

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
Lot #: 0000011351,0000011367, 0000015999, 0000016001

Dear Customers and Users of Oil for Embryo Culture

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 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.

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As a result of this finding, all finished product Lots sharing the same Raw Material, which include Oil 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 the 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**.
5. Notify and comply with all regulatory notification requirements in your country.

We will provide credit for product sales or replacement product as soon as possible.

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)

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@fujiilm.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,



Marlin Frechette
Chief Compliance & Quality Officer (CQO)
ISO Management Representative
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