Urgent: Medical Device Recall

Potential Endotoxin Issue

Model 8731SC Intrathecal Catheter Kit
Model 8598A Spinal Segment Revision Kit
(Specific Lots Only)

Dear Healthcare Professional:

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 needle within these kits may exceed USP requirements for bacterial endotoxin.

Our records indicate that you have implanted at least one product from the affected lots. Please refer to the enclosed Patient Detail Report which identifies your affected patient(s) based on registration information provided to Medtronic. A lot number lookup application is available at http://catheter.medtronic.com if you would like to confirm whether a specific Model 8731SC kit or Model 8598A kit lot number is included within the scope of the recall.

Through September 2010, Medtronic has received no complaints or reports of patient illness or injury confirmed to be due to this issue.

Endotoxins are lipopolysaccharides from the outer membrane of gram-negative bacteria. Intrathecal introduction of endotoxins via a needle may induce a clinical picture that resembles aseptic meningitis, with symptoms such as stiff, painful neck, chills, fever, rigors, tachycardia, hypotension, respiratory distress, and in severe cases, coma. Analysis of the cerebrospinal fluid would reveal pleocytosis (excessive cell numbers) and increased protein levels. CSF Gram stain and cultures would be negative. No reports of death from endotoxin contamination of the CSF were found in the medical literature. Patients would be expected to recover within 72 hours.

Action Required:

1. Medtronic requests that you do not use any of the specific lots of Model 8731SC kits and Model 8598A kits included in this recall. Any other kits that are not within the scope of this recall as indicated at http://catheter.medtronic.com may still be used.

2. Medtronic advises you to monitor any patients who have been exposed to affected product for the symptoms discussed above and manage them according to standard medical practice. Patients who have not developed symptoms within the first week after exposure to an affected product would not be expected to develop symptoms at a later time. Medtronic does not recommend prophylactic explant of a catheter based solely on exposure to a potentially affected product.

Medtronic has notified hospital risk managers at all facilities which our records indicate have unused inventory of affected product and asked them to immediately remove the product from their inventory and return the product to Medtronic. Your Medtronic representative will support them in returning the product for replacement and/or credit.
Medtronic is communicating this information to the U.S. Food and Drug Administration (FDA).


Medtronic appreciates your assistance with this matter and regrets any inconvenience this may have caused you or your patients. Medtronic is committed to providing you with the highest quality products, services and ongoing support as you care for your patients. If you have any questions or comments, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933.

Sincerely,

George Aram
Vice President of Quality
Neuromodulation Division