Medtronic

Urgent Field Safety Notice

SynchroMed®Implantable Infusion Pump - Pump Refill Procedure Safety Update

Update to the January 2011 Medical Device Correction letter titled "Important Clinical Information about Pocket Fills"

May 2013

Medtronic Ref.: FA578

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 regulatory 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 provided in the new reference card and discuss any concerns you may have with your Medtronic representative.

The Competent Authority of your country has been notified of this action.

This notice needs to be passed on all those who need to be aware within your organization.

We deeply apologize for any disruption this may cause your practice. Please know, patient safety is our top priority. Feel free to contact us <insert contact details> if you have any questions or concerns. We appreciate your time and attention to this important notification, and thank you for continuing to put your trust in Medtronic.

Sincerely,

Country Manager or BU Country Manager

Enclosure:C//m'c/ao *Refill Reference Card titled: "Critical Actions in the Pump Refill Procedure "*