

January 31, 2017

URGENT: FIELD SAFETY NOTICE
RECALL: Secura Protective Cream Z10 78g (CE)
FIELD SAFETY NOTICE: WR-2016-06

Affected Product: Secura Protective Cream Z10 78g (CE)
FSCA reference: WR-2016-06
FSCA action: Recall: Device Return / Device Destruction
Details of affected product: Product Code: 59447525
Product Lot Number: 626110

Dear Device Customer/Distributor,

Smith & Nephew informs you of a voluntary Field Safety Corrective Action (FSCA) in relation to Secura Protective Cream Z10 78g (CE).

Smith and & Nephew has identified that this product has been shipped to countries that have not completed the necessary registration activities to market the product.

The scope of this FSCA is only limited to Secura Protective Cream Z10 78g (CE), Product Code: 59447525, Product Lot Number: 626110. All other Product Codes and Product Lots remain unaffected by this issue or are still under Smith and Nephew control.

The purpose of this Field Safety Notice is to provide information to identify the affected lot of Secura Protective Cream Z10 78g (CE) and to communicate the necessary actions to be undertaken by customers and distributors.

Details on affected devices:

The affected lot of Secura Protective Cream Z10 78g (CE) in scope of this FSCA are sold in a configuration of one (1) tube in a carton. Details of the affected tubes are detailed in Table one.

Product Description	Product Code	Affected Product Lot Numbers
Secura Protective Cream Z10 78g (CE)	59447525	626110

Table one – Details of the affected devices

Details of the product code and product lot numbers are displayed on the device's primary and secondary packaging. Figures one and two illustrate the locations of the product code and product lot number on the primary and secondary packaging.

2	<p>Users are instructed to immediately inspect the Product Code (59447525) and Product Lot Code (626110) Number for all Secura Protective Cream Z10 78g (CE).</p> <p>The Product Code (59447525) and Product Lot Code (626110) Number can be found on the Primary and Secondary Packaging. The Figure A and Figure B illustrate where the Product Code (59447525) and Product Lot Code (626110) Number can be found on the Primary and Secondary Packaging.</p>
3	<p>Users are instructed to quarantine all affected Secura Protective Cream Z10 78g (CE).</p> <p>Responsible Health Care Professional should be consulted to determine an alternative protective cream.</p>
4	<p>Users are instructed to return all affected Secura Protective Cream Z10 78g (CE) to Smith & Nephew.</p>
5	<p>Users must complete the 'Acknowledgement, Receipt and Confirmation of Return Form' attached with this notice and return to your local Smith & Nephew Contact as soon as reasonably practicable.</p> <p>An 'Acknowledgement, Receipt and Confirmation of Return Form' must be return even if you do not have any affected product in your inventory. If necessary, your Smith & Nephew contact can assist you in completing the form.</p>
6	<p>Users must ensure this safety information is passed on to all those who need to be aware of it within your organization.</p>
7	<p>Users must maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p>
8	<p>Users may contact the local Smith & Nephew contact who may endeavor to provide a replacement product.</p>

If you have any questions, please contact your local Smith & Nephew subsidiary on the details listed below.

Contact Details of Subsidiary / Distributor:

Approved by:



Ajay Boodhun
 Director Regulatory Compliance and Safety
 Smith & Nephew Advanced Wound Management Division

IMPORTANT - MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE

Acknowledgement, Receipt and Confirmation of Return Form

Response is required within 15 days

WR-2016-06

January 31, 2017

Secura Protective Cream Z10 78g (CE)

I have read and understood the information contained in this letter and have distributed copies to all relevant users, as defined in the instructions.

Table A

PLEASE SELECT THE APPROPRIATE OPTION

<p>I have checked inventory for the affected products listed in the Field Safety Notice and confirm zero inventory remaining</p> <p>[IF YOU TICK THIS BOX PLEASE PROCEED TO THE APPROVAL SECTION]</p>	<input type="checkbox"/>
<p>I have checked inventory for the affected products listed in the Field Safety Notice and can confirm inventory remaining</p> <p>[IF YOU TICK THIS BOX PLEASE ALSO COMPLETE TABLE B]</p>	<input type="checkbox"/>

Table B

ONLY COMPLETE THIS TABLE IF YOU HAVE IDENTIFIED AFFECTED PRODUCTS LISTED IN THE FIELD SAFETY NOTICE IN YOUR LOCATION TO RETURN TO SMITH & NEPHEW.

Product Code:	Product Lot Number:	Quantity of product returned (Number of Boxes)
59447525	626110	

Please provide any additional information, if applicable.

Approval

Name	
Signature	
Title	
Telephone	
Email address	

PLEASE FAX OR MAIL THE COMPLETED RESPONSE FORM TO: YOUR LOCAL SMITH & NEPHEW CONTACT