FSN Ref: FSN-2025-0002 FSCA Ref: FSCA-2025-0002

Date: *[date]*

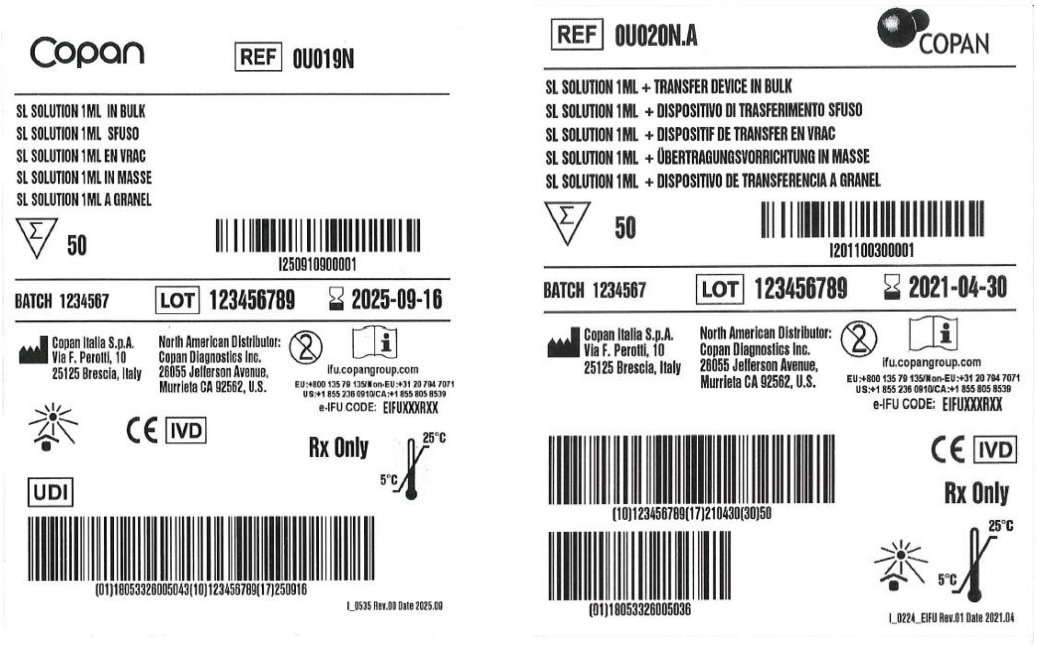
Urgent Field Safety Notice
SLsolution™
Items 0U019N and 0U020N.A

For Attention of:
[Customer information]

Contact details of local representative (name, e-mail, telephone, address etc.)
Elisabetta Zanella COPAN ITALIA Spa Via Francesco Perotti, 18 Brescia, ITALY 25125 Phone: +39 030 2687210-211 regulatory.affairs@copangroup.com

FSN Ref: FSN-2025-0002 FSCA Ref: FSCA-2025-0002

Urgent Field Safety Notice (FSN)
SLsolution™ - Items 0U019N and 0U020N.A

	1. Information on Affected Devices
1.	1. Device Type(s)*
	Copan SLsolution™ 0U019N and 0U020N.A consist of a plastic tube with screw cap containing a ready-to-use solution and are indicated for fluidification of specimens collected from the respiratory tract, *Mycobacterium spp* excluded. Copan SLsolution™ 0U020N.A includes also a sterile transfer device, Sputum Dipper, that permits the specimen transfer from the primary sample container to the SLsolution™ tube.  Exemplificative inner box label of SLsolution™ 0U019N device (on the left) and exemplificative inner box label of SLsolution™ 0U020N.A device (on the right). Copan SLsolution™ devices are NOT labelled as sterile and are intended to be used by healthcare professionals only.
1.	2. Commercial name(s)
	SLsolution™
1.	3. Unique Device Identifier(s) (UDI-DI)
	Item 0U019N: 18053326005043 (inner boxes) Item 0U020N.A: 18053326005036 (inner boxes)
1.	4. Primary clinical purpose of device(s)
	Copan SLsolution™ is a treatment reagent for fluidification of specimens collected from the respiratory tract prior to subsequent microbiological analyses.
1.	5. Device Model/Catalogue/part number(s)
	Reference numbers: 0U019N and 0U020N.A.
1.	6. Software version
	Not applicable.
1.	7. Affected serial or lot number range
	All lots on the market still valid according to their shelf life. See attached "*FSN-2025-0002 Attachment 2*" for distribution details.

1.	8. Associated devices
	Not applicable.

	2 Reason for Field Safety Corrective Action (FSCA)
2.	1. Description of the product problem
	SLsolution™ reagent includes dithiothreitol (DTT), which is oxidized when it gets in contact with air and/or metals, potentially losing its functionality in fluidification of respiratory specimens. SLsolution™ reagent must show a colourless appearance. On the other hand, when the DTT reagent is deteriorated: - the SLsolution™ reagent shows a pink or yellow discoloration (device failure), - its functionality in respiratory specimens fluidification cannot be guaranteed. Representative pictures of defective pieces (pink one and yellow one) are provided below:  
2.	2. Hazard giving rise to the FSCA
	A dedicated warning is already present in devices' instructions for use (ref. EIFU013, warning number 8) to instruct the user to discard any non-colourless piece ("*Do not use Copan SLsolution™ if the reagent is not clear/colourless (e.g. pink or yellow)*"). Moreover, the device's instructions for use indicate to check whether the specimen is actually suitable for subsequent analysis following treatment with SLsolution™ device (ref. EIFU013, section INSTRUCTIONS FOR USE, clause 6: "*Homogenize the specimen by vortexing the test tube for at least 3 seconds at 2000-2500 rpm, checking that the specimen is actually suitable for seeding.*"). Copan has verified that that the occurrence of device failure (pink/yellow discoloration of reagent) of lots already placed on the market of items 0U019N and 0U020N.A may be unexpectedly high. Should the defective devices be used, Copan cannot exclude that the functionality in fluidification of respiratory specimens of defective devices is potentially affected. In detail, health risk associated with the device failure could result either in: - potential need to repeat the sample collection procedure and subsequent potential delayed diagnosis and potential delayed treatment, if the user recognizes that the fluidification has not occurred, - in case the user does not recognize that the fluidification has not occurred, potential false negative result obtained in subsequent diagnostic test (misdiagnosis) and consequent

	absence of treatment, due to an ineffective fluidification that may not allow the detection of the microorganism in subsequent microbiological analyses. Hence, in a precautionary manner and considering the unexpectedly high defectivity that may affect marketed lots of items 0U019N and 0U020N.A, Copan is proactively and voluntarily initiating a recall on these devices.
2.	3. Probability of problem arising
	Based on Copan's knowledge, no serious injuries and/or deaths have occurred as a result of the failure of the device in question. Based on the device failure incidence and on the type of received notifications from the market, occurrence of patient's impact, varying among the ones described above, cannot be excluded.
2.	4. Predicted risk to patient/users
	Health risk associated with the device failure could result either in: - potential need to repeat the sample collection procedure and subsequent potential delayed diagnosis and potential delayed treatment, if the user recognizes that the fluidification has not occurred, - in case the user does not recognize that the fluidification has not occurred, potential false negative result obtained in subsequent diagnostic test (misdiagnosis) and consequent absence of treatment, due to an ineffective fluidification that may not allow the detection of the microorganism in subsequent microbiological analyses. It should be noted that items 0U019N and 0U020N.A can be used by healthcare professionals on specimens collected from the respiratory tract with no limitations in terms of patient population. The severity and probability of occurrence of each patient's impact scenario depend on: - the detectability of the device failure, i.e., of the pink/yellow discoloration, - the patient group, - the available amount of collected respiratory sample, - the diagnostic flow in which the device is involved (except for *Mycobacterium spp*, as indicated in device's instructions for use – EIFU013, Limitation nr. 2: "*Copan SLsolution™ is not suitable for recovery of* Mycobacterium spp.").
2.	5. Further information to help characterise the problem
	Not applicable.
2.	6. Background on Issue
	In October 2025, following an increase in notifications received from the market on detected devices showing yellow/pink reagent, related to the period August-September 2025, Copan verified that the occurrence of device failure (pink/yellow discoloration) of lots already placed on the market of items 0U019N and 0U020N.A may be unexpectedly high. As containment action, the current stock of items 0U019N and 0U020N.A has been blocked and destined for disposal.
2.	7. Other information relevant to FSCA
	No other information to be shared.

	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 Customers are asked to: - dispose of all lots of SLsolution™ 0U019N and 0U020N.A, still available in their inventory, - trace the distribution status of all lots of SLsolution™ 0U019N and 0U020N.A (if applicable) and, if the devices have been further distributed / shipped out, to provide any involved customer with a copy of FSN-2025-0002 and its attachments.	
3.	2. By when should the action be completed?	Not time critical. The product must not be used if the included reagent is not colourless, as indicated in product's instructions for use (ref. EIFU013, Warning number 8: "*Do not use Copan SLsolution™ if the reagent is not clear/colourless (e.g. pink or yellow)*").
3.	3. Particular considerations for: Not applicable. Is follow-up of patients or review of patients' previous results recommended? Not applicable. It should be noted that the following indications are included in product's instructions for use (EIFU013): - Warning number 8: "*Do not use Copan SLsolution™ if the reagent is not clear/colourless (e.g. pink or yellow)*"), - Section INSTRUCTIONS FOR USE, clause 6: "*Homogenize the specimen by vortexing the test tube for at least 3 seconds at 2000-2500 rpm, checking that the specimen is actually suitable for seeding.*").	
3.	4. Is customer Reply Required?	Yes. Please fill in "*FSN-2025-0002 Attachment 1*" (acknowledgement form) and ""*FSN-2025-0002 Attachment 2*" (product disposal form).
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None As containment action, the current stock of items 0U019N and 0U020N.A has been blocked and destined for disposal.	

	A CAPA has been opened to investigate the causes of this increased defectivity and to identify related corrective actions (CAPA0000204).	
3	6. By when should the action be completed?	Unknown at present.
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
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?	
	Not applicable.	

	4. General Information	
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable.
4.	**3.** For Updated FSN, key new information as follows:	
	Not applicable.	
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:	
	Not applicable.	
4	6. Anticipated timescale for follow-up FSN	Not applicable.
4.	7. Manufacturer information (For contact details of local representative refer to first page of this FSN*)*	
	a. Company Name	COPAN ITALIA Spa
	b. Address	Via Francesco Perotti, 10 Brescia, ITALY 25125
	c. Website address	www.copangroup.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes.	
4.	9. List of attachments/appendices:	- *FSN-2025-0002 Attachment 1* (acknowledgment form) - *FSN-2025-0002 Attachment 2* (product disposal form)
4.	10. Name/Signature	Elisabetta Zanella Chief Regulatory Officer COPAN ITALIA Spa

	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.

Attachment 1
Urgent Field Safety Notice
FSN-2025-0002

SLsolution™ - Items 0U019N and 0U020N.A

Response is Required within 72 hours

I have read and understood the instructions provided in the FSN-2025-0002.

Yes _ No_

I was able to identify, segregate or discard the Product.

Yes _ No _

If No, please explain:

_____

_____

If Yes, please include information that is applicable for affected products, filling **FSN-2025-0002 Attachment 2**.

Authorized by:

Name: _____

Signature: _____

Title: _____

Date of revision: _____

PLEASE MAIL COMPLETED FORM TO:

Customer Care Team

COPAN ITALIA Spa

Via F. Perotti, 10

Brescia, Italy 25125

customercare365@copangroup.com

Copan Italia s.p.a.
Via F. Perotti 10,
25125 Brescia, Italy

S.S.N. e n. inscr. Business Register: 01740560170
P.IVA - ID VAT nr. IT 01740560170
Registered Capital: € 6.000.000 I.V.

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Attachment 2
Urgent Field Safety Notice
FSN-2025-0002

SLsolution™ - Items 0U019N and 0U020N.A

Response is Required

I hereby declare that the following products have been handled according to the instructions provided in the FSN-2025-0002.

Product Name	Product code	Lot Nr	Received qty (pcs)
SLsolution™	*[product code]*	*[lot number]*	*[received qty]*

Please fill in the following table with all the requested traceability information:

Product code	Lot Nr	Received qty (pcs)	Qty in inventory (pcs)	Qty segregated/ destroyed (pcs)	Qty distributed / shipped / sent out (pcs)
[product code]	*[lot number]*	*[received qty]*			

Please fill in the following table with all the requested information (Countries/product code/lot number/shipped qty).
Mark the following table as "NA" only if the product was NOT further distributed/shipped/sent out.

Country	Product code	Lot number	Shipped qty

Copan Italia s.p.a.
Via F. Perotti 10,
25125 Brescia, Italy

S.S.N. e n. inscr. Business Register: 01740560170
P.IVA - ID VAT nr. IT 01740560170
Registered Capital: € 6.000.000 I.V.

t | f +39 030 2687211
@ | info@copangroup.com
www.copangroup.com

Authorized by:

Name: _____

Signature: _____

Title: _____

Date of revision: _____

PLEASE MAIL COMPLETED FORM TO:

Customer Care Team

COPAN ITALIA Spa

Via F. Perotti, 10

Brescia, Italy 25125

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