

Urgent Field Safety Notice

Covidien ReliaTack™ Articulating Reloadable Fixation Device

April 2018

Medtronic reference: FA814

Attention: Risk Management Director and O.R. Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling two (2) production lots of Covidien ReliaTack™ Articulating Reloadable Fixation Device (Item code: RELTACK4XDPT). This voluntary recall is being conducted due to a logistics issue where devices that did not have appropriate CE mark labeling were distributed in the European Union. There are no patient safety implications related to this action.

Medtronic requests that you quarantine and return any unused products of the lots detailed below. Unused products from the affected lots should be returned as described in the "Required Actions" section. If you have distributed the Covidien ReliaTack™ Articulating Reloadable Fixation Devices listed below, please promptly forward the information from this letter to those recipients. All unused products from the affected lots must be returned.

This voluntary recall affects only the item code and lots listed below.

Item Code	Item Description	Affected Lots
RELTACK4XDPT	ReliaTack™ Articulating Reloadable Fixation Device	N7K0639X
		N7L0557X

The Competent Authority of your country has been notified of this action.

Required Actions:

1. Please quarantine and discontinue use of the affected lots listed above.
2. Please complete form even if you have no inventory of the affected lots listed above.
3. Please return affected product per instructions in Appendix A:

We apologize for this inconvenience. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Local BU signature

Appendix A: Return Instructions:

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased directly from Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.

Appendix B

