May 2006

SynchroMed® EL Model 8627 Safety Alert

Important Patient Management Information

Dear Dr. _____, Managing Physician

This letter is to inform you of a device issue that affects SynchroMed® EL pumps manufactured between March and July 1999. The Catheter Access Port (CAP) on these affected devices may detach from the main body of the pump, which can interrupt drug flow to the target site. If the drug flow is interrupted, the patient may experience loss of therapy, return of underlying symptoms, and/or symptoms of drug withdrawal, which can be fatal.[1,2] Based on Medtronic's records, the list of serial numbers of affected pumps issued to your practice is included on the enclosed reply card.

Affected Devices

Medtronic has identified 1,847 active implanted pumps worldwide that are at risk for CAP detachment. The root cause of the CAP detachment is the result of gradual bond degradation between the CAP and pump; see the enclosed "Technical Brief for SynchroMed®EL Model 8627 Low CAP Adhesion". SynchroMed EL pumps manufactured before March or after July 1999 are not affected by this device safety alert.

Serial Numbers manufactured March through July 1999:

SynchroMed EL Model 8627-10	NGE000001R – NGE000242R
SynchroMed EL Model 8627L-10	NGF000001R – NGF003266R
SynchroMed EL Model 8627-18	NGG000001R - NGG000068R
SynchroMed EL Model 8627L-18	NGH000001R – NGH001780R

Patient Risk

- Medtronic anticipates that 16 of the 1,847 active implants will experience CAP detachment.
- Medtronic does not anticipate any serious injuries or death as a result of CAP detachment. While baclofen and other drug withdrawal symptoms can have serious or fatal effects, these outcomes are considered unlikely.
- The patient is approaching elective device replacement independent from this recall, as SynchroMed EL pumps have an estimated battery life of 6.5 years.

Patient Management Recommendations

- Proactively discuss this important patient management information with your affected patients.
  - **Intrathecal Baclofen Therapy:** Subject to your medical judgment, Medtronic recommends pump replacement now, because (1) the potentially severe medical consequences from intrathecal baclofen withdrawal syndrome and (2) the pumps are approaching normal end of service.
  - **Intrathecal Pain Therapy**: Determine whether pump replacement is medically appropriate.
- Emergency Recommendation: Follow-up with patients immediately if they report loss of therapy, return of underlying symptoms, and/or symptoms of drug withdrawal. In the event a

[1] For information on baclofen withdrawal refer to the Lioresal® Intrathecal (baclofen injection) Package Insert, Copyright Medtronic Inc. 2002 www.medtronic.com/lioresalpi

[2] For information on morphine withdrawal, refer to the Merck Manual of Diagnosis and Therapy, Seventeenth Edition, Copyright 1999-2005 by Merck & Co., Inc. www.merck.com/pubs/mmanual/

patient reports such conditions, promptly address their medication concerns (e.g. supplement oral prescription) and schedule a pump replacement surgery.

Physician and Patient Support

We appreciate your assistance with this matter. To address the impact of any inconvenience that patients experience related to early replacement surgery, Medtronic will work with physicians to address reimbursement concerns.

Please consult your Medtronic representative for additional assistance.

Next Steps

1. Medtronic has informed {insert name of regulatory agency} of the SynchroMed® EL Model 8627 Low CAP Adhesion issue. In accordance with {insert name of regulatory agency} regulations[3] regarding recall effectiveness checks, please fax your reply card to the following confidential fax number 763-367-1414 within ten days of receipt of this letter.
2. Return explanted products to Medtronic Return Products Analysis. Please consult your Medtronic representative to facilitate the device return procedure, if you need assistance.

We regret and apologize for the inconvenience this matter may have caused you and your patients. We are committed to providing you with the highest quality products, services and ongoing support as you care for your patients. If you have any questions or comments, please contact your Medtronic Representative.

Sincerely,

{Country Manager}

Enclosures:

Technical Brief for SynchroMed EL Model 8627 Low CAP Adhesion
Reply Form (with serial number list)

CC: Implanting Physicians

[3] {insert relevant regulation reference; e.g. 21 CFR Part 7}