Date: 2026:02:17

Field Safety Notice
HistoPot 180ml (S10-B-FOR-180ML)

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

Contact details of local representative (name, e-mail, telephone, address etc.)*
Serosep Limited, **Annacotty Business Park,** **Annacotty,** **Limerick,** **Ireland.** **Email: support@serosep.com** **Tel:+353 61358190** **www.serosep.com**

Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

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 180ml
1.	3. Unique Device Identifier(s) (UDI-DI)
	05391513871863
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-180ML
1.	6. Affected serial or lot number range
	16102525141 EXP: 2028-08 **22102525142** EXP: 2028-09 **11112525061** EXP: 2028-09 **20112525309** EXP: 2028-10 **08012625528** EXP: 2028-11

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	An issue was found that the automation line used to manufacture HistoPot 180ml could lead to a random occurrence of a defect in the plastic forming a chip in the rim of HistoPot 180ml pots along with a loose cap.

2.	2. Hazard giving rise to the FSCA*
	The risk is that if the cap is not fully tightened and the pot is not handled in accordance with the IFU, it may lead to the pot leaking if it is not in an upright position. This could lead to an indirect harm to a patient if the pot was used for a biopsy or harm to a user due to exposure to formalin solution.
2.	3. Probability of problem arising
	The probability of this problem arising is low. The current rate of occurrence predicted is <2% of HistoPot 180ml pots.
2.	4. Predicted risk to patient/users
	Indirect harm to the user and harm to the user if not following correct procedures for dealing with formalin. The likelihood of injury occurring 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 the patient or user is low.
2.	5. Other information relevant to FSCA
	This FSCA does not impact any other HistoPot product sizes. Only the HistoPot 180ml are affected.

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 The lot numbers listed above may have an increased occurrence of leaking/spillage due to loose caps. Serosep are asking users to be vigilant on receipt of HistoPot 180ml to ensure that all pots are handled as per the IFU and kept upright.	
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 if there was no incident of spillage	
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
☐ Software upgrade
☒ Other
☐ On-site device modification/inspection
☐ IFU or labelling change
☐ None

A Field Safety Corrective Action and this Field Safety Notice have been created to inform customers that the lot numbers listed above may have an increased occurrence of leaking/spillage due to loose caps.
Serosep are currently performing 100% inspection on all 180ml HistoPots before dispatch to customers. This issue is being further investigated through Serosep's Quality Management System to prevent reoccurrence.

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 Limited
	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. Name/Signature	Susan Dwane, Compliance Manager and PRRC Signed by Susan Dwane I approve this document 17-Feb-26 | 11:41:11 AM GMT 9CA214450D404EABA064BD6D615CE3DC

	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.