

2023-02-10

**URGENT SAFETY INFORMATION
IMPLEMENTATION
PRODUCT RECALL
Denu-Tip / Oocyte Aspiration Needle**

Subject: Product recall Denu-Tip

Unfortunately we, Gynemed GmbH & Co. KG as manufacturer, have to inform you that we have to recall the products:

- **Denu-Tip** (REF.: GY-XXX/XX) with the batches 44200203, 44200203A, 44200303A, 44200403, 44210103, 44210203, 44210303, 44210403, 44220103, 44220203, 44220303, 44220403
- **Oocyte Aspiration Needle** (REF.: GY-XXXXXXLF(-XXX)) with the batches 71200401, 71210101, 71210201, 71210301, 71210401, 71220101, 71220201, 71220301, 71220401, 72210201, 72220201, 72220301, 72220401, 73210101, 73210201, 73220201, 73220301, 73220401, 74220301, 79210301, 79210401, 79220101, 79220301, 79220401, 79230101, 93200201, 93200301, 93200401, 93210101, 93210201, 93220201, 93220301, 93220401

During a recent supplier audit, our supplier was unable to provide adequate documentation of the required testing and raw material controls. Discrepancies were found in the performance of the Mouse Embryo Assay at batch release.

The performance of the MEA is considered the so-called gold standard and has been part of Gynemed's quality control for years. This serves to prove that the specification of $\geq 80\%$ development rate is not fallen short of within the production and at the time of release of the products.

So far, we have not received any negative feedback from the market. Accordingly, it is a preventive measure to ensure the highest quality and safety standards for which Gynemed stands.

Please ensure in your facility that all users of the above product and other persons to be informed are made aware of this urgent safety information.

Potential safety risk	<p>It cannot be ruled out that there is a material or production defect and therefore the specified product does not meet the safety and performance specifications.</p> <p>It cannot be ruled out with certainty that harm could be caused to the embryos and oocytes.</p>	
Details of the product concerned	<p>Denu-Tips REF: GY-XXX/XX</p> <p>Lot: 44200203 Expiry date: 30. Apr 2023</p> <p>Lot: 44200203A Expiry date: 30. Apr 2023</p> <p>Lot: 44200303A Expiry date: 31. Jul 2023</p> <p>Lot: 44200403 Expiry date: 31. Oct 2023</p> <p>Lot: 44210103 Expiry date: 31. Jan 2024</p> <p>Lot: 44210203 Expiry date: 30. Apr 2024</p> <p>Lot: 44210303 Expiry date: 31. Jul 2024</p> <p>Lot: 44210403 Expiry date: 30. Oct 2024</p> <p>Lot: 44220103 Expiry date: 31. Jan 2025</p> <p>Lot: 44220203 Expiry date: 30. Apr 2025</p> <p>Lot: 44220303 Expiry date: 31. Jul 2025</p> <p>Lot: 44220403 Expiry date: 31. Oct 2025</p> <p>Basic UDI-DI: 426017319DTIPS6E</p>	<p>Oocyte Aspiration Needle REF: GY-XXXXXXLF(-XXX)</p> <p>Lot: 71200401 Expiry date: 31. Oct 2023</p> <p>Lot: 71210101 Expiry date: 31. Jan 2024</p> <p>Lot: 71210201 Expiry date: 30. Apr 2024</p> <p>Lot: 71210301 Expiry date: 31. Jul 2024</p> <p>Lot: 71210401 Expiry date: 31. Oct 2024</p> <p>Lot: 71220101 Expiry date: 31. Jan 2025</p> <p>Lot: 71220201 Expiry date: 30. Apr 2025</p> <p>Lot: 71220301 Expiry date: 31. Jul 2025</p> <p>Lot: 71220401 Expiry date: 31. Oct 2025</p> <p>Lot: 72210201 Expiry date: 30. Apr 2024</p> <p>Lot: 72220201 Expiry date: 30. Apr 2025</p> <p>Lot: 72220301 Expiry date: 31. Jul 2025</p>

Oocyte Aspiration Needle

Lot: **72220401**
Expiry date: 31. Oct 2025

Lot: **73210101**
Expiry date: 31. Jan 2024

Lot: **73210201**
Expiry date: 30. Apr 2024

Lot: **73220201**
Expiry date: 30. Apr 2025

Lot: **73220301**
Expiry date: 31. Oct 2025

Lot: **74220301**
Expiry date: 31. Jul 2025

Lot: **79210301**
Expiry date: 31. Jul 2024

Lot: **79210401**
Expiry date: 31. Jan 2025

Lot: **79220101**
Expiry date: 31. Jan 2025

Lot: **79220301**
Expiry date: 31. Jul 2025

Lot: **79220401**
Expiry date: 31. Oct 2025

Lot: **79230101**
Expiry date: 30. Apr 2026

Lot: **93200201**
Expiry date: 30. Apr 2023

Lot: **93200301**
Expiry date: 31. Jul 2023

Lot: **93200401**
Expiry date: 31. Oct 2023

		<p>Oocyte Aspiration Needle</p> <p>Lot: 93210101 Expiry date: 31. Jan 2024</p> <p>Lot: 93210201 Expiry date: 30. Apr 2024</p> <p>Lot: 93220201 Expiry date: 30. Apr 2025</p> <p>Lot: 93220302 Expiry date: 31. Jul 2025</p> <p>Lot: 93220401 Expiry date: 31. Oct 2025</p> <p>Basic UDI-DI: 426017319FASD4</p>
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Intended Use	<p>Denu-Tip: The products are used for manipulating and transferring oocytes and embryos in the context of ART treatment. The intended users are specialized personnel (laboratory technicians, embryologists, medical specialists) in special fertility practices/clinics.</p> <p>Oocyte Aspiration Needle: The oocyte aspiration needles are used for transvaginal aspiration and flushing of oocytes from the ovarian follicles of women undergoing IVF treatment. The product is intended for single use on one patient. The intended users are specialized personnel (physicians, medical doctors) in fertility clinics. The product may only be used by specifically qualified personnel with appropriate expertise, experience, and training.</p>
Safety advice	<p>Do not use the products anymore. Risks related to embryotoxicity cannot be excluded with certainty.</p>
Product troubleshooting	<p>Gynemed GmbH & Co. KG recalls all products Denu-Tips and Oocyte Aspiration Needles of the affected batches distributed by them.</p> <p>Destroy the products and please send us a photo showing the number of destroyed products with item and lot number.</p> <p>Please do this within the next 24 h and please inform us within this time.</p> <p>In case the products have already been used, it would be very helpful for further investigation to receive feedback on the achieved results of the treatments.</p>
Contact details	<p>If you have any questions, please contact Dr. Julia Heinzmann, Phone: +49 (0)4363 9032914; Fax: +49 (0)4363 9032919 Mobile: +49 (0)170 5500193 <u>ra@gynemed.de</u></p> <p>Gynemed GmbH & CO. KG Lübecker Str. 9 23738 Lensahn Deutschland</p>

Enclosed with this letter is the Corrective Action Response Form. Please forward this letter together with the Corrective Action Response Form to the appropriate department(s) at your institution so that they may take note of the information contained herein, determine the need for action, and complete the Response Form.

For distributors

In case you are a distributor of Denu-Tips and Ooycte Aspiration Needles:

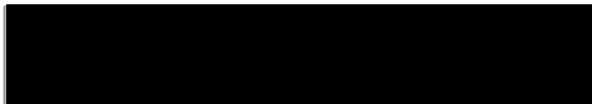
Please confirm to us in writing that you have informed your customers and instructed them to destroy or return the affected lots.

Please return the response form(s) to us within the next 24 hours!

We are extremely sorry if this action causes you any inconvenience and thank you for addressing the matter promptly.

Please contact us immediately if you have any questions.

With kind regards



Dr. Julia Heinzmann
Geschäftsführerin
Gynemed GmbH & Co. KG

PRODUCT RECALL RESPONSE FORM
Denu-Tips / Oocyte Aspiration Needle

Subject: Product Recall Denu Tips / Oocyte Aspiration Needle

Our records indicate that your facility has received products affected by this product recall.

1. please complete this form and return it by fax or e-mail to the following number/address:
+49 (0)4363 9032919, attention Dr. Julia Heinzmann or ra@gynemed.de

Please note: Please enter "None"/ "0" if you do not have any items to return.

Please remember to attach a photo where the quantity, batch and item number of the product concerned can be seen.

Article Nr.	Batch	Number in stock	Number disposed	Number returned

Comments / Feedback:

If you have any questions about this callback, please contact us at:

Tel: +49 (0)4363 9032914

Fax: +49 (0)4363 9032919

E-mail: ra@gynemed.de

Please confirm that your facility has received the urgent safety information by returning this form to Gynemed GmbH & Co. KG: +49 (0)4363 9032919 (Fax); ra@gynemed.de (E-Mail)

Representative of the user's institution Name and function in block letters	Signature:	Date:
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