Dear Healthcare Professional,

The Clinician Refill Reference Card for SynchroMed® Implantable Infusion Systems that was originally distributed with the January 2011 Medical Device Correction related to pocket fills has been updated to align with new product labeling. The January 2011 Medical Device Correction letter provided 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. 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. The January 2011 letter is available online at http://professional.medtronic.com/iddadvisories and http://professional.medtronic.com/itbadvisories.

The main title of the Clinician Refill Reference Card has been updated to read Critical Actions in the Pump Refill Procedure, and the updates to the card include:

- A description of the card’s purpose regarding pocket fill
- A reminder to clinicians of the critical steps for ensuring the pump is correctly refilled
- Detail regarding proper alignment of the refill template
- Information for actions to take if a pocket fill is suspected
- Removal of the note related to glucose testing

Medtronic has received FDA approval for updated product manuals and is in the process of deploying this new labeling. Current labeling for product manuals can be found at www.medtronic.com/manuals.

Please read this important information and discuss any concerns you may have with the Clinical Specialist delivering this new Reference Card to you today.

We are committed to continuing to improve our product performance and services to enable you to manage your patients in a safe and effective manner. You can access product performance information at: http://professional.medtronic.com. If you have questions, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am - 6pm CST. Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation Technical Services and to FDA’s MedWatch Program (www.fda.gov/medwatch).

Sincerely,

Mike Crader
Vice President Quality and Compliance
Medtronic Neuromodulation