

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

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

Date: January 16, 2023
Device Name: Oil for Embryo Culture
Device Type: Sterile light mineral Oil
Model #: 9305
Unique Device Identifier(s) (UDI-DI) : 08937270029305TH
Lot #: 0000011351, 0000011367, 0000015999, 0000016001
Attention: Satoru Nishimura
FUJIFILM Europ B.V
Oudenstaart 1, 5047, TK Tilburg, The Netherlands

Dear Mr. Satoru Nishimura,

The purpose of this letter is to advise you that FUJIFILM Irvine Scientific, Inc. is voluntarily recalling **Oil for Embryo Culture, Catalog #9305, Lots 0000011351, 0000011367, 0000015999, 0000016001.**

Issue identified and potential risks

FUJIFILM Irvine Scientific has received reports from a small number of customers concerning the performance of Oil Lots 0000011351, 0000011367, 0000015999, 0000016001. 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 lots listed above met all final product release specifications as reported on the Certificate of Analysis (CofA) before distribution, in response to the complaints, FUJIFILM Irvine Scientific conducted an extensive investigation and was able to detect oil toxicity for Lots 0000011351, 0000015999, and 0000016001. No toxicity was detected for the Lot 0000011367. However, all of these lots were derived from the same lot of Raw Material. Potential deficiencies

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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 finished product Lots sharing the same Raw Material, which include Oil for Embryo Culture Lots 0000011351, 0000011367, 0000015999, 0000016001, will be recalled in an abundance of caution.

To the Company's knowledge, we have no reports of any known patient death or serious injury associated with the affected lots, however, it is important that these devices are **not** used. No other Oil Lots 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 numbers at your facility, we request that:

1. Immediately stop selling the device (for importers/distributors)/discontinue their use (end users);
2. Quarantine any remaining product in inventory;
3. Return or destroy 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 **23 January 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)

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



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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.

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

- Phone: 1.949.261.7800 x457
- Email: Melissa Gomez, fisitmrequest@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,

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Chief Compliance & Quality Officer (CQO)

ISO Management Representative

FUJIFILM Irvine Scientific

Phone: +1 949.261.7800
1830 E Warner Avenue
Santa Ana, CA 92705, USA

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Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN2023-001
FSN Date	January 16, 2023
Product/ Device name	Oil for Embryo Culture
Product Code(s)	U0802
Lot Number (s)	0000011351 0000011367 0000015999 0000016001

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"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
<input type="checkbox"/>	Quantity of affected devices not available for destruction – enter number previously consumed	Qty:	Lot/Serial Number:
		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	Melissa Gomez, +1 949.261.7800 x457
Postal Address	1830 E Warner Avenue Santa Ana, CA 92705, USA
Fax	+1.949.261.6522

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4. Return acknowledgement to sender	
Deadline for returning the customer reply form	January 23, 2023

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Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN2023-001
FSN Date	January 16, 2023
Product/ Device name	Oil for Embryo Culture
Product Code(s)	U0802
Batch/Serial Number (s)	0000011351 0000011367 0000015999 0000016001

2. Distributor/Importer Details	
Company Name	
Account Number	
Address	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Distributors/Importers (Tick all that apply)	
<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.
<input type="checkbox"/>	I have checked my stock and quarantined inventory <i>Distributor/Importer to enter quantity, lot numbers and date</i>

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3. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list <i>Customer list may be redacted to conceal customer name as appropriate</i>	
<input type="checkbox"/>	I have informed the identified customers of this Field Safety Notice (attach additional list as needed)	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers (<i>attach additional list as needed</i>)	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Provide list totaling all quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form)
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Provide list with totaling quantity, Lot/Serial Number/Date Destroyed (same information as requested by the Customer Reply form)
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices remaining in inventory	Provide list with totaling quantity, Lot/Serial Number/Date product Consumed (same information as requested by the Customer Reply form)
	Print Name	
	Signature	
	Date	