

**IMPORTANT PATIENT SAFETY INFORMATION**

Dear Medtronic IsoMed Pump Patient:

Medtronic recently provided doctors with important safety information about the possibility of blockage or disconnection of a specific type of catheter, called the SC catheter, when used with an IsoMed pump. This notification was titled, "Medical Device Correction, Sutureless Connector (SC) Intrathecal Catheters Are Not Compatible with IsoMed® Constant-Flow Infusion Pumps; SC Catheter and Revision Kit Models: 8709SC, 8731SC, 8596SC, 8578 [when used with the] IsoMed Pump Model: 8472." Other types of intrathecal (spine) catheters and vascular catheters (that deliver chemotherapy to the bloodstream) are not affected.

A catheter is a thin, flexible tube that connects to your IsoMed pump. Your IsoMed pump delivers medicine through the catheter to a specific site in your body. If the catheter becomes blocked or disconnected from your IsoMed pump, you may not get the medicine your doctor ordered. Medtronic has received reports of this happening.

**Medtronic records do not show that you have an SC catheter connected to your IsoMed pump. However, if you have had a catheter surgery after May 2007, you should contact your doctor to be sure in case our records are not complete or are not up-to-date. If you do have an SC catheter implanted, you should talk with your doctor right away to see if anything needs to be done at this time.** Medtronic has informed your doctor which catheters work with your pump. We wanted to make sure you are aware of the information in this letter in case your catheter has been or needs to be replaced.

**If your catheter becomes disconnected or blocked, you may notice:**

- Return of symptoms treated by your drug pump (for example, pain or spasticity)
- Symptoms of drug withdrawal. These symptoms depend on the drug being used. If you are not sure of the symptoms of withdrawal from the drug in your pump, you should check with your doctor.
  - If you have baclofen in your pump, you should know that complications of withdrawal from baclofen can be life threatening if not treated promptly and effectively.
- A severe headache that may be accompanied by neck pain and vomiting, which may get better when you are lying flat and get worse when you sit up or stand.

**If any of these problems occur, you should seek immediate medical assistance.** Your doctor may recommend surgery to correct the catheter connection.

Medtronic has notified the Food & Drug Administration (FDA) about this issue. The FDA classified Medtronic's corrective action as a Class I recall. A Class I recall is a situation in which use of the device could be life threatening. In FDA terms, a patient communication for medical devices may be called a "recall" even though no removal or replacement is required.

Medtronic is committed to answering your questions, keeping you informed, and continuously improving our products. If you have additional questions, please contact Medtronic Patient Services at 1 (800) 510-6735, Monday through Friday, between 8 am - 5 pm, Central Standard Time.

Sincerely,

George Aram  
Vice President Quality  
Medtronic Neuromodulation