

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

FUJIFILM Irvine Scientific, Inc. – Urgent Field Safety Notice (product removal)

Date: 11 July 2023
Device Name: Oil for Embryo Culture
Device Type: Sterile light mineral Oil
Model #: 9305
Unique Device Identifier(s) (UDI-DI) : 08937270029305TH
Lot #: 0000015999
Attention: <Name Title>
<Facility Name>
<Facility Address>

Dear Valued Customer,

The purpose of this letter is to advise you that FUJIFILM Irvine Scientific, Inc. has become aware that your facility recently received an incorrect lot of **Oil for Embryo Culture, Catalog #9305**. Per the delivery note on your order, your facility should have received **lot 0000011349**; however, your facility received **lot 0000015999**. FUJIFILM Irvine Scientific Inc. recently performed a voluntary recall of **Oil for Embryo Culture, Catalog #9305**, which included **lot 0000015999**. Following this recall, Lot 0000015999 was placed in quarantine and should not have been shipped to you. You should immediately discontinue use of Lot 0000015999 and take the further actions described below.

Issue identified and potential risks

FUJIFILM Irvine Scientific received reports from a small number of customers concerning the performance of four lots of Oil for Embryo Culture, Catalog #9305. One of these four lots was Lot 0000015999. The complaints reported reduced blastocyst development, including complete degradation in some cases, during culture of human embryos. Additionally, some clinics performed Human Sperm Survival Assay (HSSA), as part of incoming, confirmatory Quality Control (QC) testing and reported low sperm motility.

While the four lots, including Lot 000015999, met all final product release specifications as reported on the Certificate of Analysis (CofA) before distribution, in response to the complaints,

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FUJIFILM Irvine Scientific conducted an extensive investigation and was able to detect oil toxicity for three of the four affected lots. These three affected lots included Lot 0000015999. Potential deficiencies in the affected lots of Oil for Embryo Culture may result in impairment of embryo development and result in poor blastocyst development or non-transferable blastocyst, resulting in the inability to perform the procedure.

As a result of this finding, all four lots of finished product of Oil for Embryo Culture, including Lot 0000015999, were recalled in an abundance of caution.

To the Company's knowledge, we have had no reports of any known patient death or serious injury associated with Lot 000015999, however, it is important that these devices **not** be used. This Field Safety Notice solely concerns Lot 000015999, which was wrongly shipped, and no other Oil Lots that were placed in quarantine following the voluntary recall are affected by this Field Safety Notice.

The product is not intended to come in contact with the patient and there is no evidence of any risk to health to the potential recipient of the embryo. Nevertheless, potential deficiencies in these lots of Oil for Embryo Culture may result in impairment of embryo development and result in poor blastocyst development or non-transferable blastocyst, resulting in the inability to perform the procedure.

Actions to be taken

If you have any of the above-referenced product Lot 0000015999 at your facility, we request that:

1. Immediately discontinue its use;
2. Quarantine any remaining product in inventory;
3. Return the products; and
4. Complete the reply form attached to this notice (importers/distributors and end users).

Your reply form should be sent to FISIRA@fujifilm.com by **17 July 2023**.

We will provide credit for product sales or replacement product as soon as possible. Please note that the Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Transmission of this Field Safety 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 devices have been transferred. (As appropriate)

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Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Please maintain awareness of this notice and resulting action 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 if appropriate, as this provides important feedback.

If you need any further information or support concerning this, please reach out to our company representative, Laura Wallace, Director of Marketing, Medical Business:

- Phone: 1.909.556.4270
- Email: Laura Wallace, laura.wallace@fujifilm.com

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 FUJIFILM Irvine Scientific products.

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

Best regards,

A large rectangular grey box redacting the signature of the sender.A series of five horizontal grey bars of varying lengths redacting the contact information of the sender.

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Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN2023-002
FSN Date	11 July, 2023
Product/ Device name	Oil for Embryo Culture
Product Code(s)	U0802
Lot Number (s)	0000015999

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

3. Customer action undertaken on behalf of Healthcare Organization	
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.
<input type="checkbox"/>	I performed all actions requested by the Field Safety Notice.
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.

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3. Customer action undertaken on behalf of Healthcare Organization			
<input type="checkbox"/>	Quantity of affected devices not available for destruction – enter number previously consumed	Qty:	Lot/Serial Number:
		N/A	Comments:
<input type="checkbox"/>	Quantity of affected devices available for return	Qty:	Lot/Serial Number:
		N/A	Comments:
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.		
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product). <i>Provide brief description of the inquiry and contact details, as applicable</i>		
Print Name			
Signature			
Date			

4. Return acknowledgement to sender	
Email	FISIRA@fujifilm.com
Customer Helpline	Laura Wallace, +1 909.556.4270
Postal Address	1830 E Warner Avenue Santa Ana, CA 92705, USA
Fax	+1.949.261.6522
Deadline for returning the customer reply form	July 17, 2023