

Urgent Field Safety Notice

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

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

September XX, 2021

Attention:

Contact Name

Company

Address – Line 1

Address – Line 2

Dear Valued Customer-

This letter is to provide information regarding 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, and corresponding COA are correct.

Distributor Letterhead

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 user:

- Use the product in accordance with the expiration date on the kit box (April 30, 2022)
- Continue to use the product 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”.
- Complete the attached Data Collection Form
- Sign and date the Data Collection Form and return it to <Distributor Name>.

Contact reference person:

<FISI Distributor Name, address, contact details>

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We regret any inconvenience that this action may cause and appreciate 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, <Insert email> or by phone at <Insert Phone Number> if you prefer to have your kits replaced or if have any further questions regarding this matter.

<Insert Signature Information>

Data Collection Form

PLEASE COMPLETE AND PROMPTLY RETURN THIS DATA COLLECTION FORM TO <Distributor Name> via e-mail to: <distributor contact info>

The objective of this Data Collection Form is to provide the manufacturer, FUJIFILM Irvine Scientific, Inc. (FISI) with information concerning your inventory receipt and usage of Vitrification Freeze Kit, 90133-SO210605. If there are any questions regarding this form, please contact <Distributor information>

When completed, please sign and return the completed document via email to <Distributor email>.

Please complete below tables:

Table 1: Customer Information

Item	Response
Facility Name	
Facility Address	
Completed by	
Title	
Phone	
Email	
Date	

Table 2: Product Information

Item	Response
# of kits of 90133-SO210605 received	
# of kits consumed	
# of kits remaining in inventory	

ACKNOWLEDGEMENT OF RECEIPT AND UNDERSTANDING OF LETTER

Please check/complete the responses:

We have read and understand this letter.

Signature: _____

Date: _____