

SPINE SAFETY WARNING:

**Information for Healthcare Professionals:  
Medtronic Intrathecal Catheters and Revision Kits --  
Class I Recall Due to Possibility of Obstruction or Disruption of Therapy**

According to MedWatch, FDA notified healthcare professionals of the Class 1 recall of Medtronic SC Catheters and Revision Kit Models: 8709SC, 8731SC, 8578, and 8596SC when paired with the Medtronic IsoMed Pump Model 8472, due to a design incompatibility resulting in a physical interference between the SC catheter connector and the IsoMed pump. This may prevent the SC catheter from completely connecting to the IsoMed pump, even though it may appear to be connected and feel secure and may lead to disruptions of therapy and revision surgery, which pose a risk of serious injury or death.

SC catheters are not compatible with IsoMed pumps but are compatible with Medtronic SynchroMed II and SynchroMed EL pumps. To date, Medtronic has received ten reports worldwide related to improper connection of an SC catheter to an IsoMed pump. In all ten reports, medical intervention was required to correct the condition. Medtronic has provided recommendations in their Medical Device Correction Letter (see link in FDA Recall Notice).

Read the complete MedWatch 2009 Safety summary, including a link to the Class 1 recall notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183753.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.