

Urgent Field Safety Notice

Product Name: Vitrification Freeze Kit, Catalogue Number: 90133-SO

Type of Action: Advice given by Fujifilm Irvine Scientific, Inc.

October XX, 2021

Attention:

Contact Name

Company

Address – Line 1

Address – Line 2

Dear Valued Distributor-

This second letter is to provide supplemental information about the Vitrification Freeze Kit:

Details on affected devices:

Vitrification Freeze Kit, 90133-SO

Lot number 90133-SO210605

Expiration Date 2022-04-30

Description of the problem:

A portion of the Vitrification Freeze kit (Catalogue No. 90133-SO, Lot Number 90133-SO210605) component, the VS Vitrification Solution (Part No. 90132, Lot No. 90132210403) vials, was mislabeled with an incorrect expiration date of 2023-04-30 (a 24-month expiration date). The correct expiration date is 2022-04-30 (a 12-month expiration date).



90132 Component Label



90132 Component Label

The expiration date on the device box label, Vitrification Freeze Kit (Catalogue No. 90133-SO, Lot Number 90133-SO210605), and corresponding COA are correct.

There is no effect on the safety or efficacy of the Vitrification Freeze Kit product and the product is safe to use when used in accordance with the expiration date on the kit box label and per the IFU.

In the event that the device is used beyond the expiration date as indicated on the kit label and COA, it may not perform as intended, and may negatively impact the overall sperm survival rate post-thaw.

Advise on action to be taken by the Distributor:

- Use the product in accordance with the expiration date on the kit box (April 30, 2022)
- Product kits that had already been distributed could continue to be used in accordance with the Instructions for Use (IFU), as instructed “these two solutions are to be used in sequence according to the step-wise microdrop vitrification protocol”.
- Review the attached Distributor Data Collection Form
- Review the provided Customer Notification Letter Template and input your contact information.
- Contact all affected customers and collect completed Customer Data Collection Form
- Sign and date the form and return it to fisira@fujifilm.com upon successful notification of all customers (100% notification).

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. For your convenience, a Customer Notification Letter Template is provided, please see attached.

Contact reference person:

FUJIFILM Irvine Scientific, Inc.
Attention: Ashley Werner
1830 East Warner Avenue
Santa Ana, CA 92705-5505
800 437 5706 | 949 261 7800 | Fax: 949 261 6522
Email: FISIRA@fujifilm.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

We regret any inconvenience that this action may cause and appreciates your understanding and cooperation. Please be assured that we take great pride in the quality and service that we provide to our customers and look forward to continuing to assist you in your future needs. Please feel free to contact us via email, fisira@fujifilm.com or by phone at 1 (949) 261-7800 if you prefer to have your kits replaced or if have any further questions regarding this matter.

Ashley Werner

Associate Director, Global Regulatory Affairs & Product Compliance

FUJIFILM Irvine Scientific

Cell: +1 714.721.8027

Phone: +1 949.261.7800 x297

1830 E Warner Avenue

Santa Ana, CA 92705, USA

[Website](#) | [LinkedIn](#)

Distributor Data Collection Form

PLEASE COMPLETE AND PROMPTLY RETURN THIS DATA COLLECTION FORM TO FUJIFILM IRVINE SCIENTIFIC

Via e-mail to: fisira@fujifilm.com.

The objective of this Data Collection Form is to provide FUJIFILM Irvine Scientific, Inc. (FISI) with information concerning your inventory receipt and distribution of Vitrification Freeze Kit, 90133- SO, Lot number 90133-SO210605.
If there are any questions regarding this form, please contact fisira@fujifilm.com.

When completed, please sign and scan the document and email it to fisira@fujifilm.com.

ACTIONS TO BE TAKEN BY DISTRIBUTOR, <insert Name>

Please check/complete the appropriate response:

- We have NOT received the affected product.
- We DO have the affected product and provide details immediately below*

Item	Response
# of kits of 90133-SO210605 received	
# of kits distributed	
# of customers who received kits	
# of kits remaining in inventory	

*If Distributor has affected product in inventory, please contact FISI for return & replacement.

ACKNOWLEDGEMENT OF RECEIPT AND UNDERSTANDING OF LETTER

Please check/complete the responses:

- We have read and understand this letter. We will contact FISI regarding any remaining inventory.
- We hereby certify that we have promptly and properly notified our customers/end users by providing a copy of the provided notification letter.

Signature:

Date: