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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”

Medtronic Ref.: FA578

May 2013

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 labelling. 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 labelling. Current labelling 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 Irish Medicines Board (IMB) 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 01 511 1400 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.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'L. Bridge'.

Lezlie Bridge BSc. DMS
Regulatory Affairs Manager – UK & Ireland

Critical Actions in the Pump Refill Procedure

CLINICIAN REFILL REFERENCE CARD
SYNCHROMED® IMPLANTABLE INFUSION SYSTEMS

Warning: A pocket fill may occur if the needle is not inserted through the refill port septum until it has reached the metal bottom of the refill port, or if the needle is moved from the correct position during the refill procedure. A pocket fill is the inadvertent injection of drug into the patient instead of the pump's reservoir, and **can lead to life-threatening symptoms, serious patient injury, or death due to overdose or underdose.**

To avoid the occurrence of a pocket fill, follow these critical actions to ensure that the needle is located correctly throughout the refill procedure. The critical actions in the pump refill procedure are described in this reference card under the following four categories: (1) Locating and Palpating the Pump, (2) Inserting the Needle, (3) Emptying the Pump, and (4) Refilling the Pump. This card should be used as a supplement to the Instructions for Use manuals that are included with Medtronic SynchroMed® Implantable Infusion Pump refill kits.

Locating and Palpating the Pump

Correct identification of the pump's location is the first step in performing a successful refill procedure.

- Palpate the area of the implanted pump to identify its location and orientation.
- Align the refill template appropriately based on the model of pump that is being refilled (Figure 1).
- X-ray and fluoroscopy can be used to assist in locating or determining the orientation of the pump, if deemed necessary by the clinician.

Refill Template – The clear plastic refill template is used as a guide for inserting the needle into the refill port of the SynchroMed EL and SynchroMed II pumps. The left edge of the template has the same shape and contour as the left edge of the SynchroMed EL pump. The right edge of the template has the same shape and contour as the right edge of the SynchroMed II pump. When the edge of the template is aligned correctly with the edge of the pump, the circular opening in the center of the template will be located above the pump's refill port.



Figure 1. Aligning the refill template correctly for each pump model

Inserting the Needle

To help ensure proper insertion of the needle, you should feel the needle:

1. pass through the patient's skin and subcutaneous tissue,
2. hit the silicone septum,
3. pass through the septum, and
4. hit the metal bottom of the refill port (Figure 2).

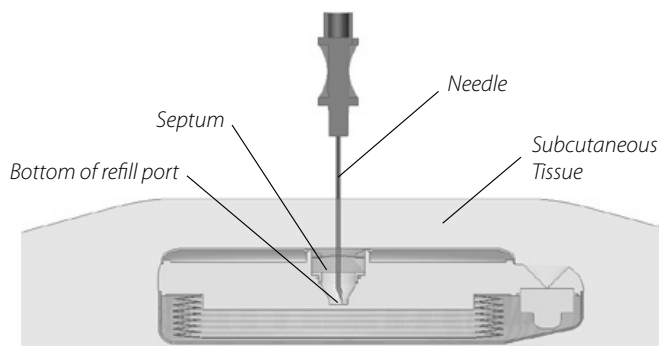


Figure 2. Inserting the Needle

(Note: This illustration represents a cross-section view of the SynchroMed II 20 mL pump.)

Emptying the Pump

To help ensure that the pump is completely emptied and the needle remains properly inserted:

- Observe the fluid as it is removed. If the withdrawn fluid does not have the expected appearance, this may indicate that the needle is not properly inserted into the pump. The pump is completely empty when:
 1. air bubbles stop flowing into the extension tubing and syringe, and
 2. negative pressure in the syringe can be felt.

Refilling the Pump

To help ensure that the pump is correctly refilled:

- As the clamp is opened, observe for the following indicators of proper needle position:
 1. The bubbles in the extension set *will* immediately be drawn into the pump.
 2. The plunger *may* move slightly as drug is initially drawn into the pump.
- During injection, periodically withdraw and observe a portion of the drug to confirm it has the expected appearance, indicating that the needle continues to be properly positioned. If you are unsure whether drug was correctly injected into the pump, completely aspirate to verify that all of the injected drug can be removed.

If it is known or suspected that a pocket fill has occurred, monitor the patient closely for an adequate amount of time and seek emergency assistance as necessary. Refer to the refill kit manual or the Indications, Drug Stability, and Emergency Procedures for SynchroMed and IsoMed Implantable Infusion Systems Reference Manual for emergency procedures associated with drug underdose and overdose. As always, you should ensure the patient is aware of the symptoms of drug overdose and underdose. Refer to the appropriate drug labeling for specific drug overdose and underdose symptoms.

If you have questions regarding the refill procedure, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933.

NEEDLE PLACEMENT REMINDERS:

- If in doubt about the needle location at any point during the procedure, reassess its position.
- Before and during drug injection, verify that the needle is fully inserted to the metal bottom of the refill port.
- If you are unsure whether drug was correctly injected into the pump, completely aspirate to verify that all of the injected drug can be removed.

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