

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 46 dated 01/3/2023 Regarding NCMDR Recall of Denu-Tip / Oocyte Aspiration Needle from (mfr: Gynemed GmbH & Co Kg).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





Circular No. 46/2023

نتقدم بثقة
Moving Forward
with Confidence



08-08-1444 H

01-03-2023

Recall of Denu-Tip / Oocyte Aspiration Needle from Gynemed Gmbh & Co Kg.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=18456
Product	Denu-Tip / Oocyte Aspiration Needle.
Description	Single use tips for IVF applications/Aspiration Needle for IVD applications
Manufacturer	Gynemed Gmbh & Co Kg.
The affected products	Refer to the attached FSN.
Reason	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. It cannot be ruled out with certainty that harm could be caused to the embryos and oocytes.
Action	1. Do not use affected products anymore. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Ph. Ahmed Al harbi

Acting Director General



Diamond Spectrum
To Att. Safety officer / risk manager
Al Batrji Street

23522 Jeddah
Saudi Arabia

Lübecker Str. 9 · D-23738 Lensahn

Tel.: +49 (0) 43 63/9 03 29-0

Fax: +49 (0) 43 63/9 03 29-19

E-mail: info@gynemed.de

Internet: www.gynemed.de

Geschäftsführerin: Dr. Julia Heinzmann

Amtsgericht Lübeck HRA 1886 OL

Zertifiziert gemäß:

DIN EN ISO 13485:2016

2023-02-08

**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.

<p>Potential safety risk</p>	<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. It cannot be ruled out with certainty that harm could be caused to the embryos and oocytes.</p>	
<p>Details of the product concerned</p>	<p>Denu-Tips REF: GY-XXX/XX</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: 31.10. 2023</p> <p>Lot: 71210101 Expiry date: 31.01.2024</p> <p>Lot: 71210201 Expiry date: 30.04.2024</p> <p>Lot: 71210301 Expiry date: 31.07.2024</p> <p>Lot: 71210401 Expiry date: 31.10.2024</p> <p>Lot: 71220101 Expiry date: 31.01.2025</p> <p>Lot: 71220201 Expiry date: 30.04.2025</p> <p>Lot: 71220301 Expiry date: 31.07.2025</p> <p>Lot: 71220401 Expiry date: 31.10.2025</p> <p>Lot: 72210201 Expiry date: 31.04.2024</p> <p>Lot: 72220201 Expiry date: 30.04.2024</p> <p>Lot: 72220301 Expiry date: 31.07.2025</p>

Oocyte Aspiration Needle

Lot: **72220401**
 Expiry date: 31.10.2025

Lot: **73210101**
 Expiry date: 31.01.2024

Lot: **73210201**
 Expiry date: 30.04.2024

Lot: **73220201**
 Expiry date: 30.04.2025

Lot: **73220301**
 Expiry date: 31.10.2025

Lot: **74220301**
 Expiry date: 31.07.2025

Lot: **79210301**
 Expiry date: 31.07.2024

Lot: **79210401**
 Expiry date: 31.01.2025

Lot: **79220101**
 Expiry date: 31.01.2025

Lot: **79220301**
 Expiry date: 31.07.2025

Lot: **79220401**
 Expiry date: 31.10.2025

Lot: **79230101**
 Expiry date: 31.04.2026

Lot: **93200201**
 Expiry date: 30.04.2023

Lot: **93200301**
 Expiry date: 31.07.2023

Lot: **93200401**
 Expiry date: 31.10.2023

		<p>Oocyte Aspiration Needle</p> <p>Lot: 93210101 Expiry date: 31.01.2024</p> <p>Lot: 93210201 Expiry date: 30.04.2024</p> <p>Lot: 93220201 Expiry date: 30.04.2025</p> <p>Lot: 93220302 Expiry date: 31.07.2025</p> <p>Lot: 93220401 Expiry date: 31.10.2025</p> <p>Basic UDI-DI: 426017319FASD4</p>
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<p>Intended Use</p>	<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>
<p>Safety advice</p>	<p>Do not use the products anymore. Risks related to embryotoxicity cannot be excluded with certainty.</p>
<p>Product troubleshooting</p>	<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>
<p>Contact details</p>	<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 ra@gynemed.de</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 Oocyte Aspiration Needles:

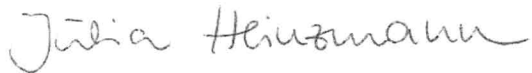
Please confirm to us in writing that you have informed your customers and instructed them to destroy or return the affected lots.

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

Diamond Spectrum
 To Att. Safety officer / risk manager
 Al Batrji Street
 23522 Jeddah
 Saudi Arabia

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: