

U.S. Food and Drug Administration
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Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Sage Products Expands Voluntary Nationwide Recall of Comfort Shield Barrier Cream Cloths Due to Microbial Contamination

For Immediate Release

August 12, 2016

Contact

Consumers

Sage Products Customer Service
☎1-800-421-6556

Media

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Announcement

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Cary, IL, Sage Products announced today it is expanding its voluntary nationwide recall to include an additional lot of Comfort Shield Barrier Cream Cloths at the distributor and healthcare facility/user level. The recall is being initiated due to product contamination with the bacteria, *Burkholderia cepacia*.

Topical administration of a product with *B. cepacia* may cause serious infections in patients whose bodies cannot fight disease or in hospitalized patients, as well as certain other patient groups. These infections could be life-threatening. To date, no adverse events have been reported associated with the recalled products, which were distributed to distributors and healthcare facilities in the United States. The product, Comfort Shield Barrier Cream Cloths is a non-sterile, topical skin protectant used to treat and prevent moisture associated skin irritation caused by urine and/or stool exposure. The package contains single-use, disposable cloths. This recall affects the following lots of Comfort Shield Barrier Cream Cloths:

Product Code	NDC Number	Lot Number	Expiration Date
7503	53462-915-50	53957	3/6/2018
7905	53462-915-80	55781	6/19/2018

Sage Products notified its distributors and healthcare facilities by letter, and they were provided instructions to discontinue use and return product to Sage Products. The affected lots were distributed to customers between March 31 - June 8, 2016 and July 18 - July 19, 2016.

Customers who received affected products should discontinue use of the affected products and return them to Sage Products for credit by contacting Sage Products customer service at 1-800-421-6556, Monday through Friday, between the hours of 8:00 a.m. to 5:00 p.m., Central Time.

Customers with questions regarding this recall, or requiring replacement product, can call Sage Products customer service at 1-800-421-6556, Monday through Friday, between the hours of 8:00 a.m. to 5:00 p.m., Central Time. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Any 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 (<http://www.fda.gov/MedWatch/report.htm>)
- Regular mail or fax: download form www.fda.gov/MedWatch/getforms.htm (<http://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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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About Sage Products

Since 1971, Sage Products has successfully developed and produced innovative prevention products that have significantly improved outcomes for patients and clinicians, while improving efficiency and profitability for healthcare facilities. In 2016, Sage was acquired by Stryker Corporation and is a business within the Stryker Medical Division.



Sage is a leading developer of products used to prevent hospital-acquired conditions such as skin injury due to incontinence, pressure ulcers, surgical site infections and healthcare worker injury. To learn more, visit

[www.sageproducts.com \(http://www.sageproducts.com/\)](http://www.sageproducts.com/)

[Original Release \(/Safety/Recalls/ucm514358.htm\)](/Safety/Recalls/ucm514358.htm)

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