Field Safety Notice (FSN)
HistoPot 5L (S10-B-FOR-5L T/P)
Incorrect expiry date on label

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Container suitable for single use and storage, transportation and fixation of samples.
1.	2. Commercial name(s)*
	HistoPot 5L
1.	3. Unique Device Identifier(s) (UDI-DI)
	05391513872006
1.	4. Primary clinical purpose of device(s)*
	For in vitro diagnostic use. The HistoPot 10% neutral buffered formalin specimen container is intended for use as a fixative in the processing of biological tissues or clinical samples. Containers with 10% buffered neutral Formalin for histological samples are used in clinical and histopathological laboratories for in vitro diagnostics. Tissue samples taken from patients are placed in containers with 10% buffered neutral formalin. HistoPot formalin containers are designed for convenient transportation and fixation of samples of biological tissues or clinical samples of a patient for subsequent processing and analysis in a histopathological laboratory. The HistoPot pre-filled specimen containers are used for collection of tissue samples from patients by trained personnel. The HistoPot pre-filled specimen containers are not to be used by laypersons or patients. The 10% neutral buffered formalin contained in the specimen containers is not to be removed from the container or applied topically to the body of a patient.
1.	5. Device Model/Catalogue/part number(s)*
	S10-B-FOR-5L T/P
1.	6. Software version
	Not applicable.
1.	7. Affected serial or lot number range
	15052524312
1.	8. Associated devices
	Not applicable.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	A data input error in the expiry date on the label of lot number 15052524312 of HistoPot 5L (S10-B-FOR-5L T/P) has been identified. The expiry date indicated on the label is 2024-08, which is incorrect. The correct expiry date of this product is 2028-04. This data input error in the expiry date on the label of the product does not affect the functionality or performance of the product. If this product has already been used, there is no risk to the patient or user.

Date: 2025:07:28

Field Safety Notice
HistoPot 5L (S10-B-FOR-5L T/P)

For Attention of*:Hospital Stores, Theatre Staff, Medical Laboratory Scientists, Distributors

Contact details of local representative (name, e-mail, telephone, address etc.)*
Serosep Ltd., **Annacotty Business Park,** **Annacotty,** **Limerick,** **Ireland.** **Email: support@serosep.com** **Tel: +353 61 358190** **www.serosep.com**

Catalogue Number	Lot Number	INCORRECT expiry date (currently stated on the label)	CORRECT expiry date
S10-B-FOR-5L T/P	15052524312	2024-08	2028-04

2.	2. Hazard giving rise to the FSCA*
	The expiration date printed on the label is incorrect. However, the product is not currently expired. Due to the error in the expiry date on the label of this product, users will assume that the product is expired. If the product is used for storage, transportation and fixation of samples, theatre staff or medical laboratory scientists may assume the product is defective and the sample has not been fixed. The sample may be discarded and not used in the histopathology procedures to which it was intended to be used, causing unnecessary disposal of patient samples.
2.	3. Probability of problem arising
	The probability of this problem arising is low, as it is expected that the expiry date of the product would be checked before the product is used by hospital staff.
2.	4. Predicted risk to patient/users
	Indirect harm to the patient and no harm to the user. The likelihood of occurrence of this hazard is rare. The probability of injury occurring to the patient is unlikely, but possible. The severity of the injury or adverse health outcome would be temporary but significant impairment. The predicted risk of this hazard to a patient is low.
2.	5. Background on Issue
	A customer reported that the expiry date indicated on the label of lot number 15052524312 of HistoPot 5L (S10-B-FOR-5L T/P) was 2024-08, while the delivery docket stated the expiry date as 2028-04. Upon investigation of the manufacturing record sheet, it was found that the incorrect expiry date was added to the label.

	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
	Lot number 15052524312 of HistoPot 5L (S10-B-FOR-5L T/P) is being recalled. Please quarantine and return all affected products with immediate effect.

3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No No patient follow up is required. This issue does not affect the functionality or performance of the product.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer*** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None A Field Safety Corrective Action and this Field Safety Notice have been created to inform customers that lot number 15052524312 of HistoPot 5L (S10-B-FOR-5L T/P) is being recalled. None of this product remains in stock at Serosep Ltd. This issue is being investigated through Serosep's Quality Management System to prevent reoccurrence.	
3.	6. By when should the action be completed?	8th August 2025
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

	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	Serosep Ltd
	b. Address	Annacotty Business Park, Annacotty, Limerick, Ireland
	c. Website address	www.serosep.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	If extensive consider providing web-link instead.

4.	6. Name/Signature	Dermot Scanlon, CEO 28 July, 2025 D Scanlon

	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.