



SAGE PRODUCTS LLC
3909 Three Oaks Road • Cary, Illinois 60013
sageproducts.com • shopsageproducts.com
800-323-2220 • 815-455-4700

August 23, 2016

ATTENTION:

EU Sage Distributor/Partner/Customer

URGENT FIELD SAFETY NOTICE

Comfort Shield® Barrier Cream Cloths

FSCA Identifier: 20160823

Type of Action: FSCA Return of Medical Device

DESCRIPTION OF THE PROBLEM:

This Field Safety Notice (FSN) is to inform you of a voluntary worldwide product recall involving specific lots of Comfort Shield Barrier Cream Cloths. The recalled products were distributed between August 2014 and August 2016. This FSN is being initiated due to potential product contamination with *Burkholderia cepacia*. See identified lots below.

Product Code	Lot Number	Expiration Date
7526-X	50694	Feb 2, 2017
7526-X	51089	Feb 25, 2017
7526-X	52427	May 23, 2017
7526-X	53031	Jul 11, 2017
7526-X	54330	Sept 27, 2017
7526-X	56130	Jan 10, 2018
7453-X	45601	Aug 31, 2016
7453-X	46142	Oct 4, 2016
7453-X	46160	Oct 5, 2016
7453-X	46684	Nov 8, 2016
7453-X	47716	Jan 27, 2017
7453-X	49857	Jun 7, 2017
7453-X	50613	Jul 29, 2017
7453-X	51417	Sept 17, 2017
7453-X	52297	Nov 12, 2017
7453-X	52947	Jan 3, 2018
7453-X	54774	Apr 24, 2018



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Product Code	Lot Number	Expiration Date
7905-X	45602	Aug 31, 2016
7905-X	46393	Oct 20, 2016
7905-X	47086	Dec 6, 2016
7905-X	47305	Dec 18, 2016
7905-X	47656	Jan 24, 2017
7905-X	48872	Apr 6, 2017
7905-X	50766	Aug 6, 2017
7905-X	50888	Aug 13, 2017
7905-X	52186	Nov 7, 2017
7905-X	52236	Nov 9, 2017

Shield Barrier Cream Cloths are applied to the perineal skin to remove urine and/or stool in order to treat and prevent incontinence-associated dermatitis. Topical administration of a product with bacterial contamination may cause infections in immunocompromised persons and in hospitalized patients, as well as certain other patient groups.

ACTIONS TO BE TAKEN BY THE DISTRIBUTOR/PARTNER/CUSTOMER:

If you have any of the above listed products, please do not use or distribute. Please ensure that this notice will be given to all those who need to be aware of it within your organization and/or other organizations you may have given this product to.

1. Check your inventory for the affected lot numbers. Lot numbers are located on the outside of the product case (over shipper). Discontinue use and/or further distribution of the affected lots. Quarantine all identified lots.
2. If you are a distributor and have distributed this product to facilities or consumers, please initiate your sub-recall process down to the facility or consumer level.
3. If you are a healthcare facility, stop use of the affected lots of product immediately.
4. Please complete the Field Safety Notice (FSN) Acknowledgment Response and return it to Sage Products no later than September 19, 2016. This form must be completed even if you do not have any of the affected product.
5. After the FSN Acknowledgment Response form is received by Sage, you will be contacted regarding how to proceed with the return/destruction of the identified lots.

Please maintain awareness of this Notice and resulting action for an appropriate period of time to ensure effectiveness of the corrective action.



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CONTACT INFORMATION:

The affected product returned will be credited or replaced by Sage Products. Contact Sage Products customer service at +1 847.516.7600, Monday through Friday, between the hours of 8:00 am and 5:00 pm CDT.

Sage Products LLC
Attn: Customer Service Department – Recall International
3909 Three Oaks Road
Cary, IL 60013

+1 847.516.7600 phone

+1 224.387.2125 fax

Email: Recall.international@sageproducts.com

All relevant National Competent Authorities have been advised of this FSCA. We regret any inconvenience this may have caused you or your firm.

Sincerely,

Sage Products LLC