Medtronic Ireland Ltd,
Unit G
Swords Business Campus
Balheary Road
Swords
Co.Dublin
Tel 01 511 1400
Fax 01 807 7220
www.medtronic.com
vat IE 9513488W

Urgent Field Safety Notice

SynchroMed® Implantable Infusion Pump Internal Shorting

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Medtronic reference: FA574

Dear Healthcare Professional,

The purpose of this communication is to provide safety information and patient management recommendations related to the potential for electrical shorting internal to the SynchroMed infusion pump.

Nature of Device Issue:
Within the SynchroMed pump, feedthroughs are components that provide an electrically insulated path for current to flow from the electronic circuitry to the motor. An electrical short can occur when ions from the drug solution and humidity permeate through the drug pathway tubing inside the pump and interact with the feedthrough over time. An electrical short circuit in a feedthrough may present as a motor stall or low battery reset/alarm and lead to a loss of or reduction in therapy which may result in the return of underlying symptoms and/or withdrawal symptoms.

Scope and Likelihood of Issue:
All SynchroMed II and SynchroMed EL pumps can potentially be affected by this issue at any time throughout the life of the device, regardless of drugs used in the pump. The SynchroMed EL has been discontinued and based on Medtronic data, at least 90% of the remaining actively implanted SynchroMed EL pumps are near expected end of service.

Medtronic has assessed reports of internal feedthrough shorting in the SynchroMed II pump since its release in 2004. There have been 380 relevant product events from approximately 181,400 pump implants worldwide. Medtronic's analysis of returned products and reports data shows the cumulative failure probability for internal feedthrough shorting to be approximately 0.28% at 48 months and 0.69% at 84 months post implant.

Severity:
SynchroMed pump internal feedthrough shorts can lead to a loss of or reduction in therapy which may result in a return of underlying symptoms and/or withdrawal symptoms. Patients receiving intrathecal baclofen therapy are at risk for baclofen withdrawal syndrome, which can lead to a life threatening condition if not promptly and effectively treated. Surgical revision to replace or remove the pumps may be required for patients with pumps experiencing repeated motor stalls, Low Battery Resets (with or without Safe State), or a premature Elective Replacement Indicator.

How to Identify Pumps Potentially Affected:
For SynchroMed II, this issue may be exhibited as one or more of the following:

- Repeated motor stalls with recovery listed in the pump event log, not associated with temporary exposure to a magnetic field (e.g. MRI).
- Multiple "Reset - Low Battery" errors (critical alarm) listed in the pump event log. After a reset, the pump may change to "Safe State". While in Safe State, the pump does not deliver at a therapeutic rate.
- Premature Elective Replacement Indicator (non-critical alarm), which is one that occurs sooner than expected based on implant duration and flow rate.

For SynchroMed EL, this issue may be exhibited as one or both of the following:

- Motor Stall as determined by rotor study
- Low battery alarm

Recommendations:

Medtronic does not recommend prophylactic replacement of SynchroMed II or SynchroMed EL pumps due to the estimated low occurrence rate, the presence of pump alarms, and the risks associated with replacement surgery. However, appropriate consideration should be given to individual patient needs.

If repeated short duration motor stalls, Low Battery Resets (with or without Safe State), or a premature Elective Replacement Indicator occur, replacement surgery should be scheduled for therapy continuation. Alternative medical management should be considered if appropriate.

Ongoing Patient Management Recommendations:

- Continue to monitor patients closely for the return of baseline symptoms. A return of baseline symptoms may potentially indicate pump failure.
- Inform patients about the importance of keeping their pump refill appointments and contacting their physician immediately if the pump alarm sounds or if they notice a change or return of symptoms. Remind patients to always carry their patient identification card.
- 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 the identified signs and symptoms appear.
- The SynchroMed II pump is designed with both critical and non-critical alarms.
  - Increase the critical alarm interval frequency. The critical alarm interval frequency may be changed 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), if there is an active alarm, the PTM will show an alarm code when a bolus is attempted.
  - Retrieve and check logs for critical alarm events when interrogating the SynchroMed II pump. Note that a motor stall with recovery is expected in the event log when the pump is exposed to a strong magnetic field, such as during an MRI. Medtronic Technical Services may be contacted for further assistance evaluating critical alarm events on logs.
- For the SynchroMed EL pump:
  - Remind patients, their caregivers, and your appropriate staff members to be alert for the low battery pump alarm.
  - For suspected motor stalls, perform a rotor study to confirm or rule out a motor stall.

The Irish Medicines Board 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 at 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,

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