



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

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**URGENT FIELD SAFETY NOTICE**

*Comfort Shield® Barrier Cream Cloths*

FSCA Identifier: 20160823

Type of Action: FSCA Return of Medical Device

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**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.

<b>Product Code</b>	<b>Lot Number</b>	<b>Expiration Date</b>
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](mailto: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



# FSN ACKNOWLEDGEMENT RESPONSE

FSCA IDENTIFIER: 20160823

**Response is Required**

For Sage Use Only	
Consignee #:	_____
Receipt Date:	_____
Processed By:	_____
RMA#:	_____

Distributor Name: Enter distributor name.      Distributor Location: Enter distributor location.

Are you a:

- Distributor      Distributor Name: \_\_\_\_\_
- Healthcare Facility
- Other      If "Other", please describe: \_\_\_\_\_

**Please print the following information:**

Facility Name:				Your Name:	
Address:				Title:	
City:				Email:	
Country:		Postal Code:		Phone:	

I have read and understand the recall instructions provided in the FSN letter dated August 23, 2016:

Yes  No

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Please check all that apply:**

- All facilities or customers to which we have distributed the affected product have been notified. Arrangements have been made to return affected product.  
Date of communication: \_\_\_\_\_
- Our inventory has been inspected, and no affected code(s) were found.
- Upon inspecting our inventory, the following affected code(s) are being quarantined and will be returned. Enter quantity for the appropriate lot # in the table on following page.

**RETURN COMPLETED FORM TO: FAX +1 224.387.2125, EMAIL [recall.international@sageproducts.com](mailto:recall.international@sageproducts.com), or MAIL to:**

**Attn:** Customer Service Department – Recall International Dept.  
**Company:** Sage Products LLC  
3909 Three Oaks Rd  
Cary, IL 60013

**Returns and orders for replacement product should be coordinated through Sage Products Customer Service at our Customer Service HOTLINE, +1 847.516.7600 or by email.**

**COMMENTS:** \_\_\_\_\_



# FSN ACKNOWLEDGEMENT RESPONSE

FSCA IDENTIFIER: 20160823

**Response is Required**

For Sage Use Only	
Consignee #:	_____
Receipt Date:	_____
Processed By:	_____
RMA#:	_____

Distributor Name: Enter distributor name.

Distributor Location: Enter distributor location.

PRODUCT CODE	LOT NUMBER	QUANTITY	
		CASES	EACHES (PARTIAL CASE)
7526-X	50694		
7526-X	51089		
7526-X	52427		
7526-X	53031		
7526-X	54330		
7526-X	56130		
7453-X	45601		
7453-X	46142		
7453-X	46160		
7453-X	46684		
7453-X	47716		
7453-X	49857		
7453-X	50613		
7453-X	51417		
7453-X	52297		
7453-X	52947		
7453-X	54774		
7905-X	45602		
7905-X	46393		
7905-X	47086		
7905-X	47305		
7905-X	47656		
7905-X	48872		
7905-X	50766		
7905-X	50888		
7905-X	52186		
7905-X	52236		