Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 7, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: ConvaTec - RECALL [Medical Device]

AFFECTED PRODUCT: **Flexi-Seal™ CONTROL Fecal Management System (FMS)**

SUMMARY: **Class I Recall; The recall is due to inconsistent performance of the Auto-Valve feature that may result in the following failure modes of the device which may result in health hazards including death:**

- **Auto-Valve fails to limit inflation to 45mL**
- **Balloon is unable to be inflated fully**
- **Balloon is unable to be deflated fully**
- **Auto-Valve leaks at Inflation Port**

Flexi-Seal CONTROL FMS (Model Number: ICC 411107, SAP codes: 1704335 for U.S. Products).

The product has been distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Customers with questions regarding the recall should contact the ConvaTec customer service center at 1-800-422-8811 (Monday-Friday, 8:30am – 7:00pm EST).**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

FDA Classifies ConvaTec's Voluntary Global Recall of Flexi-Seal™ CONTROL Fecal Management System (FMS) as Class I

Contact:
Consumer:
1-800-422-8811

Media:
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FOR IMMEDIATE RELEASE - July 3, 2014 - ConvaTec has announced that the U.S. Food and Drug Administration (FDA) has classified the company's recently initiated voluntary global recall of Flexi-Seal™ CONTROL Fecal Management System (FMS) as a Class I recall.

The FDA defines a Class I recall as a situation in which there is a reasonable probability that use of, or exposure to, a violative product will cause serious adverse health consequences or death.

ConvaTec began notifying customers in late April that all lots of Flexi-Seal CONTROL FMS (Model Number: ICC 411107, SAP codes: 1704335 for U.S. Products) were being urgently recalled. The notification requested that all lots be quarantined immediately and returned to the company as soon as possible. ConvaTec also notified regulatory agencies in all countries where product was distributed.

Flexi-Seal CONTROL FMS is a temporary containment device used for the management of acute fecal incontinence in patients who are often immobilized and critically ill and have little or no bowel control and liquid or semi-liquid stool.

In the U.S., the decision to voluntarily recall was made following the determination that Flexi-Seal CONTROL FMS should have a 510(k) clearance, rather than the use of the current Note to File that was based on existing 510(k) clearance for other Flexi-Seal products.

The company received reports from U.S. healthcare facilities of 13 adverse events, including twelve serious injuries and one death for the period February 2013 through March 2014. A causal link has not been established for all reported events.

The company also conducted an analysis following reports that the Auto-Valve feature that is unique to Flexi-Seal CONTROL FMS had not been consistently performing relative to the inflation and deflation of the device's retention balloon.

Inconsistent performance of the Auto-Valve feature may result in the following failure modes of the device:

- Auto-Valve fails to limit inflation to 45mL
- Balloon is unable to be inflated fully
- Balloon is unable to be deflated fully
- Auto-Valve leaks at Inflation Port

These failure modes may result in the following health hazards:

- Rectal damage (necrosis/ perforation/ulceration or bleeding)
- Expulsion of the device and/or leakage
- Fecal soiling of bed linen/incontinence pads leading to skin deterioration around the anus, peeling skin, and raw, irritated lesions due to skin contact with fecal matter

In addition to the above adverse health consequences, death may also occur.

For these reasons and to address any potential risk of harm, ConvaTec voluntarily initiated a global recall of all Flexi-Seal CONTROL FMS kits.

The recall does not affect any of the other Flexi-Seal products or Flexi-Seal Privacy Collection Bags, which are sold separately.

Customers with questions regarding the recall should contact the ConvaTec customer service center at 1-800-422-8811 (Monday-Friday, 8:30am – 7:00pm EST).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

About ConvaTec
ConvaTec is a global medical products and technologies company, with leading market positions in ostomy care, wound therapeutics, continence and critical care, and infusion devices. Our 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. ConvaTec has over 8,000 employees, with 11 manufacturing sites in 8 countries, and we do business in more than 100 countries. We are owned by Nordic Capital and Avista Capital Partners. More information is available at www.convatec.com.

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