URGENT FIELD SAFETY NOTICE

Covidien Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes, Pre-connect

August xx, 2015

Attention: Risk Management Director and Materials Management

Please forward this communication to all potential users of the product who may include:

- Surgical Units
- Biomedical Engineering
- Director of Nursing
- Emergency Room Director

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific production lots of Covidien Medi-Trace™ cadence adult multi-function defibrillation electrodes, pre-connect. The defibrillation electrodes are used in conjunction with AEDs (Automatic External Defibrillators). This Field Safety Corrective Action (FSCA) is being conducted due to a low-level potential for damage to the wire insulation which was identified during a review of our manufacturing process. No complaints for this issue have been reported from customers. The use of products with this condition may result in a potentially increased risk for reduced or no patient therapy, arcing of current, sparking, and patient and/or clinician burns. **No patient injuries have been reported related to this damaged wire insulation issues.**

Medtronic is requesting that customers quarantine any remaining stock of the items/lots detailed below. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below.

Item Code	Description	Lot Numbers
22550PC	Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes	517521X 519835X
22770PC	Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes	516313X 519124X 513426X

Required Actions:

1. Please quarantine and discontinue use of the affected item codes listed on Attachment A.
2. Please return affected product as follows:

• CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC

Please complete the enclosed Returns Verification Form and fax it to xxx-xxxxx for the attention of [Insert Local RA contacts name]or email it to INSERT LOCAL EMAIL ADDRESS. If you do not have any units to return, simply return the form indicting you have zero (0) units.
Upon receiving your form, Customer Service will contact you to organize the return of your products. You will receive credit for unused and unexpired device(s) that you return. Please contact your local Medtronic representative for details on alternative product options.

• CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR

Please complete the enclosed Returns Verification Form and contact your Distributor directly for direction on returning product. The completed form should be emailed to the following address: LOCAL CONTACT EMAIL ADDRESS or faxed to (XXX)-XXX-XXXX. All affected product must be returned through the Distributor with a copy of the completed form.

• ALL CUSTOMERS

We ask that all customers reply to Medtronic **WHETHER OR NOT** you have affected product at your site. Your response is vital to our monitoring of the effectiveness of this recall. Please complete the Returns Verification Form Return form and return to Medtronic via the instructions provided.

This action is being taken with the knowledge of the (INSERT LOCAL REGULATORY AUTHORITY NAME).
If you have any questions or concerns, please do not hesitate to contact your Medtronic representative.

If you are aware of any incidents related to this issue, please contact your local Medtronic Representative using the contact information stated above to provide information regarding those events so regulatory reporting obligations can be fulfilled.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative or Customer Service.

Sincerely,

Subu Mangipudi
Vice President, Quality Assurance
Patient Monitoring and Recovery
Medtronic

Attachment A
Distinguish affected product by Item Code and Lot Number.