

Urgent: Medical Device Correction
Important Clinical Information about Pocket Fills
SynchroMed[®] II and SynchroMed EL Implantable Drug Pumps

Dear Healthcare Professional:

This letter provides important reminders concerning the potential for a pocket fill during a SynchroMed[®] II or SynchroMed EL implantable drug pump refill procedure, and important patient management recommendations that will be added to our product labeling. A pocket fill is the inadvertent injection of all or some of the prescribed drug into the patient's subcutaneous tissue, which includes the pump pocket, instead of the pump. **Please share this information with any of your staff that perform pump refills.**

From May 1996 to September 2010, Medtronic has received 351 reports worldwide related to the occurrence of pocket fills with the SynchroMed infusion system. Assuming pumps are refilled 6 times per year, the reported rate of occurrence per refill opportunity is as high as 1 per 10,000 refill opportunities (0.0101%). The actual occurrence rate is likely to be higher due to under reporting, but the extent of under reporting is unknown. Of the reported events there have been 8 deaths, 270 events requiring medical intervention (serious or life threatening injury), and 58 events not requiring medical intervention (no injury or non-serious injury). There were 15 events in which the patient severity was unknown.

Issue Background and Severity:

During the refill, it is essential that the needle be inserted through the refill port septum until it has reached the needle stop in the reservoir. The clinician relies heavily on tactile feedback to determine if this has occurred, and may conclude that the needle is correctly positioned when it is not. In this event, injection of the drug may result in a pocket fill. The clinician, believing the drug has been injected into the reservoir, may not recognize a pocket fill, even if the patient exhibits symptoms of overdose or underdose. Such symptoms may not occur in every case, and symptom onset may be delayed. The following may result from a pocket fill:

- Overdose:** An overdose, which may be clinically significant, may result from drug being injected subcutaneously. The onset of overdose symptoms can vary from immediate to several hours. In addition to cases of subcutaneous overdose with morphine and ziconotide, Medtronic has also received reports that some patients treated with baclofen have experienced serious and life-threatening overdose symptoms following a suspected pocket fill. Reported symptoms are consistent with baclofen overdose.
- Underdose:** An underdose, which may be clinically significant, may result if a pocket fill is not recognized and the pump empties sooner than anticipated resulting in interruption of therapy, return of underlying symptoms, and/or withdrawal symptoms. The onset of underdose symptoms may take several days to weeks. This potential for underdose is of particular concern for patients treated with baclofen because baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively.¹

For complete information on the signs and symptoms of overdose and underdose refer to the appropriate drug labeling.

Recommendations for Avoiding Pocket Fills and Managing Patients:

- Needle placement within the pump septum should always be checked throughout the procedure to help perform a successful refill as illustrated in the attached *Clinician Refill Reference Card*.
- Be aware that pump refill difficulty may increase due to a variety of factors, for example: obesity, scar tissue, seroma, implant depth, patient position during refill, patient movement during refill, post-

¹ For complete product information refer to the Lioresal[®] Intrathecal (baclofen injection) Package Insert, Copyright Medtronic Inc. 2002 <http://www.medtronic.com/physician/itb/disclosure-package-insert.html> (Lioresal is a trademark of Novartis Corp.)

implant patient weight changes, pump orientation in the pocket, and pump movement within the pocket.

- If all or part of the drug *is known* to have been injected into the pocket during the refill procedure, monitor the patient closely for signs and symptoms of overdose in an appropriate facility for a sufficient amount of time or until the symptoms have resolved. Seek emergency assistance and follow emergency procedures for overdose as necessary.
- If a full or partial pocket fill *is suspected*, monitor the patient closely for signs and symptoms of overdose and determine if a pocket fill has occurred. While monitoring the patient, the following may help determine whether a pocket fill has just occurred:
 - Empty the pump completely and compare the expected volume to the actual volume. A volume discrepancy may indicate a pocket fill.
Note: Do not use the programmer to determine the volume of drug in the pump. The programmer and pump do not measure the actual volume of drug in the pump.
 - In some cases, swelling at the injection site may indicate that a pocket fill has occurred. However, absence of swelling does not rule out the occurrence of a pocket fill.
 - A patient report of an unusual sensation during the drug injection (e.g. burning, stinging) may indicate that a pocket fill has occurred. However, absence of an unusual sensation does not rule out the occurrence of a pocket fill.

At every refill, patients and caregivers should be reminded about the signs and symptoms of drug overdose, underdose, and withdrawal. Instruct patients to seek immediate medical assistance in the event that symptoms of drug overdose, underdose, or withdrawal appear. In addition to the overdose and underdose information that is included in the patient brochures, the enclosed *Refill Appointment Card* can be used to remind patients of their appointment, drug information, and drug overdose/underdose symptoms. The patient brochures along with additional copies of the Refill Appointment Cards can be obtained from your Medtronic representative.

Medtronic is in the process of supplementing the labeling related to improper injection with the information included in this communication. The manuals for the following products will be updated:

Pump Models:	8637-20, 8637-40, 8626-10, 8626L-10, 8626-18, 8626L-18, 8627-10, 8627L-10, 8627-18, 8627L-18
Refill Kit Models:	8551, 8555, 8561, 8562, 8564, 8565, 8566

Additional Information:

Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation Technical Services at 1-800-707-0933 and FDA's MedWatch Program (www.fda.gov/medwatch).

Medtronic has an ongoing commitment and interest in promoting better healthcare and patient outcomes by keeping you apprised of information related to our devices and associated therapies. We have notified the FDA of this communication. If you have questions please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933.

Sincerely,



George Aram
Vice President Quality and Compliance
Medtronic Neuromodulation

Enclosures:

- *Clinician Refill Reference Card; Refill Appointment Cards; Physician Reply Card; Return envelope*