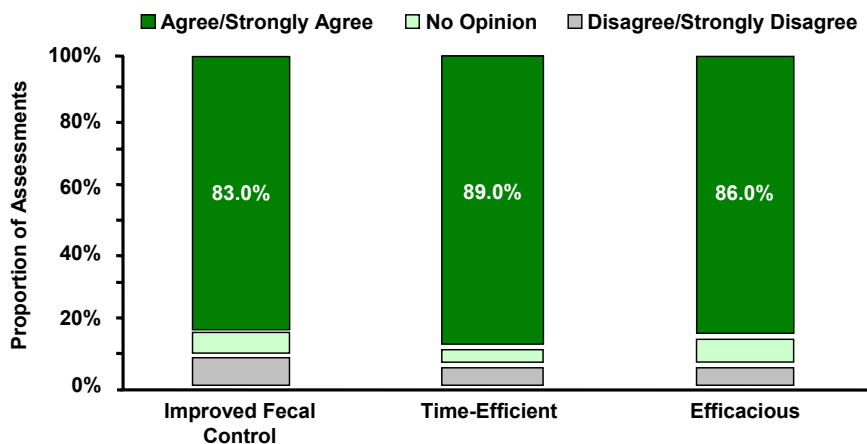
Investigators considered 37 of 38 insertions (97%) at the first visit and 34 of 35 removals (97%) at the final visit to be easy.

All of the devices were considered easy to dispose.

Flexi-Seal® Fecal Management System

Clinical Evaluation Results: Caregiver Reports of Effectiveness¹

- Caregivers rated Flexi-Seal® FMS strong on effectiveness measures³



- Based on caregiver responses for 200 daily assessments

¹Clinical Evaluation of The Flexi-Seal® FMS Incontinence Management System. ConvaTec CC:0198-03-A695. Highlights of clinical study data. August 2005. Data on File, ConvaTec.



Caregivers rates Flexi-Seal® FMS strong on effectiveness measures

Of the 200 caregiver responses recorded at daily assessments:

83.0% agreed that the device improved fecal incontinence control;

89.0% agreed that use of the device was time-efficient; and

86.0% agreed that the device was efficacious.

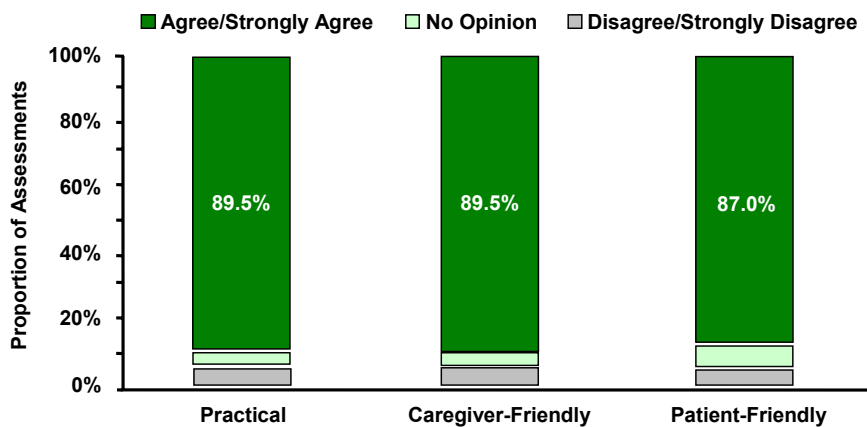
Complete responses were as follows:

	N = 200 n (%)				
	Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
Improved Fecal Control	82 (41.0)	84 (42.0)	15 (7.5)	12 (6.0)	7 (3.5)
Time-Efficient	112 (56.0)	66 (33.0)	10 (5.0)	6 (3.0)	6 (3.0)
Efficacious	84 (42.0)	88 (44.0)	15 (7.5)	8 (4.0)	5 (2.5)

Flexi-Seal® Fecal Management System

Clinical Evaluation Results: Caregiver Reports of Ease-of-Use¹

- Caregivers considered Flexi-Seal® FMS to be easy-to-use³



- Based on caregiver responses for 200 daily assessments

¹Clinical Evaluation of The Flexi-Seal® FMS Incontinence Management System. ConvaTec CC:0198-03-A695. Highlights of clinical study data. August 2005. Data on File, ConvaTec.



Caregivers considered Flexi-Seal® FMS to be easy to use.

Of the 200 caregiver responses recorded at daily assessments:

89.5% agreed that the device was practical;

89.5% agreed that the device was caregiver-friendly; and

87.0% agreed that the device was patient-friendly.

Complete responses were as follows:

	N = 200 n (%)				
	Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
Practical	84 (42.0)	95 (47.5)	9 (4.5)	7 (3.5)	5 (2.5)
Caregiver-friendly	94 (47.0)	85 (42.5)	9 (4.5)	7 (3.5)	5 (2.5)
Patient-Friendly	75 (37.5)	99 (49.5)	15 (7.5)	6 (3.0)	5 (2.5)

Flexi-Seal® Fecal Management System

Clinical Evaluation: Conclusions¹

- **In this clinical study of hospitalized subjects with diarrhea and incontinence:**
 - Flexi-Seal® FMS had an overall favorable safety profile
 - Maintained or improved skin condition was observed in 92% of subjects
 - Flexi-Seal® FMS was efficacious and time-efficient for fecal management
 - Flexi-Seal® FMS was easy-to-use and practical
 - Minimal or no leakage was observed in 82% of assessments

¹Clinical Evaluation of The Flexi-Seal® FMS Incontinence Management System. ConvaTec CC:0198-03-A695. Highlights of clinical study data. August 2005. Data on File, ConvaTec.



In this clinical study of hospitalized subjects with diarrhea (most of whom had multiple diagnoses and required intensive care), Flexi-Seal® Fecal Management System:

Flexi-Seal® generally was well-tolerated;

Maintained or improved skin condition was observed in 92% of subjects;

Caregivers reported that Flexi-Seal® was efficacious and time-efficient for fecal management;

Caregivers reported that Flexi-Seal® was easy-to-use and practical; and

Minimal or no leakage was observed in 82% of assessments.

Flexi-Seal® Fecal Management System *In-Market Success*

- **Sales Performance:**
 - 2006 Growth compared with prior year period is over 150% through September
- **GPO Acceptance (Hospital Based):**
 - Favorable Position on Key Contracts
- **Top Healthcare Organization Acceptance¹:**
 - 12 out of 14 top hospitals, as rated by *U.S. News & World Report*, purchase Flexi-Seal® FMS

¹<http://www.usnews.com/usnews/health/best-hospitals/honorroll.htm> (accessed October 30, 2006)



Proposition Validation plus a favorable Clinical Evaluation equals strong In-Market Success

Sales Performance:

2006 Growth is over 150% through September

GPO Acceptance (Hospital Based):

Strong Position on Key Contracts

Currently on all but one major GPO contract (Premier) – Accommodation pricing exists for Premier customers.

Top Healthcare Organization Acceptance:

12 out of Top 14 *U.S. News & World Reports* stock Flexi-Seal® FMS¹

FlexiSeal™

FMS

**Dramatically Advancing
Fecal Incontinence Management**

Flexi-Seal is a registered trademark of E.R. Squibb & Sons. All other trademarks are the property of their respective owners.

© 2007 E.R. Squibb & Sons, L.L.C.
US-07-492

 **ConvaTec**
A Bristol-Myers Squibb Company