Urgent Field Safety Notice

Systagenix Wound Management: TOPPER® Xtra Absorbent Dressing Pads

Date: 11th July 2014

Ref: 14-2847

Details of affected devices:

Brand	Product Code*
TOPPER Xtra Absorbent Dressing Pad	M11121N
TOPPER Xtra Absorbent Dressing Pad	M11131
TOPPER Xtra Absorbent Dressing Pad	M11141
TOPPER Xtra Absorbent Dressing Pad	P55263
TOPPER Xtra Absorbent Dressing Pad	P55264
TOPPER Xtra Absorbent Dressing Pad	P55255

* The Product Code is printed on the front of both the carton and the primary packaging.

Description of the problem:
Systagenix has become aware that the sterility of some product may be compromised due to small holes in the bottom layer of the primary pouch; its subsequent use may therefore pose a potential risk of localised infection.
Recognising that any wound has the potential to develop infection, and monitoring for infection is a fundamental element of standard wound care practice, Systagenix has elected to initiate a voluntary field action of the Product Codes listed above as a precautionary measure. To date, Systagenix has not received any complaints or adverse events related to this matter, including reports of localised infection or other complications.

Advice on action to be taken by the customer:

- Please immediately segregate and discontinue use and distribution of products with the Product Codes listed above.
- Please contact any of your customers in receipt of product with the same Product Codes and instruct them to discontinue use and distribution of these Products.
- Clinician's should immediately discontinue use of product with the Product Codes listed above, and monitor any patients who were using, or have recently used, any of the affected product for signs of localised infection, including heat, pain, redness or swelling around the wound or increased wound drainage.
- If symptoms are presented the clinician should treat appropriately.

Transmission of this Field Safety Notice: (if appropriate)
Systagenix has prepared a communication to all those who have received potentially affected product and this is provided as an attachment.

Contact reference person:
Mrs. S. L. Knight
Quality Manager
Systagenix Wound Management
Gargrave
North Yorkshire
BD23 3RX

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies

We regret any inconvenience that this action may cause, and we appreciate your cooperation.

Mrs S. L. Knight
Quality Manager
Systagenix Wound Management

Voluntary Field Action: TOPPER Xtra Absorbent Dressing Pads

To: All Distributors / Recipients of Affected Product

Date: 11th July 2014

Ref: 14-2847

Brand	Product Code*
TOPPER Xtra Absorbent Dressing Pad	M11121N
TOPPER Xtra Absorbent Dressing Pad	M11131
TOPPER Xtra Absorbent Dressing Pad	M11141
TOPPER Xtra Absorbent Dressing Pad	P55263
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TOPPER Xtra Absorbent Dressing Pad	P55255

* The Product Code is printed on the front of both the carton and the primary packaging.

This letter is to inform you that Systagenix Wound Management Limited ("Systagenix") is undertaking a voluntary field action involving the Product Codes identified above irrespective of Lot number.

Systagenix has become aware that the sterility of some product may be compromised due to small holes in the bottom layer of the primary pouch; its subsequent use may therefore pose a potential risk of localised infection. To date, Systagenix has not received any complaints or adverse events related to this matter, including reports of localised infection or other complications.

If you have received product with the Product Codes listed above please immediately segregate and discontinue distribution of the product, and return unused product to Systagenix. Further details of how to do this are provided in the "Specific Instructions" section of this communication, which outlines a step-by-step process that you should follow pursuant to this Voluntary Field Action.

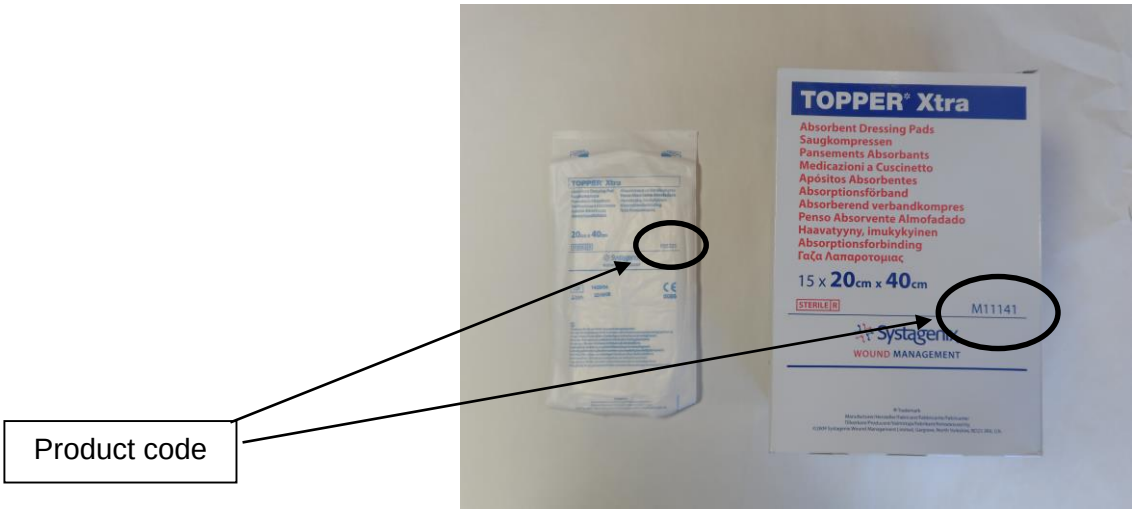
Clinician's should discontinue use of product with the Product Codes listed above and monitor any patients who were using, or have recently used, any of the affected product for signs of localised infection, including heat, pain, redness or swelling around the wound or increased wound drainage. If symptoms are presented then the clinician should treat appropriately

Importantly this action is confined to the specific Product Codes detailed above. All other Systagenix products are unaffected.

Please instruct those team members within your company and customers whose assistance is necessary to ensure full cooperation and fulfilment of this Voluntary Field Action.

SPECIFIC INSTRUCTIONS:

1. To assist us with this action, please immediately discontinue distribution and use of those Products labelled with the Product Codes listed above and quarantine the Product. The Product Code is printed on the front of the carton and also the front of the primary packaging.



2. Please forward this communication onto third-parties and customers to whom you have distributed product with the Product Codes detailed above and instruct them to follow these instructions.

3. Once the inventory has been quarantined, all parties in receipt of affected product should please complete and return the enclosed “Reply Form” with the following information.

   a) Acknowledgement of this Voluntary Field Action communication
   b) Confirmation of physical inventory check
   c) Details of product shipped and stock to be returned
   d) Confirmation of forwarding this communication to any customers who have received onward shipments.

4. After completing your inventory details, please contact **xxxxxxxx** directly on the following number : **xxxxxxxxxxxx** who will arrange for collection of the product and reimbursement.

5. Please complete the Reply Form and forward to **xxxxxxxxxxx** directly on Fax No **xxxxxxxxxxxx** and/or email to **xxxxxxxxxxx**.

Systagenix has advised the relevant EU Member State Competent Authorities and non-EU National Authorities, as necessary, of this Voluntary Field Action and will continue to keep them apprised of any further action.
We regret any inconvenience that this action may cause, and we appreciate your cooperation.

If you have any questions concerning this notice, please contact **xxxxxxxxxxxx** directly on the following number : **xxxxxxxxxxxx** or via email to **xxxxxxxxxxxx**.

Yours sincerely,

Mrs S. L. Knight
Quality Manager
Systagenix Wound Management

FAX BACK REPLY FORM

VOLUNTARY FIELD ACTION: Systagenix

PLEASE COMPLETE AND RETURN THIS FORM EVEN IF YOU DO NOT HAVE ANY OF THE AFFECTED PRODUCT ON HAND.

PLEASE CHECK ALL BOXES THAT APPLY

We have conducted a full inventory of all affected product codes, and (please tick as appropriate):

☐ We do not have any stock of products.

OR

☐ We have some of the items referenced in the Field Action Letter. We will be returning the following items.

Product Code #	Number of full cartons you have	Number of dressings you have from partial cartons

☐ We have forwarded this communication to any customers who have received onward shipments from us.

Please sign and return this form to acknowledge receipt of this Field Action Notice

Company Name & Address:	
Contact Name:	
Contact Title:	
Contact Signature:	
Contact Phone No:	
Date:	

We would appreciate it if you return this form within 3 business days to:

For the attention of: **XXXXXXXXXXX**
Fax No **XXXXXXXXXXX**