



URGENT: SAFETY ALERT
Nylatex Wraps

DJO, LLC

Dear Consignee:

A DJO Global Company

DJO Global is committed to providing safe and effective products to all of our customers around the world. The purpose of this letter is to advise you that DJO Global is executing a voluntary field action of Nylatex wrap products listed below.

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Description of Issue

We have become aware that these products distributed by DJO Global contain undeclared natural rubber latex. The use of this product may cause allergic reactions in persons sensitive to latex material. To date, DJO Global is not aware of any injuries caused by latex associated with the use of these products. Nylatex wraps are sold individually or as part of kits of other DJO manufactured medical devices. Please refer to table below for product list.

DJO Global has revised its product labeling to reflect the material composition and appropriate latex warnings on the product labels.

You are receiving this notification because our records indicates that you have ordered this product within January 1st, 2016 through December 31st, 2017, which falls within the scope of this notification.

Customer Action

DJO Global is recommending that, in a timely manner, you send a notification to all customers who have purchased, or were issued the affected products from you.

We regret any inconvenience this matter may have caused. We sincerely appreciate your cooperation and thank you for your assistance. As always, DJO Global remains committed to providing quality, innovative products to meet your needs and those of your customers.

Sincerely,

Mahta Nakic
Sr. Manager Global Regulatory Affairs (Compliance & Audits)

Date 6/21/18

Together in Motion

Listed below are the devices (including part numbers) which have been identified as part of this voluntary field action.

Part Number	Description
3114	C-5 220V PKG A INT'L STD
3448274	C-5 220-240V OEM ENRAF W/PKS
2770	STIM MODULE CH 3/4 INT'L PKG
27378	KIT LEAD INT ADVANCED 2CH
2752CC	INT ADV 2CH COLOR COMBO INT'L STD
2755CS	INT ADV 2CH COLOR STIM INT'L STD
2762CC	INT ADV 2CH COLOR COMBO, INT'L 5CM APPL
2762CC-10	INT ADV 2CH COLOR COMBO W/O EM INT'L STD, 10CM APPL
2762CC-2	INT ADV 2CH COLOR COMBO W/O EM INT'L STD, 2CM APPL
2765CS	INT ADV 2CH COLOR STIM W/EMG INTL STD
2772MC	INT ADVANCED COMBO MONOCHROME INT'L STD
2773MS	INT ADVANCED STIM MONOCHROME INT'L STD
28099	KIT, LEAD INT MOBILE STIM INTL
2777	INTELECT MOBILE 2CH STIM INT'L STD
2778	INTELECT MOBILE COMBO, INT'L STD, 5CM APPL
2778-10	INTELECT MOBILE COMBO, INT'L STD, 10CM APPL
2778-2	INTELECT MOBILE COMBO, INT'L STD, 2CM APPL
59048	KIT LEAD STIM INT CLINIC VITLS (CH 1/2)
5951	INTELECT VITALSTIM 2 CHANNEL THERAPY SYSTEM, INT'L STD
27509	KIT LEAD 4CH EPR INT'L

Together in Motion.