Date: 16/12/2024 FSN reference: SLC-FSCA-002

Urgent Field Safety Notice
SOLUSCOPE SERIE 4

For Attention of: Person in charge of vigilance, Person in charge of endoscope reprocessing

Contact details of local representative (name, e-mail, telephone, address etc.)
Laboratoires ANIOS (on behalf of Soluscope SAS) 1 rue de l'Espoir 59260 Lezennes Tél. : +33 3 20 67 67 67 email : clmvsoluscope@ecolab.com

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Urgent Field Safety Notice (FSN)
SOLUSCOPE SERIE 4
Performance of reprocessing of Colonoscope Olympus CF-H185, 190, 260, 290, 1100, 1200, 1500 long version with cycle 2

1. **Information on Affected Devices**	
1.	*1. Device Type(s)*
	Automated washer disinfector for flexible endoscopes
1.	*2. Commercial name(s)*
	SOLUSCOPE SERIE 4
1.	*3. Unique Device Identifier(s) (UDI-DI)*
	NA
1.	*4. Primary clinical purpose of device(s)*
	The SOLUSCOPE SERIE 4 PA automated washer-disinfector (WD) is intended to clean and disinfect semi-critical, heat-sensitive flexible endoscopes with or without channels. It is intended for use exclusively with its dedicated, single-use cleaner Soluscope CLN and disinfectant Soluscope PAA. It is destined to be used by trained personnel familiar with endoscope reprocessing, handling cleaners and disinfectants, in a hospital or medical setting, in endoscopy departments, operating theaters or medical offices.
1.	*5. Device Model/Catalogue/part number(s)*
	SL-V4-PA / SL-V4-SA-PA / SL-V4-RO-PA
1.	*6. Software version*
	NA
1.	*7. Affected serial or lot number range*
	Soluscope Serie 4 installed base
1.	*8. Associated devices*
	NA

2 **Reason for Field Safety Corrective Action (FSCA)**	
2.	*1. Description of the product problem*
	Difficulties to reprocess Olympus Colonoscope Serie CF-H 185, 190, 260, 290, 1100, 1200, 1500 L (long version) with cycle 2 in Soluscope S4, may lead to failed qualification of performance and/or failed routine sampling.
2.	*2. Hazard giving rise to the FSCA*
	Inadequate disinfection of Olympus Colonoscopes might lead infection risk to patients.
2.	*3. Probability of problem arising*
	Probability of problem arising is extremely unlikely based on internal investigation
2.	*4. Predicted risk to patient/users*
	Inadequate disinfection of Olympus Colonoscopes might lead infection risk to patients.
2.	*5. Further information to help characterise the problem*
	The problem occurs only with cycle 2 and Olympus colonoscope Serie CF-H 185, 190, 260, 290, 1100, 1200, 1500 L (long version)
2.	*6. Background on Issue*
	Soluscope received complaint from customers about failed qualification of performance of Olympus endoscope (e.g. CF-H 190L). Based on this, Soluscope started investigations and identified root causes for this failure. One of the root causes was difficulty to reprocess Olympus colonoscopes series CF-H 185, 190, 260, 290, 1100, 1200, 1500L (long version) reprocessed in Soluscope Serie 4 used with cycle 2. Investigations into the cause(s) are

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	ongoing and may not be specific to Soluscope devices and might be related to endoscope design itself
2.	*7. Other information relevant to FSCA*
	NA

	3. Type of Action to mitigate the risk*	
3.	**1-a Action To Be Taken by the User*** **X** Identify Device **X** Inform all users within your facility **X** Take note of the attached reinforced protocol Soluscope recommends a reinforced protocol to replace usual cycle 2 for the reprocessing of the Olympus colonoscopes CF-H 185, 190, 260, 290, 1100, 1200, 1500 L (Long version) The reinforced protocol includes an initial 10-minute manual detergent phase followed by an automated reprocessing cycle with a single detergent phase, so called cycle 1. The detailed reinforced protocol is attached to this FSN.	
3.	**1-b Action To Be Taken by the Distributor*** **X** Identify Customers/end users with the device **X** Inform End Users to proceed according to the section 3.1-a “Action to be taken by the user”. **X** Take note of the attached reinforced protocol Soluscope recommends a reinforced protocol to replace usual cycle 2 for the reprocessing of the Olympus colonoscopes CF-H 185, 190, 260, 290, 1100, 1200, 1500 L (Long version) The reinforced protocol includes an initial 10-minute manual detergent phase followed by an automated reprocessing cycle with a single detergent phase, so called cycle 1. The detailed reinforced protocol is attached to this FSN.	
3.	*1. By when should the action be completed?*	IMMEDIATE
3.	2. *Particular considerations for:* NA *Is follow-up of patients or review of patients’ previous results recommended?* NA	
3.	*3. Is customer Reply Required? ** *(If yes, form attached specifying deadline for return)*	YES 8th Jan. 2025

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3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change **X** Other ☐ None Soluscope provides reinforced protocol that includes an initial 10-minute manual detergent phase followed by an automated reprocessing cycle with a single detergent phase, so called cycle 1.	
3	*5. By when should the action be completed?*	IMMEDIATE
3.	*6. Is the FSN required to be communicated to the patient /lay user?*	NO
3	*7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?*	
	NA	

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	4. General Information	
4.	1. *FSN Type*	New
4.	2. *For updated FSN, reference number and date of previous FSN*	NA
4.	3. *For Updated FSN, key new information as follows:*	
	NA	
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:*	
	NA	
4	6. *Anticipated timescale for follow-up FSN*	NA
4.	**7.** *Manufacturer information (For contact details of local representative refer to page 1 of this FSN)*	
	a. *Company Name*	SOLUSCOPE SAS
	b. *Address*	100, Rue du Fauge – Z.I. Les Paluds – 13400 AUBAGNE - FRANCE
	c. *Website address*	www.soluscope.com
4.	8. *The Competent (Regulatory) Authority of your country has been informed about this communication to customers.* *	
4.	9. *List of attachments/appendices:*	Annexe A : Reinforced protocol (initial 10-minute manual detergent phase + automated reprocessing cycle 1) Annexe B : reply form
4.	10. *Name/Signature*	Sr Regulatory Affairs Manager
		Quality Manager HC Endoscopy

	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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