



FSN-2021-001 Rev. A

URGENT: FIELD SAFETY NOTICE (FSN)
DEVICE DESTRUCTION/DISPOSAL
CHATTANOOGA
Ultrasound Gel and Lotions

Consignee Name:
Business Name:
Street Address:
Street Address 2:
City, State, Zip Code:
Country
Date: August 30, 2021

Dear Consignee:

DJO, LLC received an urgent medical device recall notification from the physical manufacturer of a DJO, LLC supplied accessory, CHATTANOOGA ultrasound gel and lotions. The physical manufacturer of this product, Eco-Med Pharmaceutical, has initiated an urgent medical device Field Safety Corrective Action (FSCA) of this product. As the legal manufacturer, DJO, LLC / DJO FRANCE is notifying customers of this FSCA. This FSCA affects the three gel part numbers listed in the table below as well as the four part numbers associated with the lotions. As the physical manufacturer EcoMed has ceased business, DJO, LLC is also informing recipients of this FSN to immediately stop using and discard all ultrasound gels and lotions manufactured by Eco-Med Pharmaceutical, Inc due to risk of bacterial contamination.

DJO Part #	Product Description
4238	GEL CONDUCTOR 5 LITER W/DISP
4248	GEL CONDUCTOR 24-8.5OZ BOTTLES
4266	GEL CONDUCTIVE 5 LITER
4262	Ultra-Myossage Lotion 1-gallon bottle
4260	Ultra-Myossage Lotion 8.5oz
4210	Myossage Lotion 1-gallon bottle
4208	Myossage Lotion 8.5oz

Description of Issue and Health Hazard

Eco-Med Pharmaceutical, URGENT MEDICAL DEVICE RECALL, dated August 4, 2021:

“Eco-Med has initiated this recall and quarantine due to bacterial contamination in the affected lots of ultrasound gel with Burkholderia cepacia complex (Bcc). The source(s) of the bacterial contamination is currently unknown.

The effects of the bacteria, Burkholderia stabilis, a member of the Burkholderia cepacia complex (Bcc), vary widely, ranging from no symptoms at all to serious infections. Bcc bloodstream infections may result in sepsis and in certain cases, potentially death. Use of ultrasound gels manufactured by Eco-Med have been associated with at least 15 infections to date, including bloodstream infections. Additional infections have been identified that may also be associated with the use of this ultrasound gel and investigation is ongoing. 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.”



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For Distributors and Customers

The following list of kit part numbers distributed by DJO LLC contain one of the recalled items above. Only the gel in the below listed products is affected by the recall, no other parts of the kit are affected.

You are receiving this notification because our records indicate that you have received the below product(s) that contain an affected CHATTANOOGA Eco-Med product, and it falls within the scope of the DJO FSCA and FSN.

DJO, LLC Part #	Product Description	DJO, LLC Part #	Product Description
2073	INTELECT RPW 120V	2738-10	INTELECT TRANSPORT COMBO PKG US STD
2073-BR	INTELECT RPW 120V, BRAZIL	2738-2	INTELECT TRANSPORT COMBO PKG US STD
2074	INTELECT RPW 230 V	2772MC	INT ADVANCED COMBO MONOCHROMEINT'L STD
2082	INTELECT RPW 100 V	2776	INTELECT MOBILE INT'L STD, 5CM APPL
2760	INTELECT LEGEND XT COMBOUS STD	27800	ULTRASOUND ON CART
2791	INTELECT LEGEND XT COMBO US STD W/CART	2776-BR	INTELECT MOBILE INTL STD, 5CM APPL, BRAZIL
2782-10	INTELECT TRANSPORT US STD	2776-10	INT MOBIL INT'L STD, 10CM APPL
2782-2	INTELECT TRANSPORT US STD	2776-2	INT MOBILE INT'L STD, 2CM APPL
2843	INTELECT VET 4CH COMBO PKG	2778	INTELECT MOBILE COMBO, INT'L STD, 5CM APPL
2845K	KIT INTELECT VET 4CH COMBO PKG	2778-10	INTELECT MOBILE COMBO, INT'L STD, 10CM APPL
2863	SENIOR SOLUTIONS 2CH COMBO PKG US STD, 5CM	2778-2	INTELECT MOBILE COMBO, INT'L STD, 2CM APPL
2863-10	SENIOR SOLUTIONS 2CH COMBO PKG US STD, 10CM APPL	2752CC	INT ADV 2CH COLOR COMBO INT'L STD
2863-2	SENIOR SOLUTIONS 2CH COMBO PKG US STD, 2CM APPL	2756	INTELECT VET 2CH COMBO PKG INT'L STD
2864	SENIOR SOLUTIONS 4CH COMBO PKG US STD	2844K	KIT INTELECT VET 2CH COMBO PKG
2761	VECTRA GENISYS 2CH COMBO PKG US STD, 5CM APPL	2782	INTELECT TRANSPORT US STD
2792	VECTRA GENISYS 2CH COMBO, US STD W/CART	2895K	KIT CART ADAPT BL W/CT/SPEC US
2761-10	VECTRA GENISYS 2CH COMBO PKG US STD, 10CM APPL	2872	VECTRA GEN 2C COMBO W/O EMG PK US STD
2761-2	VECTRA GENISYS 2CH COMBO PKG US STD, 2CM APPL	2876	VECTR GEN 2C COMBO W/O EMG US STD W/CART
2762CC	INT ADV 2CH COLOR COMBO, INT'L 5CM APPL	2874	VECTRA GEN 4C COMBO W/O EMG PK US STD
2762CC-10	INT ADV 2CH COLOR COMBO W/O EM INT'L STD, 10CM APPL	2878	VECTR GEN 4C COMBO W/O EM, US STD W/CART
2762CC-2	INT ADV 2CH COLOR COMBO W/O EM INT'L STD, 2CM APPL	7550	INT LEGEND COMBO 4C, US STD
2788	LEGEND XT 4CH COMBO PKG, US STD, 5CM APPL	INT001	INTELECT LEGEND ULTRASOUND US STD
2795	INTELECT XT 4CH,COMBO,US STD 5CM APPL W/CART	INTC B	INT CB PKGD US STD
2788-10	LEGEND XT 4CH COMBO PKG,US STD 10CM APPL	39-0701	DIRECT SUPPLY PANACEA VECTRA 2-CHNL ULTRASOUND/ESTIM COMBO
2795-10	INTELECT XT,4CH COMBO,US STD 10CM APPL	39-0702	DIRECT SUPPLY PANACEA VECTRA 4-CHNL ULTRASOUND/ESTIM COMBO
2788-2	LEGEND XT 4CH COMBO PKG,US STD 2CM APPL	13-4248	GEL CONDUCTOR 24-8.5OZ BOTTLES
2795-2	INTELECT XT 4CH COMBO, US STD 2CM APPL	15-1200	INTELECT MOBILE 2 ULTRASOUND INTL SET EU PLUG
2789	VECTRA GENISYS 4CH COMBO PKG US 5CM APPL	15-1201	INTELECT MOBILE 2 ULTRASOUND INTL SET ALL PLUGS
2796	VECTRA GENISYS 4CH COMBO US STD W/CART	15-1204	INTELECT MOBILE 2 COMBO INTL SET EU PLUG
2796K	KIT VECTRA GENISYS 4CH COMBO P	15-1205	INTELECT MOBILE 2 COMBO INTL SET ALL PLUGS
2789-10	VECTRA GENISYS 4CH COMBO PKG US STD, 10CM APPL	2173KIT	INTELECT RPW 2 120V, INTERNATIONAL KIT, US PLUG
2796-10	VECTRA GENISYS 4CH COMBO, US US STD, 10CM APPL	2174KIT	INTELECT RPW 2 230V, KIT EU PLUG
2789-2	VECTRA GENISYS 4CH COMBO PKG US STD, 2CM APPL	2175KIT	INTELECT RPW 2 100V, KIT JPN PLUG
2796-2	VECTRA GENISYS 4CH COMBO, US STD, 2CM APPL	2176KIT	INTELECT RPW 2 120V, USA KIT
2738	INTELECT TRANSPORT COMBO PKG US STD	12-2756-1	INTELECT VET 2CH COMBO PKG INTL STD
8250KP	KIT TRITON DTS PROMO	2756K	KIT INTELECT VET 2CH COMBO PKGUS STD
6001	INTELECT NEO	70002	NEO MODULE ULTRASOUND

Important

DJO, LLC / DJO FRANCE is conducting a voluntary medical device FSCA for all gel and lotion products manufactured by Eco-Med (EcoGel/MediChoice/Mac Medical ultrasound gel).

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Please take the following action:

- a) **Immediately remove and destroy the gel products located in the DJO, LLC kits as listed above that contain the affected product. Follow all local/state or country regulations for disposal**
- b) **Immediately stop use of ALL ultrasound gels and Myossage lotions labeled manufactured by Eco-Med Pharmaceutical and/or for CHATTANOOGA (regardless of lot) and dispose per local/state or country specific regulation**
- c) **In addition, if you have further distributed this product, please identify your customers, and notify them at once of this product FSCA by sharing this FSN letter.**
- d) **DJO, LLC has partnered with Stericycle as our vigilance partner. Stericycle will be contacting distributors and customers on DJO's behalf. Please complete the attached Return Response and return to DJOglobalrecall@sedgwick.com**

General Contact Person:

Luke Evans

Sedgwick , 60 Fenchurch Street, London, England, EC3M 4AD

DIRECT +44 (0) 7834 800 457 | EMAIL luke.evans@sedgwick.com

Local contact person with name, address, telephone number for translated versions:

Hannah Muzsnyai

Sedgwick , 60 Fenchurch Street, London, England, EC3M 4AD

DIRECT +44 (0) 7824 143765 | EMAIL Hannah.muzsnyai@sedgwick.com

The relevant National Competent Authorities have been advised of the FSCA.

Health professionals, consumers and patients can voluntarily report observed or suspected adverse events to the local competent authority.

Sincerely,

James McMahon
Vice President, Regulatory Affairs



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RETURN RESPONSE

**CONSIGNEE MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form**

**CHATTANOOGA
Ultrasound Gel and Lotions**

Response is Required

Consignee Information:

Consignee Name:

Street Address:

Street Address:

City, State/County, Zip/Postal Code

Country:

I have read and understand the recall instructions provided in the **08/30/2021** letter.

Yes ___ No ___

Are there any adverse events associated with recalled product? Yes ___ No ___

If yes, please explain (include on separate sheet in needed):

Questions (include on separate sheet in needed):



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<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A	

Please have Customer Service contact me.

Signature of Receipt _____ Date: _____

Name/Title	
Telephone	
Email address	

Please provide a response to DJO Global no later than 24 September, 2021.

Please return this response to: DJOglobalrecall@sedgwick.com

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.