

To Whom it may concern

10 February 2016Coloplast A/S
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Denmark
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www.coloplast.com
CVR-nr. 69749917**FIELD SAFETY NOTICE ref.: DKTG-2016-0202-1000****Coloplast recommends to cease use of and to return the below listed devices:**

SpeediCath® Compact Eve® female intermittent catheter CH 10 & CH14

Tina Gotschalk
Vigilance Officer

Sizes	CH 10		CH 14
Item codes	281100		281140
Lot numbers	4932245	4932274	4974661
	4932246	4942604	
	4932247	4942605	
	4932248	4942606	
	4932249		

Dir. tel. +45 4911 3339
dktg@coloplast.com

Please note this recall does not concern size CH 12.

Background information and scope of the product recall

The sterility of aforementioned medical devices made by Coloplast may be compromised due to a quality issue that has occurred in the production process. Investigations to find the root cause and to solve this matter are ongoing.

Safety concerns

SpeediCath Compact Eve is a sterile, single-use device intended for sterile intermittent catheterisation. The quality issue can affect the sterility of the finished product, potentially compromising user safety, however this risk is deemed to be minimal.

We want to stress that the recall is a precautionary measure as no users, customers or authorities have filed complaints or adverse events related to this issue, however we want to maintain the highest standards for product and end user safety.

Advice on preventive action to be taken by the user:

The customers affected by this Field Safety Notice are kindly advised to cease use of the listed devices and return these to Coloplast.

Transmission of this Field Safety Notice:

Please forward this message to relevant persons in your organization. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

In addition, if you have further distributed this product, please notify the consignees at once of this notification. Your notification to your customers may be enhanced by including a copy

of this notification letter. This notification should be carried out to the user level. Your assistance is appreciated and necessary.

The undersigned confirms that this notice has been forwarded to the appropriate Competent Authorities.

Yours sincerely,
Tina Gotschalk



FSN ref.: DKTG-2016-0202-1000**Confirmation of receipt of the FSN**

Please fill out the form and send it to the email address given below - even if you do not have the products on your stock please fill out the document.

E-mail: gb_trade@coloplast.com**Recalled product:****SpeediCath Compact Eve female intermittent catheter – CH 10 and CH 14**

Item number	281100	281140
Lot number		
Volume in your possession to return		

 We have checked all the stocks and the products concerned are not on stock.

Name of customer: _____

Name / profession: _____

Date / signature:

Return address:
Coloplast UK
Unit 1,
The Links,
Bakewell Road,
Orton Southgate,
Peterborough
PE2 6B
Att.: David Prior

Please return the confirmation of receipt no later than: 1 March 2016

