FSN Ref: FSN_ Elefant_20200903 FSCA Ref: FSCA_Elefant_20200903

Date: 2020/09/14.

Urgent Field Safety Notice
ELEFANT® SUCTION/IRRIGATION DEVICE
for Specific lots

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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Urgent Field Safety Notice (FSN)
ELEFANT® SUCTION/IRRIGATION DEVICE
Risk addressed by FSN

1. Information on Affected Devices*

1. Device Type(s)*

Elefant® is a single use disposable suction-irrigation device and can be used whenever laparoscopic procedures are performed. The cannula is inserted through a trocar and the device is connected on a suction system and irrigation bag(s).

The device is composed mainly of:
- 1 connecting tube
- 1 handling grip
- 1 cannula with eyes on the distal end

2. Commercial name(s)

ELEFANT® SUCTION/IRRIGATION DEVICE

3. Primary clinical purpose of device(s)*

The Elefant Suction/Irrigation device is intended for use in laparoscopic procedures as an operating tool with irrigation and suction capabilities

4. Device Model/Catalogue/part number(s)*

ASP145; ASP185

5. Affected lot number range

Product references	Lot number	Expiry date
ASP145	7459530	15/05/2025
ASP185	7424848	17/05/2025
ASP185	7440796	18/05/2025
ASP185	7440801	19/05/2025

2 Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*

Sterility issue was detected in Coloplast's facilty on Elefant products. A weakness on the Elefant packaging welding has been identified during manufacturing process. Defect is not easily visible by the users.

2. Hazard giving rise to the FSCA*

2.	The risk associated with the use of an insufficiently sealed Elefant peel pouch may be associated with a lack in sterility. This can lead to a nosocomial infection of the operated field. Provided the location, a severe infection like a sepsis cannot be excluded in some rare cases.
2.	3. Background on Issue The issue was detected in Coloplast's facility during manufacturing process.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Return Device The customers affected by this recall are kindly advised to return any product covered by the list above to the address mentioned below: Distribution Center of Coloplast Champlan Recall Elefant Service Retour 2 bis route du Chemin Blanc ZAC du Clotais 91160 CHAMPLAN France	
3.	2. By when should the action be completed?	2020/10/02
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Coloplast A/S**
	b. Address	**Holtedam 1** **3050 Humlebæk** **Denmark**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	5. List of attachments/appendices:	**Customer Reply Form**
4.	6. Name/Signature	**……** **……** **……**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.