Lumenis (Germany) GmbH
Heinrich-Hertz-Str. 3
D-63303 Dreieich

Tel: +49-(0) 61 03-83 35-0
Fax: +49-(0) 61 03-83 35-300
www.lumenis.de

Eco-Med Pharmaceutical's Coupling Gel Recall Notification Letter

October 14, 2021

To our Valued Customer,

This letter is to inform you that FDA has recently recalled all coupling gels manufactured by Eco-Med Pharmaceutical Inc., some of which are distributed by Lumenis Be or its distributors worldwide. Our shipping records show that you have received one or more of the affected products within the last three years, which are subject to this recall.

Which product numbers are affected by this recall?
The following Coupling Gels: "EcoGel 200" with the following article number and contents:
AX1009012 (0.25 litre bottle),
AX1009013 (1-litre- bottle),
AX1009018 (12-pack with 0.25 litre bottles),
AX1009019 or AX1009063 (6-pack with 1-litre bottles)

Example of product labelling:

Who is the legal manufacturer of the product and its EU representative?
Eco-Med Pharmaceutical Inc. is the legal manufacturer of the product.
The EC representative is MDSS GmbH (Schiffgraben 41, Hannover Germany).

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In accordance with FDA's recall announcement, we ask you to immediately stop using and discard all Eco-Med's coupling gels due to risk of bacterial contamination with Burkholderia cepacia complex (Bcc). The effects of Bcc range from no symptoms to serious infections, including bloodstream infections that may result in sepsis or death. Though Lumenis Be has not received any health-related complaints regarding the coupling gel, we are committed to following FDA's guidance on this matter. See additional information of the FDA recall letter on the next page, which also requests to fill out the attached Recall Return Response Form.

Lumenis Be apologizes for any difficulty this situation may have caused you or your facility. We are committed to continue serving you in the best way possible. Following the FDA letter and Response Form, please see additional Q&A section to help clear any potential uncertainties. For any additional questions, please feel free to contact your local Lumenis Be support.

We value our relationship with you and regret for this unanticipated burden.

Sincerely,

Martin Steinborn
EMEA Technical Manager & QA Manager
Person Responsible for Regulatory Compliance" (PRRC) in accordance with Article 15 MDR
Laser safety officer
Eu.representative@lumenis.com
Lumenis (Germany) GmbH
Heinrich-Hertz-Str. 3
63303 Dreieich (Germany)

Martin Steinborn
Digitally signed by Martin Steinborn
Date: 2021.10.14 16:48:13 +02'00'

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URGENT MEDICAL DEVICE RECALL – Eco-Med's Coupling Gels

Attention: Health care facilities and distributors

This is to inform you of a product recall involving all coupling gels, originally manufactured by Eco-Med Pharmaceutical Inc.

We are instructing you to immediately stop using and discard all coupling gels manufactured by Eco-Med Pharmaceutical Inc. due to risk of bacterial contamination with *Burkholderia cepacia* complex (Bcc). The effects of Bcc range from no symptoms to serious infections, including bloodstream infections that may result in sepsis or death.

This product was shipped to you within the last three years.

Eco-Med initiated a voluntary recall on Aug. 4, 2021, to stop use of EcoGel 200 Ultrasound Gel due to risk of bacterial contamination. However, the FDA has determined that **all** ultrasound gels and lotions manufactured by Eco-Med are at risk for bacterial contamination.

The FDA's determination is based on concerns that Eco-Med did not complete its investigation of the issues, the root cause and extent of bacterial contamination was not identified, and multiple products could be affected by manufacturing issues associated with the company's ultrasound gel (such as inappropriate testing of finished product, inadequate testing of raw materials, and a lack of environmental controls).

Eco-Med has shut down all operations and is no longer manufacturing or distributing any products.

Description of the problem and health hazard:

The FDA recently received information from the CDC indicating that unopened bottles of nonsterile, multiuse ultrasound gel, manufactured by Eco-Med, tested positive for Bcc. While investigating this issue, the FDA independently confirmed that distributed product tested positive for bacterial contamination.

The effects of Bcc range from no symptoms to serious infections, including bloodstream infections that may result in sepsis or death. To date, the use of Eco-Med ultrasound gels has been associated with at least 59 infections, including 48 bloodstream infections. Additional possible infections may have been associated with the use of Eco-Med ultrasound gels.

Potential routes of transmission leading to bloodstream infections associated with a contaminated non-sterile ultrasound gel may include:

- Use of the gel for visualization prior to, in preparation for, or during an invasive procedure, where instruments are introduced into the patient's body, or
- Application of the gel inside the sterile ultrasound probe sleeve during an invasive procedure using ultrasound guidance

Contact Information:
Customers must contact Lumenis Be or its distributors by returning the attached (Recall Return Response Form) to confirm receipt of this notice by either scanning and e-mailing the completed form to: eu.representative@lumenis.com or sending it by Fax to: +49 (0) 6103 8335 300

In addition, if you have further distributed this product, please identify your customers, and notify them at once of this product recall by sharing this recall notification letter. Please complete the form indicating the product and the lot numbers you have identified and actions taken in the comment section.

Your assistance is appreciated and necessary to prevent any consumer illness or patient harm.

Health professionals, consumers and patients can voluntarily report observed or suspected adverse events for human medical products to FDA via the following link: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

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Recall Return Response Form

Please complete this response form even if you do not have any involved product by using one of the following methods.

a. Scan and e-mail the completed form to: eu.representative@lumenis.com

b. Fax the completed form to+49 (0) 6103 8335 300

c. Mail completed form to: Lumenis Germany GmbH
Heinrich-Hertz-Str. 3
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Please check ALL appropriate boxes.

- ☐ I have read and understand the recall instructions provided in the October 14, 2021 letter.
- ☐ I have checked my stock and I have no inventory of this product.
- ☐ I have checked my stock and have disposed or destroyed (ie. made unusable) of an inventory consisting of [ ] units.

Did you or your staff or patients experience any adverse events associated with recalled product? ☐ Yes ☐ No

If yes, please explain:_____

Please check the appropriate box(es) to describe the nature of your business:

- ☐ Wholesaler/Distributor
- ☐ Hospital/Medical/Clinic Facility
- ☐ Other: _____

Date: _____

Institution: _____ Telephone: _____

Address: _____ Country: _____

City: _____ State: _____ Zip Code: _____

Email: _____

Print Name: _____ Title: _____

Authorized Signature: _____

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Q&A Regarding Eco-Med's Coupling Gel Recall

Q: What product numbers are affected by this recall?
A: A: Die folgenden Coupling Gels: „EcoGel 200" mit folgender Artikelnummer und Inhalt:
AX1009012 (0,25-Liter-Flasche),
AX1009013 (1-Liter-Flasche),
AX1009018 (12er-Packung mit 0,25-Liter-Flaschen),
AX1009019 oder AX1009063 (6er-Packung mit 1-Liter-Flaschen)

Q: Why did FDA recall Eco-Med's gels?
A: FDA recalled Eco-Med's gels due to risk of bacterial contamination with Burkholderia cepacia complex (Bcc), with symptoms ranging from none to serious injury and even death. See the above FDA recall letter for further details.

Q: Is this recall relevant also outside of USA?
A: Yes. While FDA regulates medical devices in USA only, additional regulatory authorities may have already issued similar notifications, and this recall is in effect worldwide.

Q: I have used Eco-Med's coupling gel for years with no related adverse events. Can I continue using it?
A: No. FDA and other regulatory authorities worldwide have banned any use of Eco-Med's coupling gels, and we encourage you to fully adhere to the recall notification and not put yourself or your patients at risk.

Q: I have used Eco-Med's coupling gel many times, including recently. Do I need to alert my patients?
A: No, you do not need to alert your patients about this issue related to Eco-Med's coupling gel.

The FDA is concerned that ultrasound gels manufactured by Eco-Med Pharmaceutical, Inc., are at risk of containing a bacterial contamination with Burkholderia cepacia complex (Bcc). Bcc is an opportunistic human pathogen that most often causes pneumonia in immunocompromised individuals with underlying lung disease such as cystic fibrosis. Bcc organisms are typically found in water and soil and can survive for prolonged periods in moist environments. Bcc is not considered to be pathogenic to healthy people, therefore a short exposure to Eco-Med's Gel on intact skin during IPL/laser treatment is not expected to cause an infection in healthy patients. If you do learn of a patient that suffered from a skin infection after being exposed to Eco-Med's gel please contact your local Lumenis Be support.

Q: I have Eco-Med's coupling gel in my clinic. What should I do?
A: You should discard immediately any closed or opened bottles of Eco-Med's gels, and return the attached Recall Return Response Form by either scanning and e-mailing the completed form to: eu.representative@lumenis.com or sending it by Fax to: +49 (0)6103 8335 300

Q: I have patients scheduled for tomorrow to be treated with Lumenis IPL. Do I need to cancel their appointment?
A: The use of Lumenis Be IPL or M22/Stellar Nd:YAG requires an appropriate clear coupling gel. If you are able to use an alternative from a known supplier, you may keep using the device and keep your patient's appointment.

Q: Where can I get a coupling gel replacement?
A: Lumenis Be is currently in the process of validating alternatives to the Eco-Med coupling gel. In the meantime, you may use any approved clear coupling gel in your area in accordance with its directions for use.

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Q: I have ordered from Lumenis Eco-Med's coupling gel and have not yet received my order. Can I cancel it?

A: Please contact your local sales representative or distributor to check the option to cancel any pending order that was not yet delivered.