

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 81 dated 30/4/2023 Regarding NCMDR Recall of Soft Denudation Tips and Follicle Punction Systems from (mfr: Reproline medical GmbH).

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



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

🐦 dgpa_dc Email: dg-padcc@moh.gov.om



Circular No. 81 / 2023

نقدم بأمان
Moving Forward
with Confidence

رؤية عمان 2040
Oman Vision 2040

09-10-1444 H

30-04-2023

Recall of Soft Denudation Tips and Follicle Punction Systems from Reproline medical GmbH.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=19508
Product	Soft Denudation Tips and Follicle Punction Systems.
Description	Contraception – others.
Manufacturer	Reproline medical GmbH.
The affected products	(please refer to attachment for more information).
Reason	In the past, there was a systematic error in the release process of the products. At present, the safety of the products with regard to embryotoxicity in particular cannot be demonstrably confirmed for all batches produced.
Action	1. Please return them to Reproline medical GmbH or destroy them. 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

/ Dr. Mohammed Hamdan Al Rubaie

Director General



PADC
المديرية العامة للصيدلة والرقابة الدوائية
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Reproline medical GmbH, Zeissstrasse 15, 53359 Rheinbach

February 12th, 2023

CUSTOMER ADDRESS

urgent safety information
PRODUCT RECALL
CONCERNING
SOFT DENUDATION TIPS AND FOLLICLE PUNCTION SYSTEMS

Dear Ladies and Gentlemen,

This letter is to inform you that we are conducting a voluntary product recall of the following products.

Please ensure that all users and necessary persons are informed of this urgent safety information.

Medical devices concerned:

Article	LOT	Prod. – Date	EXP - Date
Soft Denudation Tips	44200203	2020-04	2023-04
	44200303	2020-07	2023-07
	44200403	2020-10	2023-10
	44210103	2021-01	2024-01
	44210203	2021-04	2024-04
	44210303	2021-07	2024-07
	44210403	2021-10	2024-10
	44220103	2022-01	2025-01
	44220203	2022-04	2025-04
	44220303	2022-07	2025-07
	44220403	2022-10	2025-10
	44230103	2023-01	2026-01
Follicle puncture Systems	46200201	2020-04	2023-04
	46200301	2020-07	2023-07

Reproline medical GmbH

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info@reproline-ivf.de / www.reproline-medical.com

Managing Director Sparkasse

Ludger Hoppe / Thomas Willutzki IBAN

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St.Nr.: 222/5716/1135

VAT ID No. DE 812344275

Köln Bonn / Swift-Code COLSDE33XXX Volksbank

IBAN DE 96 3706 9627 0035 4330 15

Bonn Rhein-Sieg / Swift-Code GENODE1BRS

DE 56 3705 0198 0005 4049 26 IBAN DE 38 3806 0186 0706 9230

Köln / Swift-Code COKSDE33XXX

IBAN DE 38 3705 0299 0045 8438 69



ANNIVERSARY

Article	LOT	Prod. - Date	EXP - Date
Follicle puncture Systems	46200401	2020-10	2023-10
	46210101	2021-01	2024-01
	46210201	2021-04	2024-04
	46210301	2021-07	2024-07
	46210401	2021-10	2024-10
	46220101	2022-01	2025-01
	46220201	2022-04	2025-04
	46220301	2022-07	2025-07
	46220401	2022-10	2025-10
	46230101	2023-01	2026-01
	48200201	2020-04	2023-04
	48200301	2020-07	2023-07
	48200401	2020-10	2023-10
	48210101	2021-01	2024-01
	48210201	2021-04	2024-04
	48210301	2021-07	2024-07
	48210401	2021-10	2024-10
	48220101	2022-01	2025-01
	48220201	2022-04	2025-04
	48220301	2022-07	2025-07
	48220401	2022-10	2025-10
	71200201	2020-04	2023-04
	71200301	2020-07	2023-07
	71200401	2020-10	2023-10
	71210101	2021-01	2024-01
	71210201	2021-04	2024-04
	71210301	2021-07	2024-07
	71210401	2021-10	2024-10
	71220101	2022-01	2025-01
	71220201	2022-04	2025-04
	71220301	2022-07	2025-07
	71220401	2022-10	2025-10
	72200201	2020-04	2023-04
	72200301	2020-07	2023-07
	72200401	2020-10	2023-10
	72210101	2021-01	2024-01
	72210201	2021-04	2024-04
	72210301	2021-07	2024-07
	72210401	2021-10	2024-10
	72220101	2022-01	2025-01
	72220201	2022-04	2025-04
	72220301	2022-07	2025-07
	72220401	2022-10	2025-10
	73200201	2020-04	2023-04
	73200301	2020-07	2023-07
	73210201	2021-04	2024-04

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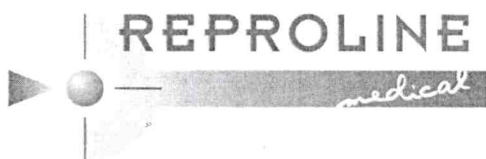
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IBAN DE38 3705 0299 0045 8438 89



Article	LOT	Prod. - Date	EXP - Date
Follicle puncture Systems	73210301	2021-07	2024-07
	73220101	2022-01	2025-01
	73220201	2022-04	2025-04
	73220401	2022-10	2025-10
	73230101	2023-01	2026-01
	79200201	2020-04	2023-04
	79200301	2020-07	2023-07
	79200401	2020-10	2023-10
	79210101	2021-01	2024-01
	79210201	2021-04	2024-04
	79210301	2021-07	2024-07
	79210401	2021-10	2024-10
	79220101	2022-01	2025-01
	79220201	2022-04	2025-04
	79220301	2022-07	2025-07
	79220401	2022-10	2025-10
	93200201	2020-04	2023-04
	93200301	2020-07	2023-07
	93200401	2020-10	2023-10
	93210101	2021-01	2024-01
	93210201	2021-04	2024-04
	93210301	2021-07	2024-07
	93210401	2021-10	2024-10
	93220101	2022-01	2025-01
	93220201	2022-04	2025-04
	93220301	2022-07	2025-07
	93220401	2022-10	2025-10

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Reasons for this recall:

In the past, there was a systematic error in the release process of the products. At present, the safety of the products with regard to embryotoxicity in particular cannot be demonstrably confirmed for all batches produced.

Health risk:

In the course of the risk assessment, the present situation was evaluated. The embryotoxicity that may be present could cause harm to embryos and oocytes. Therefore, customers are requested to return or destroy the products.

Do not continue to use the products. We ask you to check your stock to see if you have one or more products. **Please return them to us or destroy them and send us one or more meaningful photos clearly showing the number of affected LOT numbers you have destroyed.**

Once your inventory is complete, please sign and return the enclosed "Recall Confirmation and Return Form". This confirms that you have received the recall notification and that you intend to comply with it.

Please return the form within 24 hours.

We are very sorry for the inconvenience caused to you, please be assured that we are working to resolve the matter fully.

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**CONFIRMATION AND RETURN FORM FOR THE RECALL
SOFT DENUDATION TIPS & FOLLICLE PUNCTURE SYSTEMS**

CUSTOMER ADDRESS

I have read and understood the information given in
the letter of 12.02.2023.

Recall instruction read and understood

☐

exclusively to distributors:

I have my customers to whom these products were supplied
identified and notified. (Attach attachment, including date
and type of notification)

☐

TABLE WITH INFORMATION ON THE PRODUCTS CONCERNED

ART-No.	LOT	Delivered on	Delivered QTY	QTY destroyed
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FIELD FOR REPLY:

Please provide additional information if applicable.

A large, empty rectangular box with rounded corners, intended for the recipient to provide additional information.

Name / Title

Telephone number

Email address

Please send the completed reply by e-mail or FAX to:

e-mail: recall@reproline-ivf.de

Fax number: +49(0)2226/900555

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DE56 3705 0198 0005 4049 26 IBAN DE38 3806 0186 0706 9230

Köln / Swift-Code COKSDE33XXX

IBAN DE38 3705 0299 0045 8438 69



CONTACT INFORMATION

If you have any questions, please contact

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Mobile: +49(0)171/9573576
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With kind regards
Reproline medical GmbH

Ludger Hoppe
-Managing Director-

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