FSN Ref: SLC-FSCA-003_FSN_IE_en_1 FSCA Ref: SLC-FSCA-003

Date: 2026-05-12

Follow-up to previous Field Safety Notice
No new incident – No new identified risk
SOLUSCOPE ENT

For Attention of*: Vigilance or Quality Managers of healthcare facilities, users of the affected devices, and distributors, as applicable.

Dear customer,

This document is issued as part of the Field Safety Corrective Action (FSCA) referenced **SLC-FSCA-003** and is being provided for the first time in this country. **No new incident and no new risks have been identified since the initial notice.**

Investigations previously performed identified a potential contamination of the leak test socket related to routine operation and maintenance. To date, no transfer of germs to reprocessed endoscopes has been observed.

The purpose of this follow-up is to:

- Extend the scope of the previously communicated measures to other impacted products based on the same root cause and with same technical configuration of the medical devices: end of life devices present on the field, **Soluscope ENT.**
- Inform users of the implementation of **a temporary risk reduction measure** for Soluscope ENT devices still in service during the transitional period preceding their effective end of life.

The customers using Soluscope ENT have been informed by the legal manufacturer about the end-of-life service obligations. A such, no updated disinfection protocol is provided or integrated into the user manual for these devices. The final corrective action for these devices remains the cessation of use and their removal from clinical service, as described in more detail in Section 3.

However, considering that certain Soluscope ENT devices may remain in operation for a limited transitional period prior to their effective withdrawal, a temporary risk reduction measure is provided exclusively for these devices, in order to reduce the identified risk during this period.

Please review the information in this notice and follow the appropriate actions outlined below and in section 3:

- Please review the attached updated leak test socket disinfection protocol and ensure that this information is communicated to all impacted users within your facility, or to your impacted customers if you are a distributor.
- Please complete and return the attached Customer Reply Form within four weeks of receipt of this communication. If you have distributed the products to your customers, please collect their responses and submit one consolidated reply form with aggregated data.

SOLUSCOPE SAS, an ECOLAB company
Address: 100, rue Fauge – Z.I. les Paluds, 13400 Aubagne – France
Website : www.soluscope.com Email: info@soluscope.com

We sincerely apologize for any inconvenience this may cause and appreciate your understanding and cooperation.

Best regards,
ECOLAB VIGILANCE
On behalf of Soluscope SAS

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Follow-up to previous Field Safety Notice (FSN)
Soluscope ENT
Update of daily maintenance protocol: leak test socket disinfection

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Automated washer disinfector for flexible endoscopes.
1.	2. Commercial name(s)*
	SOLUSCOPE ENT.
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The Soluscope ENT are automated washer-disinfectors (WD) that have been classified according to medical devices according to Medical Device Directive Class IIB. These devices are intended for used according to intended use by trained personnel only.
1.	5. Device Model/Catalogue/part number(s)*
	All installed base of SOLUSCOPE ENT.
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	All installed base of SOLUSCOPE ENT.
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	As previously communicated in the initial FSN, investigations identified a potential contamination of the leak test socket over time, related to their operation and maintenance. This situation may be associated with the leak test connector itself and, with simulators used during maintenance activities.
2.	2. Hazard giving rise to the FSCA*
	As previously described, if the leak test socket were contaminated, this could in rare cases lead to contamination of the reprocessed endoscope and a potential risk of cross-contamination to the patient. To date, no transfer of germs from the leak test socket to reprocessed endoscopes has been observed.

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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 ☒ Inform all users within your facility ☒ Take note of the attached leak test socket reprocessing protocol* ☐ Other ☐ None ***: Corrective measures previously implemented under SLC-FSCA-003 remain applicable. This follow-up FSN also includes updates and additional measures as described below:** • **Soluscope ENT: a temporary risk mitigation measure is provided with this FSN to limit the identified risk during the transitional period preceding the device's effective end of life. Discontinuation of use and withdrawal from clinical service remain the recommended final corrective action.**	
	2. Action To Be Taken by the DISTRIBUTOR*	
	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ Inform all users within your facility ☒ Take note of the attached leak test socket reprocessing protocol* ☐ Other ☐ None ***: Corrective measures previously implemented under SLC-FSCA-003 remain applicable. This follow-up FSN also includes updates and additional measures, which shall be communicated according to the support status of the affected devices.** • **Soluscope ENT: distributors must communicate to their customers the temporary risk mitigation measure provided with this FSN. This measure applies on a transitional basis until the device's effective end of life. Discontinuation of use and withdrawal from clinical service remain the recommended final corrective action.**	
3.	3. By when should the action be completed?	Immediately
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes Within 4 weeks after receipt of this communication

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3.	**5. Action Being Taken by the Manufacturer***

☐ Product Removal ☐ On-site device modification/inspection

☐ Software upgrade ☒ IFU or labelling change*

☐ Other ☐ None

***: Preventive measures previously implemented under SLC-FSCA-003 remain applicable. This follow-up FSN also includes updates and additional measures implemented by the manufacturer.**

- **Soluscope ENT: a temporary risk mitigation measure applicable during the transitional period preceding the device's effective end of life is provided with this FSN. This document does not constitute an update to the user manual and does not affect discontinuation of use as the final corrective action.**

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4. General Information*		
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	SLC-FSCA-003_FSN_Master_EN_en_7 dated July 30, 2025 (not previously distributed in Ireland)
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Soluscope SAS
	b. Address	100, rue Fauge – Z.I. les Paluds, 13400 Aubagne – France
	c. Website address	www.soluscope.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	**Annex A:** *Customer reply form* ***Annex B:*** *ENT_Temporary risk mitigation measure for End of Life Devices_EN*

	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.

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