



FUJIFILM Irvine Scientific, Inc.
1830 East Warner Ave
Santa Ana, CA 92705

FSCA Attachment 1

Revised Distributor FSN

Urgent Field Safety Notice

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

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

November 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 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 have not yet had your kits replaced or if you 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:



FUJIFILM Irvine Scientific, Inc.
1830 East Warner Ave
Santa Ana, CA 92705

FSCA Attachment 2

Revised Customer FSN

Urgent Field Safety Notice

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

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

November XX, 2021

Attention:

Contact Name

Company

Address – Line 1

Address – Line 2

Dear Valued Customer-

This revised Field Safety Notice is to provide supplemental 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 certificate of analysis (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 survival rate post-thaw.

Advise on action to be taken by the user:

If you still have inventory that bears an expiration date of April 30, 2022 (Lot No. 90133-DSOC210605), we ask that you inform your staff as to the contents of this letter. To assist you in doing so, included in this Notification is a small placard with information about the mislabeled product that instructs personnel to verify that the product is within its expiration date based on the outer kit date when selecting it for use. We ask that you **place a copy of the placard inside each affected box of your** remaining Vitrification Freeze Kits (Lot No. 90133-DSOC210605) in your inventory until affected product is depleted or discarded on April 30, 2022 to ensure that the product is used by the April 30, 2022, expiration date.

We kindly request that you promptly check your inventory and complete the attached revised Data Collection Form and return to us. Please complete the form, even if you have previously completed and provided the form. Complete the form as follows:

- Fill in the Customer Information in Table 1;
- Review your current inventory for Vitrification Freeze kits and fill in the Product Information for Table 2;
- Read each of the check box items to select the appropriate box(es); and
- 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	

Please select one of the following boxes:

- We do NOT have any remaining affected product, as all product has been used, and details were provided above in Table 2.
- We DO have the affected product, and details were provided above in Table 2, we have notified all staff of the issue and placed the Placard **inside each box** of the current inventory of the Vitrification Freeze Kit.

ACKNOWLEDGEMENT OF RECEIPT AND UNDERSTANDING OF LETTER

Please check/complete the responses:

- We have read and understand this letter.

Signature:

Date:

FUJIFILM Irvine Scientific, Inc.
1830 East Warner Ave
Santa Ana, CA 92705

FSCA Attachment 3 Placard

Important Notice

Re: Fujifilm Irvine Scientific Vitrification Freeze Kit

Catalog #90133-SO Lot No. 90133-SO210605

Please verify that the kit is used by the kit expiration date on the box label: 04/30/2022

Please note that in some cases, the Vitrification Solution- VS contained within the kit may be labeled 04/30/2023 and should only be used until the kit's expiration date of 04/30/2022.

For more information, please reach out to: Ashley Werner, FISIRA@FUJIFILM.COM

Please place **this placard inside each affected kit box in your inventory** until all kits bearing the 04/30/2022 expiration date are consumed or the kits reach their expiration date of 04/30/2022 and are removed from inventory