URGENT: MEDICAL DEVICE RECALL

Model 8731SC Intrathecal Catheter Kit & Model 8598A Spinal Segment Revision Kit
Potential Endotoxin Issue

IMMEDIATE ACTION REQUIRED

September 2010

Dear Inventory/Risk Manager:

Medtronic is recalling specific lots of Model 8731SC intrathecal catheter kits and Model 8598A intrathecal catheter spinal revision kits. We are performing this recall because there is the potential that the 11.4 cm introducer needles within these kits may exceed USP requirements for bacterial endotoxin.

The enclosed Recall Reply Card identifies products that, according to our records, have been sold to your facility but not used. The following website also can be used to identify (based on product lot serial number) whether a specific product is potentially affected by this issue: http://catheter.medtronic.com.

Enclosed is an image of the package label for both the Model 8731SC intrathecal catheter kit and Model 8598A spinal revision kit that displays the location of the model number and the lot number.

Actions Required:

- Review the affected product identified in the enclosed Recall Reply Card.
- Immediately segregate your entire affected unused inventory
- Return affected product to Medtronic Neuromodulation per the enclosed Product Return Instructions form. Please contact your Medtronic representative if you require further assistance.
- Complete the enclosed Recall Reply Card and return to Medtronic in the envelope provided.

Medtronic is continuing to investigate this matter and will be issuing a future communication to physicians with details on this issue and information regarding potential patient impact.

The US Food and Drug Administration (FDA) has been made aware of this issue. Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation at rs.neuadverseeventreporting@medtronic.com and FDA’s MedWatch Program at www.fda.gov/medwatch.

Sincerely,

George Aram
Vice President of Quality
Neuromodulation Division

Enclosures: Labeling Images, Recall Reply Card, Product Return Instructions, Return Envelope
The image above contains an example of the outer box label for both the 8731SC Intrathecal Catheter Kit and the 8598A Intrathecal Catheter Spinal Segment Revision Kit.

Circled in red are the locations for the Model number and the Lot number.