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Chamber of commerce 23038479
VAT NL01240912B01

Contact

Direct dialling number

Email

Date

Our reference
FSN2018-1

Subject
URGENT- Field Safety Notice – End User
Curion CuriSoft catheters - Recall

Dear Sir/Madam,

Medeco BV initiated a product recall for specific product codes of intermittent urinary catheters, based on a voluntarily initiated recall of these products by the supplier of the device. Please not that it does not affect all product codes of Curion Curisoft catheters.

Description of the problem:

According to the supplier, an internal assessment of this product's packaging integrity has confirmed that these devices are not meeting their expectations or those of their customers. Transportation testing conducted on the product packaging failed, confirming the potential for a breach in the sterile barrier. Using a non-sterile device on a patient may expose the patient to infectious agents increasing the patient risk of developing infection. Medeco BV or the supplier has not received any reports of incidents related to the packaging seal issue.

Only the identified product part codes within this notice may have a potential to breach in the sterile barrier packaging.

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 comparing product code and manufactured date to the recalled product list (see attachment 1). There is no other discernible differences between the affected and unaffected products. Attachment 2 gives an example of a packaging label that highlights the location of the product code and manufactured date on the device labels. The label can be found on the primary packaging and the shipping carton. The product code (reference number) is preceded by the word REF. The manufactured date is preceded by  and is in YYYY-MM-DD format.

Advice on action 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.
4. Contact your distributor to arrange return of affected products, if applicable, and to arrange credit. The products are not automatically replaced. Replacement products are currently not available.

Please provide a completed response as soon as possible.

Transmission of this 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.

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 advised 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 code	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 code	LOT No.	Quantity (pieces)

EN USER FORM Completed and returned from:

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

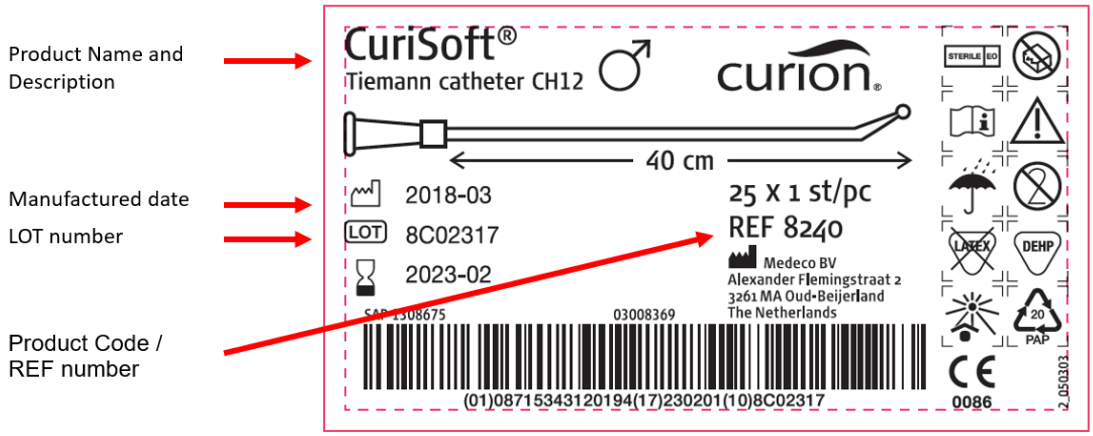
Appendix 1

Products Affected:
The following Codes with a manufactured date between 2013-07-01 and 2018-06-30

Medeco SAP Number	Product REF number	Name and description
3028660	8204	CURION CURISOFT NELATON CH10 40CM
3028662	8208	CURION CURISOFT NELATON CH14 40CM
3028663	8210	CURION CURISOFT NELATON CH16 40CM
3028664	8212	CURION CURISOFT NELATON CH18 40CM
3028685	8240	CURION CURISOFT TIEMANNN CH12 40CM
3028686	8242	CURION CURISOFT TIEMANNN CH14 40CM
3028688	8246	CURION CURISOFT TIEMANNN CH18 40CM

Appendix 2 Example of packaging labelling

Primary packaging:



Shipping carton: