Urgent Field Safety Notice

Use of Unapproved Drugs with the SynchroMed® Implantable Infusion Pump

IMPORTANT MEDICAL DEVICE INFORMATION

Medtronic ref : FA553

November 2012

Dear Doctor,

This letter provides important updated information on Medtronic Neuromodulation's continuing efforts to investigate and communicate the impact of unapproved drugs on the performance of the SynchroMed infusion pump system. Use of unapproved drugs with SynchroMed pumps can result in an increased risk of permanent motor stall and cessation of drug infusion. Approved drugs for infusion therapy with the SynchroMed systems contain morphine sulfate, morphine hydrochloride, floxuridine, methotrexate, baclofen or ziconotide in solution. More drug detail is attached to this letter in the *Summary of Approved Drugs*.

Explanation of the Issue:
Based on data from Medtronic's Implantable Systems Performance Registry (ISPR), the *overall* failure rate of the SynchroMed II pump at 78 months post implant is 2.4% when used to dispense approved drugs, and 7.0% when used to dispense unapproved drugs. The use of unapproved drugs can lead to intermittent or permanent pump motor stalls which may be reported as a loss of or change in therapy. Therapy changes could potentially result in serious injury and/or death. Pumps can experience motor stalls when used with either approved or unapproved drugs, however pump motor stalls have been reported at a significantly lower rate when approved drugs are exclusively used.

Medtronic continues to investigate motor gear corrosion, which has been identified as a primary contributor to permanent motor stall in both SynchroMed II and SynchroMed EL pumps. Enclosed you will find a document titled *Increased Risk of Motor Stall and Loss of or Change in Therapy with Unapproved Drug Formulations* that provides additional details.

Recommendations:
To minimize the potential for motor stall, only use the approved drugs that are identified in the SynchroMed infusion system labeling. Do not use compounded drugs, unapproved concentrations or unapproved formulations.

- Continue to monitor patients closely for the possible return of baseline symptoms. A return of baseline symptoms could potentially indicate pump damage.
- Reinforce with patients and caregivers information on the signs and symptoms of withdrawal due to therapy cessation, and the importance of contacting their healthcare provider immediately if these signs and symptoms appear.

- The SynchroMed II pump is designed with a critical alarm for pump motor stall. For patients implanted with a SynchroMed II pump, you can change the critical alarm interval frequency to sound every 10 minutes.
    - Remind patients, their caregivers, and your appropriate staff members to be alert for pump alarms.
    - At implant or follow-up visits, perform an alarm test to provide an opportunity for patients and caregivers to hear and differentiate between the critical and non-critical pump alarms.
    - For patients with a Personal Therapy Manager (PTM), the PTM will show alarm code 8476 if there is an active alarm.
- Retrieve logs when interrogating the SynchroMed II pump in order to check for motor stall events. Note that a temporary motor stall with recovery is expected behavior when the pump is exposed to a strong magnetic field such as during an MRI. Medtronic Technical Services can be contacted for further assistance evaluating motor stall events on logs.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all hospital pharmacists who prepare drug refills, to all health care professionals who perform pump refills and in general to those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Additional Information:
We are committed to continuing to advance the practice of intrathecal drug delivery and 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 online at: http://professional.medtronic.com.

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

We regret any difficulties this may cause you and your patients. If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative.

Sincerely,

Country BU Manager

Enclosures:
- Increased Risk of Motor Stall and Loss of or Change in Therapy with Unapproved Drug Formulations
- Summary of Approved Drugs