

# Safety Notice

## Medical Devices

### Comfort Shield Barrier Cream Cloths



#### Priority 2 – Warning

HPRA Safety Notice: SN2016(27)

Issue Date: 16 September 2016

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Sage Products LLC	V29086

#### ISSUE

Sage Products LLC is voluntarily recalling product codes 7526-X (24-pk), 7453-X (3-pk), 7905-X (8-pk) of Comfort Shield Barrier Cream Cloths due to potential product contamination with the bacteria, *Burkholderia cepacia*.

#### ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- 1 Please read and follow steps in the field safety notice (FSN).
- 2 Check your inventory for the affected lot numbers. Lot numbers are located on the outside of the product case (over shipper).
- 3 Stop use of product immediately and quarantine all identified lots.
- 4 Complete the field safety notice (FSN) Acknowledgement Response and return it to Sage Products.

- 5 Ensure that this HPR Safety Notice and the attached Field Safety Notice is passed on to any organisation or end user where the potentially affected devices have been transferred.

### TARGET GROUPS

All Hospital staff	Purchasing / Procurement Managers
All Nursing Home staff	Carers
Risk Managers	Community users
Nursing Managers	General public

### BACKGROUND

Sage has initiated this recall action due to potential product contamination with *Burkholderia cepacia*.

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.

Contact the manufacturer regarding how to proceed with the return/destruction of the identified lots:



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



Product Code	Lot Number	Expiration Date
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



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

### MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

**Sage Products LLC**  
 3909 Three Oaks Road  
 Cary  
 IL 60013  
 USA

Telephone: +1 847-516-7600  
 Fax: +1 224-387-2125  
 E-mail: [Recall.international@sageproducts.com](mailto:Recall.international@sageproducts.com)  
 Website: [www.sageproducts.com](http://www.sageproducts.com)

## HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority  
Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
Dublin 2

Telephone: +353-1-6764971  
Fax: +353-1-6344033  
E-mail: [devicesafety@hpra.ie](mailto:devicesafety@hpra.ie)  
Website: [www.hpra.ie](http://www.hpra.ie)