

**IMPORTANT PATIENT SAFETY INFORMATION**

Dear <patient name>:

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."

A catheter is a thin, flexible tube that connects to your IsoMed pump. Your IsoMed pump delivers medicine to your spine through the catheter. 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 show that you received an IsoMed pump and a Model <model number> catheter. You should talk with your doctor right away to discuss whether anything needs to be done at this time.** Medtronic has informed your doctor which catheters work with your pump.

**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. If you have had your pump or catheter replaced with a new one, please discuss with your doctor if there is anything else you need to do.

If your SC Catheter becomes blocked or disconnected from your IsoMed pump due to this issue, Medtronic may provide a free replacement Medtronic catheter and/or pay up to \$1,000 of reasonable surgical expenses that remain unpaid after payment by insurance or other medical plan such as Medicare, Medicaid or MediCal. Medtronic has given full details of these supplemental warranties to your doctor's office.

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.

We sincerely apologize for any difficulties this may cause you and your family. We are committed to answering your questions, keeping you informed, and continuously improving our products. If you have additional questions, please contact Medtronic Neuromodulation 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