Urgent Field Safety Notice

S-Cryolock Lot # S220615-B

Type of action: Voluntary Recall

Date: March 30, 2023

For Attention of*:

Name of the ship-to party	Address	Postal code	Distributor	Location of the ship-to party	Name of sold-to party

Contact details of local representative (name, e-mail, telephone, address etc.)*
Importer: FUJIFILM Europe B.V. Contact person: Johann Zauner Head of Compliance QA/RA & Environment, Corporate Division phone: +49 (0) 2102 5364 137 email: johann.zauner@fujifilm.com FUJIFILM Europe GmbH Balcke-Dürr Allee 6 40882 Ratingen, Germany

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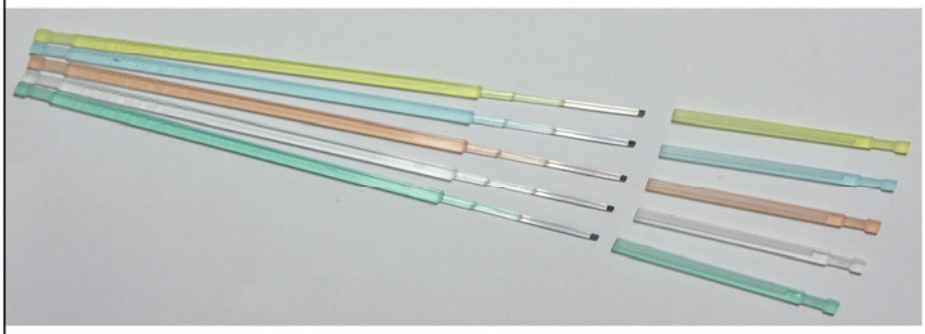
Type of action: Voluntary Recall

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	S-Cryolock® is designed to hold, cryopreserve, and store oocytes or embryos under Liquid Nitrogen (LN2) temperatures. S-Cryolock® is square shape sticks, with 4 flat surfaces. Both, cap and body are produced from the same material (polystyrene medical grade). The cap and body possess the same coefficient of expansion, ensuring an equally secure coupling at room temperature as well as at low cryogenic temperatures facilitating even temperature conduction from each side of the device. Body and cap have gaps on their extremes that allow easy grip with forceps during handling. S-Cryolock® is duly sterilized by gamma radiation. Available in five different colors: blue, green, clear, yellow, and orange, for easy traceability in laboratory. Available in pouches of five devices of the same color as primary packaging and a box with 10 pouches for a total of 50 devices or a box with 2 pouches for a total of 10 devices. 
1.	2. Commercial name(s)
	S-Cryolock
1.	3. Unique Device Identifier(s) (UDI-DI)
	Primary packaging (pouch): +B056SCLB1 Secondary packaging (box of 10 pouches): +B056SCLB2
1.	4. Primary clinical purpose of device(s)*
	S-Cryolock devices are cryopreservation storage devices that are intended for use in vitrification procedures to contain and maintain human 1-cell stage embryos. For non-US countries: for Oocytes and/or Embryos.
1.	5. Device Model/Catalogue/part number(s)*
	S-CL
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot # S220615-B
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*

2.	1. Description of the product problem*
	FUJIFILM Irvine Scientific USA exported a S-Cryolock lot # S220615-B, which was created for markets that did not require the CE mark. The product was manufactured during the transition period of the expiration of the MDD certificate (2022-04-17) and obtaining the MDR certificate (2022-11-09), which is the reason why the label did not contain the EU representative information nor the CE mark. The production processes and materials of the non-CE marked product is equal to the product that contains CE marking, which complies with the quality standards.
2.	2. Hazard giving rise to the FSCA*
	The only major risk identified was that the exporter (FUJIFILM Irvine Scientific, Inc) and importer (Fujifilm Europe B.V.) accepted and placed on the market product that was not CE marked. (Exportation / importation issue). The production processes and materials of the non-CE marked product is equal to the product that contains CE marking, which complies with the quality standards. No additional safety and performance risks were identified for the end-user (embryologists) and embryos/oocytes because there is not CE mark.
2.	3. Probability of problem arising
	This is the first occurrence of this event during the last 11 years. The probability is low.
2.	4. Predicted risk to patient/users
	Non new predicted risk to end-users due to use of S-Cryolock product without CE mark.
2.	5. Further information to help characterize the problem
	Incorrect lot picked for shipment.
2.	6. Background on Issue
	Biotech became aware by email from FUJIFILM Product Compliance QA/RA Team on Monday March 27, 2023, notifying the incident that they received a batch of S-Cryolock lot number S220615-B that were missing the CE mark. Since then, Biotech has been in contact with FUJIFILM Irvine Scientific, Inc, Fujifilm Europe B.V, Fujifilm distributors in Europe to identify the customers involved, how many devices were delivered and shipment records of the lot in question. Event overview: One lot (35 boxes of 50 devices) of S-Cryolock Blue, S220615-B shipped to Europe. 19 boxes sent to 14 customers in 6 countries (Spain, Italy, Germany, France, Portugal and Greece) through the following distributors: Fujifilm Europe B.V., Fujifilm Italy, Fujifilm Spain, Fujifilm France, and Fujifilm Portugal. 16 boxes remaining in importer Fujifilm Europe B.V inventory and blocked. Root cause identified by FUJIFILM Irvine Scientific, Inc is: Incorrect lot picked for shipment – Human error. Containment Action: Importer / distributor will call customers who purchase the involved lot to inform of the issue and advise to quarantine or return the unused product. Importer / distributor provide refunds or replacements of unused units, and provide information back to Biotech for closure.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User* ☐ 1. Identify Device ☐2. Quarantine Device ☒ 3. 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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: None Is follow-up of patients or review of patients' previous results recommended? None No required because the quality of the product is not in question. This is an exporter/importer issue.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes 2 days from notification.
3.	5. Action Being Taken by the Manufacturer ☒ Product Removal ☐On-site device modification/inspection ☐ Software upgrade ☐IFU or labelling change ☐ Other ☐None	
3.	6. By when should the action be completed?	15 to 30 days from notification.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
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?	
	N/A	

	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? *	None.
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 page 1 of this FSN)	
	a. Company Name	Biotech Inc
	b. Address	5975 Shiloh Rd, Suite 101 Alpharetta GA 30005 USA
	c. Website address	www.cryolock.info.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes, in process.	
4.	9. List of attachments/appendices:	None
4.	10. Name/Signature	[redacted] CEO

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organizations 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.