

Urgent: Medical Device Recall

SynchroMed[®] EL Model 8627 Recall

Important Patient Management Information

Dear Healthcare Provider,

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} The enclosed reply card lists the patients in your practice who have affected devices, based on Medtronic's records.

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 recall.

Serial Numbers manufactured March through July 1999:

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

Patient Risk

- While interruption of therapy and drug withdrawal symptoms can have serious or fatal effects, Medtronic considers these outcomes possible, but not likely, for patients in whom the device is implanted. Medtronic anticipates that 16 of the 1,847 active implants will experience CAP detachment.
- The SynchroMed EL pumps have an average expected battery life of 7 years at a flow rate of 0.5ml/day. These pumps are approaching their effective device replacement dates.

Patient Management Recommendations

- Discuss this important patient management information with your affected patients. Sample patient letters for intrathecal baclofen (ITB) therapy and pain therapy patients are attached for your convenience, should you choose to use them.
 - **Intrathecal Baclofen Therapy:** Subject to your medical judgment, Medtronic recommends pump replacement now, because (1) the medical consequences from therapy interruption or intrathecal baclofen withdrawal syndrome may be severe, (2) the pumps are approaching normal end of service, and (3) you and your patients should be observant for early symptoms of treatment withdrawal including return of baseline spasticity, pruritus, hypotension, paresthesias, high fever, and altered mental status.

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/

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- **Intrathecal Pain Therapy:** Determine whether pump replacement is medically appropriate.

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 reimburse patients up to \$1000 for non-reimbursed expenses incurred in connection with such replacement surgery. The sample patient letter provides further information about how patients should seek such reimbursement.

The following resources are available for additional assistance:

1. Patients may contact Medtronic Neurological Patient Services at 1-800-510-6735
2. Clinicians may contact Medtronic Neurological Technical Services at 1-800-707-0933

Next Steps

1. Medtronic has informed FDA of the SynchroMed[®] EL Model 8627 Low CAP Adhesion issue. In accordance with FDA regulations³ 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,

Jon Tremmel
President, Medtronic Neurological

Enclosures:

Technical Brief for SynchroMed EL Model 8627 Low CAP Adhesion
Reply Form (with patient list)
Patient Letter Template(s)

CC: Implanting Physicians

SynchroMed® EL Model 8627 - Low CAP Adhesion

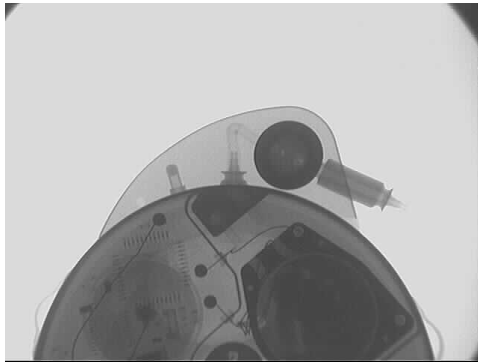
The SynchroMed EL pump models 8627-10, 8627L-10, 8627-18, 8627L-18 come with a Catheter Access Port (CAP). The CAP is attached to the side of the pump with silicone medical adhesive. It is used to bypass the pump and directly access the catheter.

To date, there have been 47 observations of pumps with detached catheter access ports in more than 86,000 of these models sold. Most of the 47 pumps were returned with detached catheter access ports with no therapy complaints or patient adverse events associated with the detached CAP. An internal investigation revealed the root cause is the result of gradual bond degradation between the CAP and pump related to component cleaning of pumps manufactured between March 1999 and July 1999. There were a total of 4,317 SynchroMed EL pumps sold from this manufacturing time frame and given an average expected battery life of 7 years at a flow rate of 0.5ml/day, these devices are approaching their expected replacement dates.

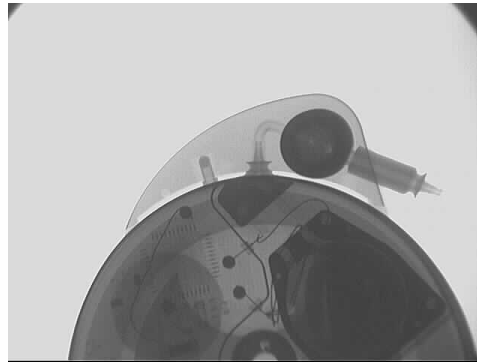
A failure analysis was performed using the observed failure rate, device registration records, and typical service life. It predicted a total of 63 CAP detachments prior to normal battery depletion from the suspect population of pumps. Our records show that as many as 1,847 pumps of the original 4,317 pumps are still in service. Based on this analysis, we expect up to 16 CAP detachments worldwide (2 in the EU) between now and April 2009. Medtronic does not anticipate any serious injuries or death. Severe baclofen withdrawal symptoms are estimated to affect less than 1% of patients who experience loss of therapy¹.

On January 27, 2006, there was an ITB patient death in the United States where, upon explant of the pump by the medical examiner, the CAP was observed to be detached from the pump. Medtronic has not received the official cause of death and is uncertain if this death is associated with the CAP detachment.

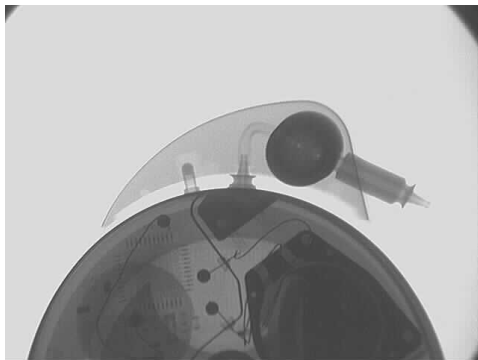
The CAP snaps onto the pump's catheter fitting and forms a seal. The CAP adhesive bond could fail and continue to function normally or intermittently, as long as the CAP does not fully detach from the pump. If the CAP detaches from the pump with the catheter disconnected, no drug will flow to the target site. The pump will continue infusing at the programmed rate but the medication will be dispensed into the pump pocket. The detachment will lead to a cessation of therapy, return of underlying symptoms, and drug withdrawal symptoms. This is of particular concern in intrathecal baclofen (ITB) patients where there is the possibility of a rare but severe baclofen withdrawal syndrome that could be fatal, if not detected and treated early.



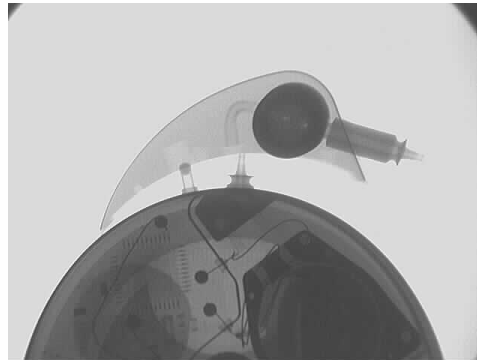
Adhered CAP



Delaminated CAP



Detached CAP (catheter still connected)



Detached CAP (catheter disconnected, no drug flow to target site.)

¹ Medtronic sponsored Expert Physician Panel Review , April 2006

Sample ITB Patient Letter

Dear [patient name],

Medtronic, Inc., the manufacturer of your implantable pump, has recently informed us of a pump reliability concern. The Catheter Access Port (CAP) of your pump may detach from the main body of the pump reservoir and could result in drug not being delivered through the catheter. Although the chance of this happening to your pump is rather low, if it occurs, it could cause drug delivery to stop abruptly, resulting in loss of therapy, return of your underlying symptoms, and symptoms of drug withdrawal which can cause death in the most severe cases.

As you may know, the pump that delivers your therapy has an average battery life of 5 to 7 years. Because your pump is nearing its normal end of battery life, we recommend that you consider having the pump replaced now. Please contact our office at XXX-XXX-XXXX.

To address the impact of any inconvenience to you that results from early replacement surgery, Medtronic will reimburse you for up to \$1000 of non-reimbursed expenses incurred in connection with such surgery. If there are expenses after your medical bills have been submitted and paid by your insurance (for example, Medicare and/or private insurance), please retain the relevant documentation (for example, itemized medical bills and the matching insurance payments statements, or parking receipts related to the surgery). Then, contact Medtronic Patient Services, 1-800-510-6735.

In the meantime, please continue to watch for the signs and symptoms of baclofen withdrawal. Early symptoms of abrupt withdrawal from intrathecal baclofen may include high fever, itching, low blood pressure, tingling sensations, altered mental status, return of baseline spasticity, and muscle rigidity. As always, it is very important that you contact us right away if you experience any of the above symptoms.

We look forward to hearing from you soon.

Sincerely,

Physician name

Sample Pain Patient Letter

Dear [patient name],

Medtronic, Inc., the manufacturer of your implantable pump, has recently informed us of a pump reliability concern. The Catheter Access Port (CAP) of your pump may detach from the main body of the pump reservoir and could result in drug not being delivered through the catheter. Although the chance of this happening to your pump is rather low, if it occurs, it could cause drug delivery to stop abruptly, resulting in loss of therapy, return of your underlying symptoms, and symptoms of drug withdrawal.

As you may know, the pump that delivers your therapy has an average battery life of 5 to 7 years. Because your pump is nearing its normal end of battery life, we recommend that you consider early elective replacement. Please contact our office at XXX-XXX-XXXX.

To address the impact of any inconvenience to you that results from early replacement surgery, Medtronic will reimburse you for up to \$1000 of non-reimbursed expenses incurred in connection with such surgery. If there are expenses after your medical bills have been submitted and paid by your insurance (for example, Medicare and/or private insurance), please retain the relevant documentation (for example, itemized medical bills and the matching insurance payments statements, or parking receipts related to the surgery). Then, contact Medtronic Patient Services, 1-800-510-6735.

As always, please contact us if you notice an increase in your pain.

Sincerely,

Physician name