Medeco BV
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The Netherlands

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Chamber of commerce 23038479
VAT NL01240912B01

Contact

Direct dialling number

Email

Date

Our reference
FSN2020-1

Subject
URGENT- Field Safety Notice – End User
Klinion Kliniray Gauze Compress X-Ray
Klinion Kliniray Abdominal Gauze Compress X-Ray

Dear Sir/Madam,

Medeco BV initiated a product recall for specific product codes and lot numbers of the Klinion Kliniray Gauze Compress X-Ray and Klinion Kliniray Abdominal Gauze Compress X-Ray, based on a recall of these products initiated by our production partner. Please note that it does not affect all product codes of Klinion Kliniray Gauze Compress X-Ray and Klinion Kliniray Abdominal Gauze Compress X-Ray.

Description of the problem:

After an internal assessment of these products, it became known that under tension x-ray contrast threads in gauze compresses with x-ray contrast thread can break and fray at individual points. Internal assessment has confirmed that these products are not meeting the criteria.

Theoretically, small pieces of thread could occur when the x-ray thread breaks or frays. This may, for example, lead to inflammation and/or granuloma formation when remaining in the body.

Medeco BV has not received any reports or incidents related to the x-ray threads issue.

The identified product codes and lot numbers within this notice are affected. For this reason and to address any potential risk of harm, all of the affected products should not be used.

Product identification procedure:

The only way to identify affected products is by checking product code and lot number to the recalled product list (see attachment 1).
Attachment 2 gives an example of a packaging label that highlights the location of the product code and lot number on the device labels. The label can be found on the primary packaging and the carton. The product code (reference number) is preceded by the word REF. The lot number is preceded by  and is in 4500xxxxxx format.

Advice on actions to be taken by End User

Our records show that you have taken delivery of affected product. Please follow the steps below:

1. Please stop the use of all affected devices as defined in this document.
2. Check stock and ensure that all affected devices that you have in stock are quarantined.
3. Complete the enclosed 'Recall Response Form for END USERS' which should be forwarded to us as soon as possible.
   Contact your distributor to arrange return of affected products, if applicable, and to arrange credit.

Please provide a completed response as soon as possible.

Transmission of this Field Safety Notice

This notice should be sent to all others who have received the affected devices within your organisation and to any organisation where the affected devices have been transferred to.

We are committed to deliver products of high quality to our customers and we apologize for any inconvenience that this notice can cause.
If you have any questions relating to this recall, please contact us at number provided above.

The relevant National Authorities have been informed about this Field Safety Corrective Action.

Authorisation:

Name:	
Function:	
Date: Signature:	

RECALL RESPONSE FORM for END USER

URGENT – FIELD SAFETY NOTICE

Please complete and return by email to *Please provide Mediq contact details*

Consignee:

Consignee Name:	
Consignee Address:	

Deliveries to your facility:

Invoice #	Product Code (REF number)	SAP no.	LOT no.	Quantity delivered (pieces)

Please answer each of the following questions:

1. Do you have any affected product Yes / NO

If yes: We have the following affected product:

Record quantity (pieces) for each LOT to be disposed:

Product Code (REF number)	SAP no.	LOT no.	Quantity (pieces)

Please provide details of affected products that were distributed to your customers:

Customer / Company name	Product Code (REF number)	SAP no.	LOT no.	Quantity (pieces)

EN USER FORM Completed and returned from:

Name:	
Function:	
Company name:	
Address:	
Email address:	
Phone number:	
Signature:	
Date:	

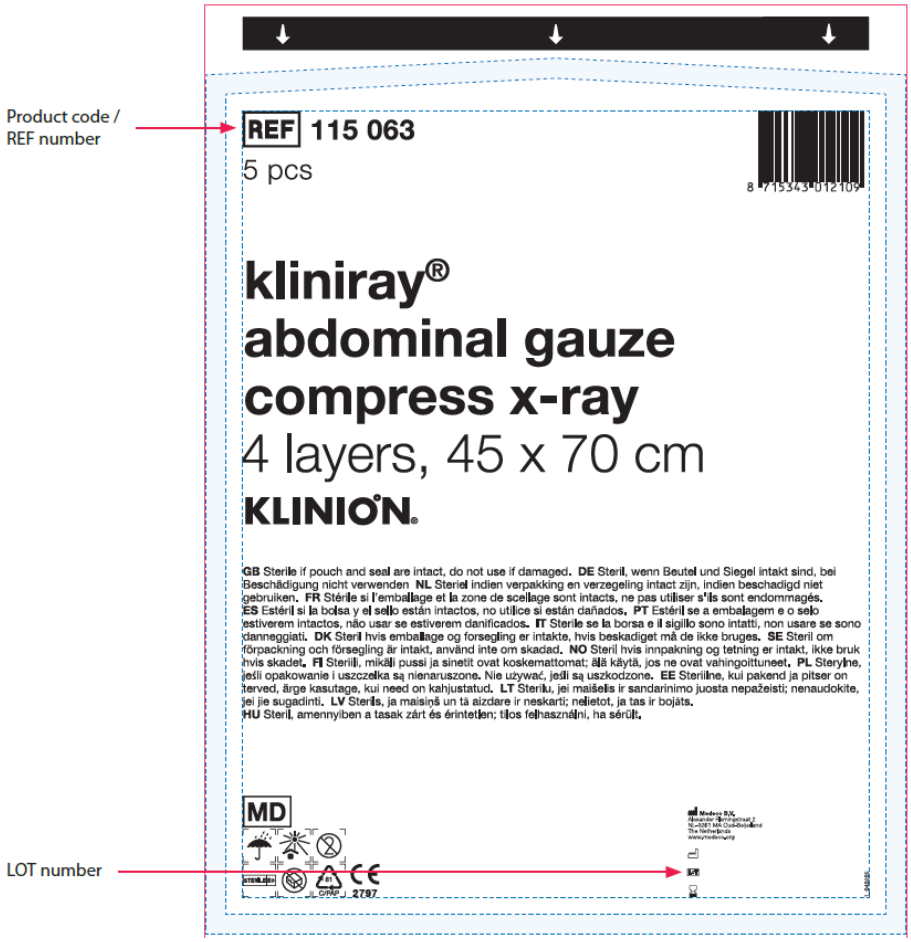
Appendix 1

Products including lot numbers affected:

Medeco SAP Number	Product REF number	LOT no.	Name and description
3016736	115001	4500150886	GAUZE COMP 5X 5 12L XRAY *S* PIP10
3016736	115001	4500154489	GAUZE COMP 5X 5 12L XRAY *S* PIP10
3016736	115001	4500159101	GAUZE COMP 5X 5 12L XRAY *S* PIP10
3016736	115001	4500157249	GAUZE COMP 5X 5 12L XRAY *S* PIP10
3016737	115005	4500154489	GAUZE COMP 10X10 12L XRAY *S* PIP5
3016737	115005	4500148507	GAUZE COMP 10X10 12L XRAY *S* PIP5
3016739	115007	4500154489	GAUZE COMP 10X10 12L XRAY *S* PIP10
3016739	115007	4500157249	GAUZE COMP 10X10 12L XRAY *S* PIP10
3016747	115050	4500148507	ABDOMINAL GAUZE 45X30CM 4L X-RAY *S*
3016747	115050	4500150887	ABDOMINAL GAUZE 45X30CM 4L X-RAY *S*
3016750	115063	4500154490	ABDOMINAL GAUZE 45X70CM 4L X-RAY *S*
3016750	115063	4500157251	ABDOMINAL GAUZE 45X70CM 4L X-RAY *S*
3016750	115063	4500159103	ABDOMINAL GAUZE 45X70CM 4L X-RAY *S*

Appendix 2
Example of packaging labelling

Primary packaging



Outer carton label