Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL08-01 October 23, 2007

Item: Medtronic SynchroMed EL implantable infusion pump;
models: 8626-10, 8626L-10, 8626-18, 8626L-18, 8627-10, 8627L-10, 8627-18, 8627L-18

Specific Incident: Medtronic issued an Urgent Medical Device Correction "SynchroMed EL Pump Motor Stall Due to gear Shaft Wear" in August 2007. (Attachments)

As of June 15, 2007, Medtronic received 354 inquiries/complaints from health care professionals worldwide, regarding gear shaft wear on the SynchroMed EL implantable drug infusion pumps. Medtronic estimates that approximately 52,000 of these pumps, that may experience gear shaft wear, are still implanted in patients worldwide. If a pump motor stall occurs, drug delivery will stop abruptly without warning and result in loss of therapy. Drug withdrawal from Intrathecal Baclofen (ITB) therapy can be fatal if not treated properly and effectively.

Actions: 1. If you have these devices in stock do not use them.

2. By close of business (COB) Friday, October 26, 2007 identify all affected patients by implementing each of the following steps a through c.
It is important that ALL INFORMATION sources be reviewed to insure that patients will not be overlooked, as affected patients may be found on one list and not on another.

a) Review the manufacturers letters (Attachment 1 and 2).

b) Review the VA physician/caregiver list and their associated patients with an affected device available from your Network (VISN) Patient Safety Officer (PSO) and contact the physician/caregiver to implement action 3 below.

c) Review patient records for all other patients with implanted Medtronic SynchroMed EL devices affected by this recall that might have been implanted at a non-VA facility and have their VA physician/caregiver implement action 3 below.

3. By close of business (COB) Friday, November 30, 2007 physicians/caregivers must follow Patient Management Recommendations #1 through #4 contained in the manufacturer's letters (Attachments 1 and 2) and reproduced below:

Patient Management Recommendation #1

If a patient presents symptoms of underinfusion or withdrawal, a clinician can confirm a pump motor stall through a drug refill volume discrepancy and x-ray pump roller study. If a pump motor stall is confirmed, immediate replacement of this pump is necessary for continued intrathecal therapy.

Patient Management Recommendation #2

Discuss this important information with your patients and caregivers, reminding them that pumps can fail without warning, and that the patient may not become aware of the pump failure until he/she experiences return of underlying symptoms, and/or symptoms of drug withdrawal.

Patient Management Recommendation #3

Educate patients and caregivers about the early signs and symptoms of drug underdose or withdrawal.

Patient Management Recommendation #4

Instruct patients to seek immediate medical assistance in the event that signs or symptoms of drug underdose or withdrawal appear.

Source: Medtronic

Contact: Medtronic Neuromodulation Technical Services at (800) 701-0933 or
Mr. Bryanne Patail, National Center for Patient Safety (NCPS) at (734) 930-5890

Attachments: 1) Medtronic Urgent: Medical Device Correction letter for pumps manufactured prior to September 1999.
2) Medtronic Urgent: Medical Device Correction letter for pumps manufactured since September 1999.

ATTACHMENT 1

Medtronic
When Life Depends on Medical Technology

Aug 2007

Urgent: Medical Device Correction

SynchroMed® EL Pump Motor Stall Due To Gear Shaft Wear

Pumps with Motors Manufactured Prior to September 1999

Models Affected: 8626-10, 8626L-10, 8626-18, 8626L-18, 8627-10, 8627L-10, 8627-18, 8627L-18

Important Patient Management Information

Dear Health Care Professional,

This letter is to inform you of a potential pump motor stall issue that affects SynchroMed EL pumps **with motors manufactured prior to September 1999**.

This population of pumps can stall at a higher rate due to gear shaft wear. If a pump motor stall occurs, drug delivery will stop abruptly and without warning resulting in loss of therapy, return of underlying symptoms, and/or symptoms of drug underinfusion or withdrawal. Drug withdrawal from Intrathecal Baclofen (ITB) therapy can be fatal if not treated promptly and effectively.[1,2]

Affected Devices

Medtronic estimates that approximately 8,000 pumps from this population remain implanted worldwide. Because this failure mode is random, it is not possible to predict which of these devices may fail in the future. The enclosed list of pump serial numbers and patient names identifies your patients who, according to our device registration records, are currently implanted with pumps in this affected population.

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[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/

ATTACHMENT 1

Medtronic
When Life Depends on Medical Technology

Aug 2007

Urgent: Medical Device Correction

Pumps with Motors Manufactured Prior to September 1999

As of June 15, 2007, Medtronic has received 354 health care professional inquiries/complaints worldwide which have been confirmed, through returned product analysis, to be due to gear shaft wear. Medtronic has determined that 220 of these events are associated with the subset of devices that are the subject of this letter. Medtronic has submitted Medical Device Reporting (MDR's) to the FDA for all 354 cases. No patient deaths or permanent injuries have been directly attributed to pump motor stall due to gear shaft wear. The following table provides an overview of these MDR's.

MDR Events Related to Devices with Motors Manufactured Prior to September 1999

MDR Overview	MDR Qty	% Total
Return of underlying symptoms	94	43%
No Symptoms Reported*	86	39%
Withdrawal	34	15%
Overdose	4	2%
Death (not associated with motor stall)	2	1%
Total	220	100%

(*No symptoms reported: end of service, malfunction, volume discrepancy, return w/o complaint)

The highest reported rate of pump motor stalls due to gear shaft wear has been among patients who are administered ITB therapy[3]. Using Medtronic's Returned Product Analysis data, this subset of pumps exhibits a cumulative gear shaft wear failure rate of 2.2%, at 7 years post implant. SynchroMed EL pumps have an expected battery longevity between 78 and 90 months (between 6.6 to 7.5 years), depending on daily infusion rate. This means that most of the affected pumps in this subset of devices are either at or approaching normal end of battery life. Physicians should consider this battery life information when discussing treatment options with their patients. Please refer to the enclosed Figures 1 and 2 for details regarding ITB and Pain failure rates.

This specific gear shaft wear issue does not affect the SynchroMed II pump, because the SynchroMed II pump has a different motor design.

Patient Risk

Pump motor stalls due to gear shaft wear result in the abrupt cessation of therapy. After a patient presents with symptoms of underinfusion, a clinician can only confirm a pump motor stall condition via drug refill volume discrepancy and x-ray pump roller study (refer to the attached Pump Stall Troubleshooting Procedure[4]).

The SynchroMed EL pump does not provide an alarm to alert the patient or clinician to a stalled motor condition.

The affected patient population can experience the following signs and symptoms:

[3] Based on analysis of available data, there is no evidence that the type of drugs used in the different patient populations can account for the difference observed in gear shaft wear failure rates. Spasticity patients exhibit more clinically obvious signs of therapy cessation which may be responsible for an increased rate of pump motor stall detection and reporting.

[4] Medtronic ITB Clinical Reference Guide; UC199601184b EN NP2584b

- Abrupt cessation of ITB therapy which can lead to serious medical complications and, if not treated promptly and effectively, can be fatal. Also, ITB patients have a higher risk of serious medical complications that are potentially life threatening, if their device fails, than pump patients receiving other Medtronic approved infusion therapies.
- Abrupt cessation of morphine for intrathecal pain therapy, which can result in a return of underlying symptoms and/or withdrawal symptoms.
- Abrupt cessation of chemotherapy for hepatic arterial infusion, which can result in missing part or all of the planned treatment. This can have potentially serious consequences for the patient.
- To ascertain the patient risk associated with abrupt cessation of other drugs being administered via the pump, refer to the applicable drug labeling and/or the most current Physician's Desk Reference[5].

Because this failure mode is random, it is not possible to predict which of these devices may fail in the future.

Patient Management Recommendations

We realize that each of your patients is unique, and we support your clinical judgment in caring for them. Sample patient letters for intrathecal baclofen (ITB) therapy and pain therapy patients are attached for your convenience, should you choose to use them. If you are concerned about motor stalls in implanted devices, please consider Medtronic's patient management recommendations below.

Patient Management Recommendation #1

If a patient presents symptoms of underinfusion or withdrawal, a clinician can confirm a pump motor stall through a drug refill volume discrepancy and x-ray pump roller study (refer to the attached Pump Stall Troubleshooting Procedure[6]). If a pump motor stall is confirmed, immediate replacement of this pump is necessary for continued intrathecal therapy.

Patient Management Recommendation #2

Discuss this important information with your patients and caregivers, reminding them that pumps can fail without warning, and that the patient may not become aware of the pump failure until he/she experiences return of underlying symptoms, and/or symptoms of drug withdrawal.

Patient Management Recommendation #3

Educate patients and caregivers about the early signs and symptoms of drug underdose or withdrawal.

Patient Management Recommendation #4

Instruct patients to seek immediate medical assistance in the event that signs or symptoms of drug underdose or withdrawal appear.

[5] Note that the SynchroMed EL pump is approved for use with Lioresal and morphine.
[6] Medtronic ITB Clinical Reference Guide; UC199601184b EN NP2584b

ATTACHMENT 1

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Urgent: Medical Device Correction
Pumps with Motors Manufactured Prior to September 1999

Recommendations for Specific Therapies

In addition, please consider the following information for the appropriate therapy segment:

- **ITB Therapy:** Use your professional medical judgment in considering early pump replacement due to the potentially severe medical consequences of ITB withdrawal. You and your patients should be vigilant for early symptoms of ITB withdrawal. These may include a return of baseline spasticity, pruritis, hypotention, parasthesias, high fever, and/or altered mental status. Special attention should be given to patients at apparent risk (e.g. spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral baclofen or ITB). **Please refer to the enclosed "Lioresal® Intrathecal (Baclofen Injection) Emergency Procedures Sheet" and "Lioresal Emergency Medication Information Patient Wallet Card" for patient management recommendations.** (Additional copies of each of these publications are available free of charge from your Medtronic representative.)
- **Intrathecal Pain Therapy:** Determine whether early pump replacement is medically appropriate, considering the risks incident to continued pump usage as compared to risks incident to a pump replacement procedure. As always, you and your patients should be vigilant for early symptoms of drug underdose or withdrawal.
- **Chemotherapy:** Determine whether early pump replacement or other type of medical treatment is appropriate, considering the risks incident to continued pump usage as compared to risks incident to a pump replacement procedure.

Next Steps

1. FDA has knowledge of this SynchroMed® EL Gear Shaft Wear recall communication. **Your local Medtronic representative will follow up with you to review this information and confirm notification.**
2. Report any malfunction or adverse event related to this device to Medtronic Neuromodulation Technical Services at 1-800-707-0933, and to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch
3. **Should you decide to replace any pumps in this population, please return the explanted SynchroMed EL pumps to Medtronic Returned Products Analysis. Please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933, or your local Medtronic representative to facilitate the device return procedure, if you need assistance.**
4. **Please maintain a copy of this notification in your SynchroMed EL User Manual.**

ATTACHMENT 1

Medtronic
When Life Depends on Medical Technology

Aug 2007

Urgent: Medical Device Correction
Pumps with Motors Manufactured Prior to September 1999

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 $1,000 of reasonable, non-reimbursed expenses incurred in connection with surgical procedures taken to explant the device, in accordance with Medtronic's applicable Supplemental Limited Warranty. The sample patient letters enclosed provides further information about how patients should seek such reimbursement.

The following resources are available for additional assistance.

- Patients may contact Medtronic Neuromodulation Patient Services at 1-800-510-6735.
- Physicians may contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 or their local Medtronic representative.

We appreciate your assistance with this matter. 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.

For immediate assistance, please contact your local Medtronic representative.

Sincerely,

George Aram
VP Quality
Medtronic Neuromodulation Sector

Enclosures:

- Patient/Pump Serial Number List
- Figure 1: "SynchroMed EL Survival Plot – ITB Therapy"
- Figure 2: "SynchroMed EL Survival Plot – Pain Therapy"
- Pump Stall Troubleshooting Procedure
- Lioresal® Intrathecal (Baclofen Injection) Emergency Procedures Sheet
- Lioresal Emergency Medication Information Patient Wallet Card
- Sample Patient Letters

ATTACHMENT 2

Medtronic
When Life Depends on Medical Technology

Aug 2007

Important Patient Management Information

SynchroMed® EL Pump Motor Stall Due To Gear Shaft Wear

Pumps with Motors Manufactured Beginning September 1999

Models Affected: 8626-10, 8626L-10, 8626-18, 8626L-18, 8627-10, 8627L-10, 8627-18, 8627L-18

Purpose

This letter provides important patient management information for patients with the Medtronic SynchroMed® EL pumps **with motors manufactured beginning September 1999.**

The most common failure mode for the SynchroMed EL pump is pump motor stall due to gear shaft wear. If a pump motor stall occurs, drug delivery will stop abruptly and without warning resulting in loss of therapy, return of underlying symptoms, and/or symptoms of drug underinfusion or withdrawal. The SynchroMed EL pump does not provide an alarm to alert the patient or clinician to a stalled motor condition. Drug withdrawal from Intrathecal Baclofen (ITB) therapy can be fatal if not treated promptly and effectively.[1,2]

Background

In late 1999, changes were made in manufacturing that significantly reduced the incidence of gear shaft wear in the SynchroMed EL pumps. Using Medtronic's Returned Product Analysis data, SynchroMed EL pumps manufactured **after** the change exhibit a cumulative shaft wear failure rate of 0.5%, at 7 years post implant. In contrast, pumps manufactured **before** the manufacturing changes exhibit a shaft wear failure rate of 2.2%, at 7 years post implant. Refer to the enclosed Figures 1 and 2 for details regarding ITB and Pain failure rates.

Although the likelihood of motor stall due to gear shaft wear has been reduced by manufacturing improvements, it has not been entirely eliminated. **Gear shaft wear remains the most common cause of the pump failure in the SynchroMed EL.**

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[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/

ATTACHMENT 2

Medtronic
When Life Depends on Medical Technology

Aug 2007

Important Patient Management Information

Pumps with Motors Manufactured Beginning September 1999

As of June 15, 2007, Medtronic has received 354 health care professional inquiries/complaints worldwide which have been confirmed, through returned product analysis, to be due to gear shaft wear. Medtronic has determined that 134 of these events are associated with the subset of devices that are the subject of this letter. Medtronic has submitted Medical Device Reporting (MDR's) to the FDA for all 354 cases. The highest reported rate of pump motor stalls due to gear shaft wear has been among patients who are administered ITB therapy[3]. No patient deaths or permanent injuries have been directly attributed to pump motor stall due to gear shaft wear. The following table provides an overview of the events.

MDR Events Related to Devices with Motors Manufactured Beginning September 1999

MDR Overview	MDR Qty	% Total
No Symptoms Reported*	58	43%
Return of underlying symptoms	55	41%
Withdrawal	21	16%
Death	0	0%
Overdose	0	0%
Total	134	100%

(*No symptoms reported: end of service, malfunction, volume discrepancy, return w/o complaint)

Affected Devices

Medtronic estimates that approximately 44,000 pumps from this population remain implanted worldwide. The potential for gear shaft wear affects all SynchroMed EL pumps; however, pumps with motors manufactured beginning September 1999, exhibit a lower failure rate associated with gear shaft wear. Because this failure mode is random, it is not possible to predict which pumps in the affected population may fail in the future.

This specific gear shaft wear issue does not affect the SynchroMed II pump, because the SynchroMed II pump has a different motor design.

Patient Risk

Pump motor stalls due to gear shaft wear result in the abrupt cessation of therapy. After a patient presents with symptoms of underinfusion, a clinician can only confirm a pump motor stall condition via drug refill volume discrepancy and x-ray pump roller study (refer to the attached Pump Stall Troubleshooting Procedure[4]).

[3] Based on analysis of available data, there is no evidence that the type of drugs used in the different patient populations can account for the difference observed in gear shaft wear failure rates. Spasticity patients exhibit more clinically obvious signs of therapy cessation which may be responsible for an increased rate of pump motor stall detection and reporting.

[4] Medtronic ITB Clinical Reference Guide; UC199601184b EN NP2584b

ATTACHMENT 2

Medtronic
When Life Depends on Medical Technology

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Important Patient Management Information

Pumps with Motors Manufactured Beginning September 1999

The SynchroMed EL pump does not provide an alarm to alert the patient or clinician to a stalled motor condition.

The affected patient population can experience the following signs and symptoms:

- Abrupt cessation of ITB therapy which can lead to serious medical complications and, if not treated promptly and effectively, can be fatal. Also, ITB patients have a higher risk of serious medical complications that are potentially life threatening, if their device fails, than pump patients receiving other Medtronic approved intrathecal therapies.
- Abrupt cessation of morphine for intrathecal pain therapy, which can result in a return of underlying symptoms and/or withdrawal symptoms.
- Abrupt cessation of chemotherapy for hepatic arterial infusion, which can result in missing part or all of the planned treatment. This can have potentially serious consequences for the patient.
- To ascertain the patient risk associated with abrupt cessation of other drugs being administered via the pump, refer to the applicable drug labeling and/or the most current Physician's Desk Reference[5].

Patient Management Recommendations

We realize that each of your patients is unique, and we support your clinical judgment in caring for them. If you are concerned about motor stalls in implanted devices, please consider Medtronic's patient management recommendations below.

Patient Management Recommendation #1

If a patient presents symptoms of underinfusion or withdrawal, a clinician can confirm a pump motor stall through a drug refill volume discrepancy and x-ray pump roller study (refer to the attached Pump Stall Troubleshooting Procedure[6]). If a pump motor stall is confirmed, immediate replacement of this pump is necessary for continued intrathecal therapy.

Patient Management Recommendation #2

Discuss this important information with your patients and caregivers, reminding them that pumps can fail without warning, and that the patient may not become aware of the pump failure until he/she experiences return of underlying symptoms, and/or symptoms of drug withdrawal.

Patient Management Recommendation #3

Educate patients and caregivers about the early signs and symptoms of drug underdose or withdrawal.

[5] Note that the SynchroMed EL pump is approved for use with Lioresal and morphine.
[6] Medtronic ITB Clinical Reference Guide; UC199601184b EN NP2584b

ATTACHMENT 2

Medtronic
When Life Depends on Medical Technology

Aug 2007

Important Patient Management Information

Pumps with Motors Manufactured Beginning September 1999

Patient Management Recommendation #4

Instruct patients to seek immediate medical assistance in the event that signs or symptoms of drug underdose or withdrawal appear.

Recommendations for Specific Therapies

In addition, please consider the following information for the appropriate therapy segment:

- **ITB Therapy: Please refer to the enclosed "Lioresal® Intrathecal (Baclofen Injection) Emergency Procedures Sheet" and "Lioresal Emergency Medication Information patient wallet card" for patient management recommendations.** (Additional copies of each of these publications are available free of charge from your Medtronic representative.) Remind your patients and their caregivers to be observant for early symptoms of treatment withdrawal including return of baseline spasticity, pruritis, hypotention, parasthesias, high fever, and altered mental status, in order to prevent the potentially severe medical consequences from intrathecal baclofen withdrawal syndrome which can be fatal if untreated. Special attention should be given to patients at apparent risk (e.g. spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral baclofen or ITB).
- **Intrathecal Pain Therapy:** As always, you and your patients should be observant for early symptoms of treatment withdrawal.
- **Chemotherapy:** Determine whether alternative treatment is appropriate based on your medical judgment and your specific patient condition.

Physician and Patient Support

Please return any failed SynchroMed EL pump to Medtronic for further analysis. If Medtronic determines that the device has experienced a motor stall due to the gear shaft wear problem, Medtronic will reimburse patients up to $1,000 of reasonable, non-reimbursed expenses incurred in connection with surgical procedures taken to explant the device, in accordance with Medtronic's applicable Supplemental Limited Warranty. For reimbursement assistance or questions, please contact Medtronic Neuromodulation Patient Services.

The following resources are available for additional assistance.

- Patients may contact Medtronic Neuromodulation Patient Services at 1-800-510-6735.
- Physicians may contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 or their local Medtronic representative.

Report any malfunction or adverse event related to this device to Medtronic Technical Services or your local Medtronic Representative. You should also provide a report to the United States FDA MedWatch Program. You can contact the MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch/how.htm

ATTACHMENT 2

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When Life Depends on Medical Technology

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Important Patient Management Information

Pumps with Motors Manufactured Beginning September 1999

We appreciate your assistance with this matter. We are committed to providing you with the highest quality products, services and ongoing support as you care for your patients.

Please maintain a copy of this notification in your SynchroMed EL User Manual.

For immediate assistance, please contact your local Medtronic representative.

Sincerely,

George Aram
VP Quality
Medtronic Neuromodulation Sector

Enclosures:

- Figure 1: "SynchroMed EL Survival Plot – ITB Therapy"
- Figure 2: "SynchroMed EL Survival Plot – Pain Therapy"
- Pump Stall Troubleshooting Procedure
- Lioresal® Intrathecal (Baclofen Injection) Emergency Procedures Sheet
- Lioresal Emergency Medication Information Patient Wallet Card

Medtronic, Inc. 710 Medtronic Parkway NE, Minneapolis, MN 55432-5604, USA
Internet: www.medtronic.com Tel. 763-505-5000 Fax 763-505-1000