July 2006

URGENT: WORLDWIDE MEDICAL DEVICE RECALL

MODEL 8731 INTRATHECAL CATHETER
MODEL 8598 INTRATHECAL CATHETER DISTAL REVISION KIT

IMMEDIATE ACTION REQUIRED

Dear Healthcare Provider:

Medtronic is conducting a voluntary recall of the Model 8731 Intrathecal Catheter and the Model 8598 Intrathecal Catheter Distal Revision Kit. Medtronic is recalling these products because the platinum-iridium tip may be dislodged by the guide wire during implantation. Dislodgement of the tip can result in the risk of infection or other potentially serious adverse health consequences.

This recall is limited to devices identified on the attached list that have not been implanted. The attached list contains the following information:

- **In the United States, forty-five (45) lots of non-implanted model 8731 catheters and model 8598 kits, having a Use-By-Date (UBD) on or before 28 Aug 06; and one lot of non-implanted model 8598 kits having a Use-By-Date (UBD) of 28 Oct 06**
- **Outside the United States, all non-implanted model 8731 catheters and model 8598 kits having a Use-By-Date on or before 28 Aug 06**

Medtronic has received twenty-two (22) reports of tip dislodgements. Most of the dislodged tips remain in the intrathecal space. One incident involved post-operative leg pain, in a patient with chronic back pain. The leg pain could have been related to a dislodged catheter tip in the intrathecal space.

Model 8731 Catheters and Model 8598 Distal Revision Kits not identified in the attached list have been manufactured with a stronger bond to the platinum iridium tip, and are not subject to this recall.

IMMEDIATE ACTION REQUIRED BY YOU

In accordance with this recall and with the assistance of your Medtronic representative, please:

- Locate all units of the Model 8731 Intrathecal Catheter and the Model 8598 Intrathecal Catheter Distal Revision Kit identified on the attached list and remove them from your active inventory. **NOTE: This recall only affects units of the Model 8731 Intrathecal Catheter and the Model 8598 Intrathecal Catheter Distal Revision Kit that have not been implanted.**
- Immediately cease distribution and/or use of the recalled devices and quarantine them for return to Medtronic.
- If you no longer have any of the recalled products in inventory because they are implanted or not available, include this information on the attached Reply Card.
- Please complete, sign and return the attached Reply Card.
- Your representative will follow-up with you by July 28, 2006.
- All unexpired recalled product will be given a warranty credit (based on the original purchase price) which can be used for future procurement of Medtronic Neurological Products. Warranty credits will not be given for expired product.

- Report any malfunction or adverse event related to this device to Medtronic, and to the FDA's MedWatch Program. You can contact the MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch/how.htm.

This recall is being made with the knowledge of the Food and Drug Administration.

We appreciate your assistance with this matter and regret any inconvenience this may have caused you or your patients. If you have any questions or comments, please contact Medtronic Neurological Tech Services at 1-800-707-0933. This telephone number is staffed 24/7 for any product or clinical questions.

Sincerely,

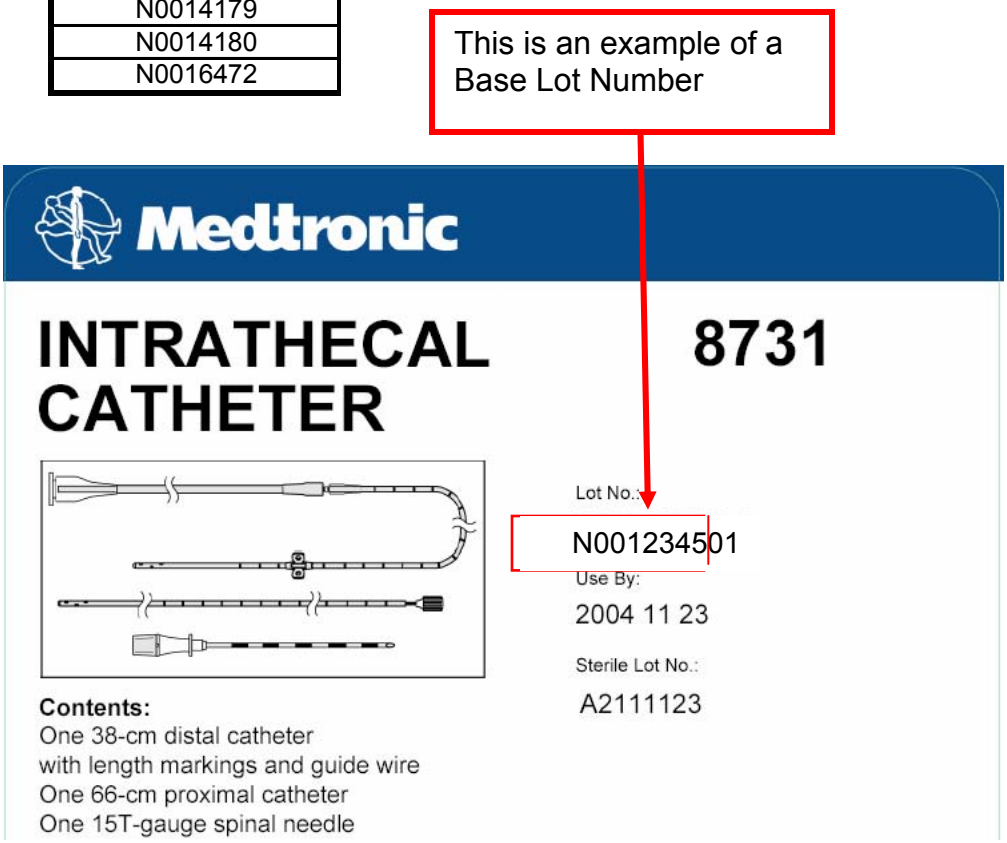
Jon Tremmel
Vice President and President,
Medtronic, Incorporated
Core Neurological

(Enclosures)

Model 8731 and Model 8598 Lot Numbers under Recall in the United States:

Model 8731 Base Lot Number
B011311N
B011421N
B011422N
B011500N
B011721N
B011737N
B011738N
B011786N
N0012097
N0012140
N0012141
N0012521
N0012692
N0012814
N0012815
N0012816
N0013149
N0013150
N0013352
N0013353
N0013354
N0013355
N0013707
N0013710
N0013936
N0014007
N0014236
N0014237
N0014330
N0014331
N0014332
N0014722
N0015050

Model 8598 Base Lot Number
B011468N
B011893N
B011894N
N0012129
N0012612
N0012969
N0012970
N0012971
N0014057
N0014058
N0014179
N0014180
N0016472



* Model 8731 Catheters and Model 8598 Distal Revision kits have a Base Lot Number of eight (8) characters plus a two (2) digit suffix that represents serialization within these recalled lots. This list provides just the Base Lot Number (the first eight characters of the product Lot No. found on the product labeling).

Example: lot number N001234501
The Base Lot Number is N0012345 with a two (2) digit suffix of 01.

Outside the United States, all model 8731 catheters and all model 8598 kits with a Use-by-Date on or before 28 Aug 06 are subject to this recall.

Model 8731/Model 8598

Reply Card for July 2006 Recall Letter

Within two days receipt of this letter, please complete this Reply Card and FAX to 763-514-5789, attention:

Pat Eichers
Medtronic, Inc
800 53rd Avenue NE N335
Minneapolis, Minnesota 55421

Customer Name	
Customer Signature	
Telephone	
Hospital	
City	
State	

8731 or 8598 found, to be returned to Medtronic listed by Lot Number:

_____
_____
_____
_____
_____

8731 or 8598 not found, listed by Lot Number:

_____
_____
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