

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

FUJIFILM Irvine Scientific, Inc.

**URGENT FIELD SAFETY NOTICE  
(MEDICAL DEVICE RECALL)  
ISolate, Catalog #99264-2x100mL**

**Date:** 2 November 2023  
**Device Name:** ISolate  
**Device Type:** Sperm separation Kit  
**Catalog #:** 99264-2x100mL  
**Lot #:** 0000020693  
**Attention:** <Name Title>  
<Facility Name>  
<Facility Address>

Dear Valued Customer,

The purpose of this Field Safety Notice is to advise you that FUJIFILM Irvine Scientific, Inc. is voluntarily recalling ISolate lot 0000020693 (the “Product” or the “Kit”).

**Reason for the Voluntary Recall:**

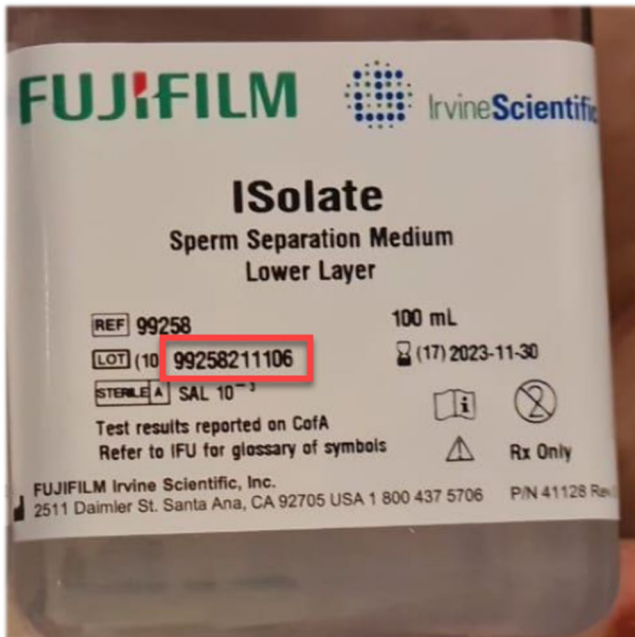
The FISI Product is a sperm separation Kit which is intended for the separation of the motile fraction of sperm from seminal fluid for assisted reproductive procedures that involve the manipulation of human sperm. The Kit contains two components: the Upper and the Lower Layer components. According to the certificate of analysis (“COA”), the Product should contain Isolate Upper Layer Lot 0000020682 and ISolate Lower Layer Lot 0000020686.

[Click here to enter text.](#)

[Click here to enter text.](#)

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

FUJIFILM Irvine Scientific received one (1) report where the lot number of the Lower Layer component within the Product did not match the lot number on the COA. Instead of containing Isolate Lower Layer with Lot number **0000020686 with a shelf life of 31 December 2024** it was reported that the Kit incorrectly contained ISolate Lower Layer with Lot number **9925811106 and a shelf life of 30 November 2023**, as illustrated below:



Our investigations indicate only some kits of the Product contain the incorrect Lower Layer lot number. While both Lower Layer lots listed above met all final Product release specification, only Lot 0000020686 should be within the Kit per the COA.

**Risk to Health:**

Our investigations conclude that the potential incorrect lot number of ISolate Lower Layer within the Kit will not result in a risk to patient health. However, ISolate Lower Layer Lot 9925811106, which was incorrectly found in the Kit, will expire on **30 November 2023**, earlier than ISolate Lower Layer Lot 0000020686 which has an expiration date of 31 December 2024. Therefore, it is important that users confirm the ISolate Lower Layer Lot number within the Kit they received.

**Actions to be taken by you:**

If you have any of the ISolate, Lot 0000020693 at your facility, we request that you:

[Click here to enter text.](#)

[Click here to enter text.](#)

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

1. Immediately confirm the lot number of the ISolate Lower Layer, catalog #99258, contained in the kit at your facility (Lot 0000020686 being the correct lot number).
2. If the ISolate Lower Layer lot number is incorrect per the COA (not with lot number 0000020686), please stop using the FISI Product, return/destroy it, and request a replacement or credit for the FISI Product amount.

Note: As stated above, in the event that the incorrect lot number of ISolate Lower Layer was already utilized or is being utilized as of the date of this notification, there are no anticipated performance issues or risk to patient health.

3. Please complete and return the enclosed **Field Safety Notice Customer Reply Form**.
4. Email the completed **Field Safety Notice Customer Reply Form** to [fisira@fujifilm.com](mailto:fisira@fujifilm.com) by **8 November 2023**.

We will provide credit for this Product or replacement Product promptly. In addition, we want to let you know that the national Competent (Regulatory) Authority of your country has been informed about this communication to our customers.

### **Transmission of this Notice**

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected Product has been transferred, as appropriate. Please also transfer this notice to other organizations on which this action has an impact, as appropriate.

Please maintain awareness of this notice and resulting actions for an appropriate period to ensure effectiveness of the recall.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority of your country if appropriate, as this provides important feedback.

If you need any further information or support concerning this, please reach out to our company representative, Melissa Gomez, Customer Service Manager, Medical Business:

- Toll free telephone number in the US: 1.800.577.6097
- Telephone number: 1.949.261.7800 x457
- Email: [fisitmrequest@fujifilm.com](mailto:fisitmrequest@fujifilm.com)

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

FUJIFILM Irvine Scientific places the highest priority on the quality of all our products. This action is intended to reflect this priority and to preserve your confidence and trust in our products.

We thank you for your partnership, and we remain at your disposal to respond to any questions that you may have in relation to this request.

Best regards,

<Name Title>

<Facility Name>

<Facility Address>

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

**Field Safety Notice Customer Reply Form**  
**Acknowledgement and Receipt Form**  
**Response is Required**

<b>Field Safety Notice (FSN) information</b>	
FSN Reference number	FSN2023-003
FSN Date	2 November 2023
Product/ Device name	ISolate
Catalog #	99264-2x100mL
Lot Number (s)	0000020693

<b>Customer Details</b>	
Account Number	
Healthcare Organization Name	
Organization Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

Click here to enter text.

Click here to enter text.

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

## ISolate, Catalog #99264-2x100mL

Please confirm the quantity of ISolate 0000020693 (“ISolate Kit”) received at your facility, the quantity already consumed, and the Lot number appearing on the bottle of the ISolate Lower Layer contained in the Isolate Kit.

Quantity of ISolate Kit Received	Quantity ISolate Kit already consumed	Quantity Confirmed to have correct ISolate Lower Layer Lot, 0000020686	Quantity with incorrect ISolate Lower Layer Lot	Quantity to be destroyed	Quantity to be returned

<b>Action undertaken by Customer’s Healthcare Organization</b>	
<input type="checkbox"/>	I confirm receipt of the URGENT: Field Safety Notice and that I read and understood its content.
<input type="checkbox"/>	I performed all actions requested by the URGENT: Field Safety Notice.
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users within my organization or any organization to which my organization transferred any quantity of Isolate 0000020693 and executed.
<b>Print Name</b>	
<b>Signature</b>	
<b>Date</b>	

PLEASE SEND COMPLETED RESPONSE FORM VIA EMAIL TO: [FISIRA@fujifilm.com](mailto:FISIRA@fujifilm.com)

Click here to enter text.

Click here to enter text.