URGENT MEDICAL DEVICE RECALL
For Products Manufactured by Eco-Med®

August 25, 2021

Attention: Therapy/Rehabilitation Departments

ACTION REQUIRED:

Voluntary medical device recall is being conducted for products manufactured by Eco-Med, including but not limited to Omnisound® Gel and EcoGel® 200. The FDA and Eco-Med have confirmed bacterial contamination from yet unidentified sources.

Please take the following action:

1. Immediately stop use of, and destroy and render unusable by disposing along with your general medical waste, all products manufactured by Eco-Med and supplied by Accelerated Care Plus Leasing, Inc. (ACPL).

2. Please complete the attached form indicating the product you have identified, and actions taken.

3. In addition, if you have further distributed this product, please identify your customers, and immediately notify them of this product recall by sharing this recall notification letter.

Description of the problem and health hazard:

The FDA has determined that all ultrasound gel and lotion manufactured by Eco-Med are at risk for bacterial contamination by the Burkholderia cepacia complex (Bcc). The effects of Bcc infection on people vary widely, ranging from no symptoms at all to serious consequences. Bcc bloodstream infections may result in sepsis and in certain cases possible death.

Contact Information:

To contact ACPL directly with questions, call Mr. Lee Grasseschi, Manager Quality Assurance, at 775.336.1827.

Sub-recalls must take place where the ACPL customer has further shipped the product to their customers. Such sub-distributors should complete the attached form indicating the quantity of products identified, and actions taken.

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

Accelerated Care Plus Leasing
4999 Aircenter Circle, Suite 103, Reno, NV 89502
Web: acplus.com Tel: 800.350.1100 Fax: 800.350.1102

Please complete and return the enclosed response form as soon as possible. If you have any questions, please contact Mr. Lee Grasseschi.

This recall is being made with the knowledge of the Food and Drug Administration.

Sincerely,

Zlatko Larry Hodin
Director, Compliance and QA

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Eco-Med Product Recall Response Form
(including Omnisound Gel and EcoGel 200)

****** REPLY REQUIRED ******

Please complete ALL appropriate areas:

_____ I have read and understand the recall letter dated August 25, 2021.
(Initials)

Complete the below table for inventory on hand. If you have zero inventory, please put the quantity of zero in the table below:

Product	Unit of Measure	Quantity on Hand	Quantity Destroyed
EcoGel 200, Part No. 45539	250 ml bottle		
Omnisound Gel, Part No. 45539	250 ml bottle		
Omnisound Gel, Part No. 32060	5 Liter container		

Note: If you have case quantities of any gel, please include the number of bottles rather than the number of cases.

Follow all Federal, State, County, and City ordinances for disposal of general medical waste.

Please document the following:
Date of destruction: _____
Method of destruction:

Please document method of destruction with photos if possible. Photos can be emailed to Lee Grasseschi lgrasseschi@hanger.com.

Any adverse events associated with recalled/failed product? Yes No
If yes, please explain: _____

Please email or mail the completed form to attention of Lee Grasseschi at address below. For your convenience, a postage paid addressed envelope is included in this mailing.

Accelerated Care Plus
4999 Aircenter Circle, Suite 103
Reno, NV 89502
lgrasseschi@hanger.com
775-336-1827

This form was completed by:

Signature: _____ Date: _____

Name: _____ Title: _____

Company: _____

Address: _____

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