Coloplast

Ostomy Care
Urology & Continence Care
Wound & Skin Care

To Whom it may concern

04 May 2016

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CVR-nr. 69749917

FIELD SAFETY NOTICE ref.: DKTMD-2016-0426-2000

Coloplast recommends to cease use of and to return the below listed devices:

SpeediCath® Compact Eve® intermittent catheter CH 12

[redacted]

Item code	28112
Lot numbers	DE: 5071038

Please note: This recall does not concern size CH 10 & 14.

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. The root cause for this issue has been identified. Initiatives to solve the 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 user affected by this Field Safety Notice is kindly advised to cease use of the listed lot numbers of the SpeediCath Compact Eve CH12 and return these to Coloplast.

Transmission of this Field Safety Notice:

Please forward this message to relevant persons in your organization.

This notification must be delivered to the end user level. If you are a Wholesaler, Distributor, Pharmacy or similar, it is your responsibility to notify your customers, whether professional or end user, that they must cease use of and return the affected products.

This action should be carried out without undue delay. You may include a copy of this letter in your communication with your customers.

Please dedicate attention to this notice and the resulting actions for the duration of this recall. In line with requirements from Health Authorities you are required to confirm the actions taken to Coloplast. This includes an overview of amount of customers reached as well as quantity of returned products.

Your assistance is appreciated and necessary.

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

Yours sincerely,

Illustration of issue concerning FSCA Coloplast ref.: DKTMD-2016-0426-2000

Fig. 1 Outer layer incomplete

Fig. 2 Reference

	Lot number	Manufacturing date	Expiry date
BE	5081644	22-03-2016	16-03-2018
BE	5107109	06-04-2016	01-04-2018
CH	5081639	23-03-2016	16-03-2018
CH	5105449	06-04-2016	31-03-2018
DE	5071038	16-03-2016	07-03-2018
DK	5071035	15-03-2016	07-03-2018
DK	5078049	21-03-2016	10-03-2018
FI	5078052	17-03-2016	10-03-2018
FR	5071036	10-03-2016	07-03-2018
FR	5071037	10-03-2016	07-03-2018
FR	5078050	21-03-2016	10-03-2018
FR	5078051	30-03-2016	10-03-2018
IT	5071032	14-03-2016	07-03-2018
NL	5071033	16-03-2016	07-03-2018
NL	5081638	22-03-2016	16-03-2018
NO	5071034	21-03-2016	07-03-2018
NO	5081640	30-03-2016	16-03-2018
UK	5071031	10-03-2016	07-03-2018
UK	5078045	21-03-2016	10-03-2018
UK	5081635	23-03-2016	16-03-2018

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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: service@coloplast.com

Recalled product:

SpeediCath Compact Eve intermittent catheter – CH 12

Item number	28112			
Lot number				
Volume in your possession to re-turn				

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

Name of customer: _____

Name / profession: _____

Date / signature:

Return address: Coloplast Distribution GmbH
Rückruf SpeediCath Compact EVE, CH 12
Werner Schröder Straße 1
21035 Hamburg

Please return the confirmation of receipt no later than: May 25th 2016