FSN Ref: FSCA/FSN_20250808_Elefant Suction
FSCA Ref: FSCA_20250808_Elefant Suction

Date: 2025.08.20

Urgent Field Safety Notice
ELEFANT® Suction-Irrigation devices

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.)*
[redacted]

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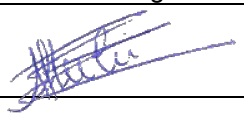
Urgent Field Safety Notice (FSN)
ELEFANT® Suction-Irrigation devices
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Elefant® Suction-Irrigation Device is a disposable suction/irrigation device composed of a handling grip, a fiberglass cannula with a 6-eye Yankauer tip and is provided with or without 3m long double tubing (1 tube for irrigation and 1 tube for suction). The device is a single use, sterile device.
1.	2. Commercial name(s)
	ELEFANT® Suction-Irrigation devices
1.	3. Unique Device Identifier(s) (UDI-DI)
	570893263590085
1.	4. Primary clinical purpose of device(s)*
	The devices are intended to be used in laparoscopic procedures as an operating tool with irrigation and suction capabilities. It is a single use device designed for introduction and use through a properly-sized trocar
1.	5. Device Model/Catalogue/part number(s)*
	ASP145 – ASP150 – ASP165 – ASP170 - ASP18x
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	AT: 10361472, 10361473, 10361474, 10376807, 10376814, 10376817, 10376825, 10392400, 10392418 BE: 10361465, 10361467, 10361470, 10361472, 10361474, 10361478, 10376811, 10376814, 10392401, 10392416, 10392418 CZ: 10376811, 10376818, 10376819, 10376822, 10376824, 10392399 FR: 10361464, 10361465, 10361466, 10361467, 10361468, 10361470, 10361471, 10361472, 10361474, 10361477, 10361478, 10376801, 10376807, 10376808, 10376809, 10376810, 10376816, 10376819, 10376821, 10376822, 10376825, 10392399, 10392401, 10392402, 10392418, 10392420, 10403531 DE: 10361464, 10361465, 10361466, 10361467, 10361468, 10361469, 10361470, 10361471, 10361472, 10361473, 10361474, 10361477, 10376807, 10376808, 10376809, 10376810, 10376811, 10376814, 10376816, 10376817, 10376819, 10376822, 10376825, 10392400, 10392401, 10392402, 10392418, 10392420, 10403536 GR: 10376812, 10376813, 10376815, 10376816 HU: 10376825, 10392398 IE: 10361472, 10376806 IT: 10361464, 10361465, 10361466, 10361467, 10361469, 10361471, 10361472, 10361473, 10361474, 10361477, 10361478, 10376805, 10376809, 10376814, 10376821, 10376822, 10376825, 10392400, 10392403, 10392416, 10392418 LU: 10392400

	NL: 10361465, 10361467, 10361469, 10361470, 10361472, 10361473, 10361477, 10376805, 10376810, 10376811, 10376817, 10392400, 10392416, 10392418, 10392420 PT: 10361465, 10361467, 10361469, 10361470, 10361474, 10361477, 10376809, 10376811, 10376818, 10376819, 10376822, 10392400, 10392418 SK: 10376806, 10376807 ES: 0361464, 10361465, 10361467, 10361468, 10361470, 10361472, 10361473, 10361474, 10361477, 10376805, 10376808, 10376909, 10376810, 10376811, 10376814, 10376817, 10376821, 10376822, 10376824, 10376825, 10392400, 10392416, 10392418, 10392420 SE: 10361467, 10361470, 10361473, 10376814, 10392400 CH: 10361465, 10361467, 10361472, 10361474, 10361477, 10376810, 10392399, 10392420 ZA: 10376805, 10376806, 10376808, 10376810, 10392398, 10392399 MA: 10392402

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	The devices are not functioning properly as no suction or irrigation can be performed. During preparation of the procedure, the IFU states to “Test the correct functioning of the device before use”. This Notice is to emphasize to the impacted customers that the devices are not working.
2.	2. Hazard giving rise to the FSCA*
	The malfunction described is classified as a safety risk, as it may lead to a prolonged surgical procedure and require the device to be replaced. The Instructions for Use clearly state that the device’s functionality must be tested prior to use. If this step is followed, the malfunction would be identified before patient contact, and the device would be discarded and replaced, minimizing clinical impact.
2.	3. Probability of problem arising
	All items with the affected lot numbers are affected and unable to provide suction or irrigation.
2.	4. Predicted risk to patient/users
	Clinical assessment has concluded that the most likely clinical outcome of the issue is a prolonged procedure. At a worst-case, the procedure may need to be rescheduled if no replacement or alternative device is available.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	25 complaints have been received reporting the issue.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions for Use (IFU) ☐ Other ☐ None All distributors and customers must ensure that the FSN is sent to treating clinicians at facilities within 24 hours of receipt of this Notice.	
3.	2. By when should the action be completed?	Immediately upon receipt of this notice
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes 10 September
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Customers are asked to destroy all products with the affected lot numbers.	
3	6. By when should the action be completed?	Immediately upon receipt of this notice
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	3. For Updated FSN, key new information as follows:	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
4	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Coloplast A/S
	b. Address	Holtedam 13050 Humlebæk Denmark
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	FSN Reply Form
4.	10. Name/Signature	Magali MERLIN Regulatory Affairs Manager
		

	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.