

13th May 2014

ATTENTION: FIELD SAFETY NOTICE
REF: CAPA 53
PRODUCT: DETEX X-RAY DETECTABLE SWABS

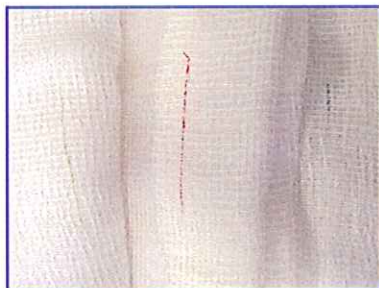
Dear Customer,

Please be advised that Synergy Health [UK] Ltd has identified a quality issue with the following products listed below:

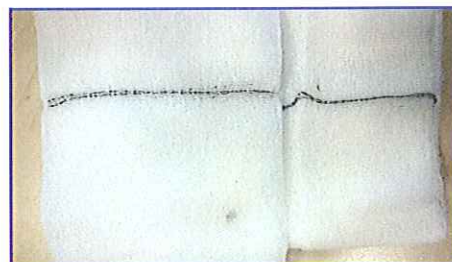
Details of affected devices: DETEX X-RAY DETECTABLE SWABS

Product Code	Product Description	LOT Number
28932	X-Ray detectable swabs tied 5's 15 x 10cm 24ply	289322913
28933	X-Ray detectable swabs tied 5's 10 x 10cm 32ply	289331213
		289331613
		289331913
28934	X-Ray detectable swabs tied 5's 10 x 7.5cm 32ply	289341213
		289341913
		289343213
		289343613
		289344313
28936	X-Ray detectable swabs tied 5's 36 x 11cm 16ply	289362913

Description of the problem: Synergy Health [UK] Ltd has identified product with contamination [photos provided below] and incorrect count. These issues are apparent on opening and the swabs should not be used.



Thread contamination



Contamination marks

Field Safety Notice instructions:

- All products as identified above should be quarantined.
- The attached Field Safety Notice Response Form should be completed and returned to acknowledge receipt of this notice.

Synergy Health (UK) Ltd
 1 Western Avenue
 Matrix Park, Chorley
 Lancashire PR7 7NB
 T +44 (0)1772 299 900
 F +44 (0)1772 299 901
 info@synergyhealthplc.com
 www.synergyhealthplc.com

Registered in England Number : 979716
 VAT Registered Number: GB 706 1634 56
 Reg Office: Ground Floor Stella
 Windmill Hill Business Park, Whitehall Way,
 Swindon, Wiltshire SN5 6NX


- Contact the Customer Service Department at Synergy Health [UK] Ltd on Tel: +44 [0] 1772 299 999 to arrange collection and replacement of affected stock.

Transmission of this Field Safety Notice: This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please maintain awareness of this notice until all required actions have been completed in your organisation.

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

We appreciate your cooperation and apologise for any inconvenience this may cause. We value our relationship with you and trust that with your cooperation this issue shall be resolved. If you have any further questions or concerns, please do not hesitate to contact your customer service representative.

Signed on behalf of Synergy Health [UK] Ltd;



Colleen Phythian

Head of Quality - EME

Hospital Sterilisation Services, HealthCare Solutions & Linen Management Services

Synergy Health (UK) Ltd
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ATTENTION: FIELD SAFETY NOTICE RESPONSE FORM
REF: CAPA 53
PRODUCT: DETEX X-RAY DETECTABLE SWABS

Please complete as appropriate and return for the attention of Nadine Turner [Principal RA/QA Officer]

Email RA/QA: nadine.turner@synergyhealthplc.com
 Email Customer Services: csenquiries@synergyhealthplc.com
 Tel: +44 [0] 1772 299 999
 Fax: +44 [0] 1772 299 934

- I hereby confirm receipt of your Field Safety Notice and will ensure that the information is shared with those who need to be aware within the organisation and to any organisation where the potentially affected devices have been transferred.
- As indicated by your records, the following products were shipped and I have advised below the quantity used and quantity to be returned:

Product Code	LOT Number	Customer PO number	Quantity Used	Quantity to be Returned

- None of the products referenced in the Field Safety Notice are in our possession.

Company Name and Address			
Telephone/E-mail			
Contact Name		Title	
Signature		Date	

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