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January 31, 2017

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

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



Location of the Product Code and Product Lot Number on the Secondary Packaging



Figure one - location of the product code and product lot number on the secondary packaging



Location of the Product Code and Product Lot Number on the Primary Packaging

Figure two - locations of the product code and product lot number on the primary packaging

Description of the problem:

Secura Protective Cream Z10 78g (CE) was incorrectly sent to countries that have not yet registered this product.

Smith & Nephew has identified that the proper systematic blocks were not applied to ensure product was released only to markets with the appropriate Market Approval.

Upon the identification of the root cause, Smith & Nephew has implemented appropriate corrective action(s).

Actions to be taken by customers and distributors:

No.	Actions to be undertaken
1	Identify users of the affected Secura Protective Cream Z10 78g (CE).
	This requires you to identify all users of Secura Protective Cream Z10 78g (CE), who may be in possession and who need to be made aware of this issue and actions to be executed in this Field Safety Corrective Action.
	Users may be distributors, healthcare professionals, home care workers or patients. Provide copies of this notice to all identified users as soon as is reasonably practicable.



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

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

Contact Details of Subsidiary / Distributor:

Approved by:

A

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	
I have checked inventory for the affected products listed in the Field	
Safety Notice and confirm zero inventory remaining	
[IF YOU TICK THIS BOX PLEASE PROCEED TO THE APPROVAL SECTION]	
I have checked inventory for the affected products listed in the Field	
Safety Notice and can confirm inventory remaining	
[IF YOU TICK THIS BOX PLEASE ALSO COMPLETE TABLE B]	

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