



Urgent – Medical Device Recall (Norco Ultrasound Gel, EcoLotion Transmission Lotion, Myossage Lotion)

Monday, August 23rd, 2021

Title: Urgent – Medical Device Recall (Norco Ultrasound Gel, EcoLotion Transmission Lotion, Myossage Lotion)

Dear Customer,

This notice is to inform you of a voluntary product recall involving all Norco Ultrasound Gel, EcoLotion Transmission Lotion, and Myossage Lotion products.

Eco-Med initiated a voluntary recall on [Aug. 4, 2021](#), to stop use of eight contaminated lots (Table 1) EcoGel 200 Ultrasound Gel due to bacterial contamination, *Burkholderia cepacia complex* (Bcc). Eco-Med is also no longer manufacturing and distributing product and has subsequently closed their factory.

Table 1

Product	Lot Numbers	Initial Distribution Date
Eco Gel 200 MediChoice M500812	B029	March 26, 2021
	B030	March 30, 2021
	B031	April 5, 2021
	B032	April 7, 2021
	B040	April 26, 2021
	B041	April 26, 2021
	B048	May 7, 2021
	B055	May 26, 2021

Due to Eco-Med's shut down the FDA has announced in a public notice on August 18th, 2021 that all ultrasound gels and lotions manufactured by Eco-Med are at risk for bacterial contamination.

“The effects of Bcc infection on people vary widely, ranging from no symptoms to serious consequences. Bcc bloodstream infections may result in sepsis and in certain cases possible death. Potential routes of transmission leading to bloodstream infections associated with a contaminated nonsterile gel may have included the use of the gel for visualization prior to, in preparation for, or during an invasive procedure or application of the gel inside the sterile ultrasound probe sleeve during an invasive procedure using ultrasound guidance.”

North Coast Medical, Inc. has determined that none of the products distributed from our warehouses were from Eco-Med's disclosed contaminated lots. Nevertheless, North Coast Medical Inc. will no longer be selling any Eco-Med product and is following FDA request of a recall for all product within its expiry date.

North Coast Medical advises to immediately discontinue use for all lots of Norco Ultrasound Gel, EcoLotion Transmission Lotion, and Myossage Lotion products within the expiration date. Product substitution can be found at ncmedical.com.

North Coast Medical Inc.

800 821 9319 - Monday thru Friday 6:00AM-4:00PM (PST)

NCMRecall@ncmedical.com • www.ncmedical.com

Recall Notice of Eco-Med Products



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Table 2

Item	Item Description
NC70479	Norco Ultrasound Gel, 250 mL
NC70479	North Coast Ultrasound Gel, 250 mL
NC70479-5	Norco Ultrasound Gel, 5 liters
NC70479-5	North Coast Ultrasound Gel, 5 liters
NC70479-5C	Norco Ultrasound Gel, 5 liters (4)
NC70479-5C	North Coast Ultrasound Gel, 5 liters (4)
NC70479C	Norco Ultrasound Gel, 250 mL (24)
NC70479C	North Coast Ultrasound Gel, 250 mL (24)
NC70481	Eco Lotion, 5 liters
NC70482	Eco Lotion with Aloe, 5 liters
NC70482C	Eco Lotion with Aloe, 5 liters (4)
NC31208	Myossage Lotion, 1 Gallon

Recall Instruction:

- 1) Immediately examine your inventory and discontinue use, quarantine, and stop distribution of Norco Ultrasound Gel, EcoLotion Transmission Lotion, Myossage Lotion.
- 2) If affected product has been further distributed, notify customers, and forward the recall notification down to the user level. If you have any questions concerning this communication, please don't hesitate to contact NCMRecall@ncmedical.com.
- 3) Complete and return the Recall Acknowledgment and Disposal Form via email/mail, by 10SEP2021 date.

Email: NCMRecall@ncmedical.com

Mail: ATTN: Eco-Med Recall

780 Jarvis Dr #100,

Morgan Hill, CA 95037

This recall is being made with the knowledge of the Food and Drug Administration. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online at www.fda.gov/medwatch/report.htm, regular mail, or fax.

Contact Information:

Email: NCMRecall@ncmedical.com

Phone: 800 821 9319 Monday thru Friday 6:00AM-4:00PM (PST)

Sincerely,

North Coast Medical, Inc.

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