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Field Safety Corrective Action

August 2007

SynchroMed® EL Pump Motor Stall Due To Gear Shaft Wear

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

Sold in Europe between 1999 and 2005

Dear Health Care Professional,

This letter is to inform you of important patient management information for patients with the Medtronic SynchroMed® EL pumps.

Based on analysis of returned SynchroMed EL pumps, Medtronic has determined that 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, the implanted pump system will cease delivering drug to your patient without warning resulting in loss of therapy, and resultant return of underlying symptoms, and/or symptoms of drug underinfusion or withdrawal. The SynchroMed EL pump's alarm systems do not 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}.

In late 1999, Medtronic successfully implemented changes 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 **before** the manufacturing changes exhibit a statistically different failure rate than those manufactured **after** the manufacturing changes.

- Pumps with motors manufactured "Before September 1999" exhibit a cumulative shaft wear failure rate of 2.2%, at 7 years post implant.
- Pumps with motors manufactured "During and After September 1999" exhibit a cumulative shaft wear failure rate of 0.5%, at 7 years post implant.

Refer to the enclosed Figures 1 and 2 for pump reliability details.

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

¹ For information on baclofen withdrawal refer to the applicable drug labeling and/or the most current national compendium of medicines
² For information on morphine withdrawal, refer to the applicable drug labeling and/or the most current national compendium of medicines



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cause of the pump failure in the SynchroMed EL. The highest reported rate of pump motor stalls due to gear shaft wear has been among patients who are administered ITB therapy³.

This specific gear shaft wear issue does not affect the SynchroMed II pump, because the SynchroMed II pump has a different motor design. In Europe, the SynchroMed II pump replaced the SynchroMed EL product in 2004.

Affected Devices

Refer to the enclosed SynchroMed EL pump serial number list to identify which of the pumps fall within the “before September 1999” group, and which pumps fall within the “During and After September 1999” group.

Pump with motors manufactured before September 1999.

As noted above, Medtronic’s analysis shows that gear shaft wear occurs at a higher rate in this population of pumps than pumps with motors manufactured during and after September 1999. SynchroMed EL pumps have expected battery longevity between 6.6 and 7.5 years (depending on daily infusion rate), meaning that most of the affected pumps are either at or approaching normal end of battery life.

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. As stated previously, this subset of pumps exhibits a worst case gear shaft wear failure rate of 2.2%, at 7 years post implant.

As of 15 June 2007, Medtronic has identified 220 SynchroMed EL pumps from the “before September 1999” population that have been confirmed, through returned product analysis, to be affected by gear shaft wear. 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 reported clinical outcome related to these pumps.

The highest reported rate of pump motor stalls due to gear shaft wear has been among patients who are administered ITB therapy⁴.

Clinical outcome - Pre Sept 1999	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)		

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 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.



Pump with motors manufactured during and after September 1999.

Medtronic estimates that approximately 44,000 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. As stated previously, this subset of SynchroMed EL pumps exhibits a worst case gear shaft wear failure rate of 0.5%, at 7 years post implant.

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. The highest reported rate of pump motor stalls due to gear shaft wear has been among patients who are administered ITB therapy⁵.

As of 15 June 2007, Medtronic has identified 134 SynchroMed EL pumps from the “during and after September 1999” population that have been confirmed, through returned product analysis, to be affected by gear shaft wear. 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 clinical outcome related to these pumps.

Clinical outcome - Post Sept 1999	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)		

⁵ 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.



Patient Risk

The following Patient Risk, Patient Management Recommendations and Physician and Patient Support apply to both populations of SynchroMed EL pumps regardless the manufacturing date of the motor.

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). 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 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 national compendium of medicines⁶.

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. If you are concerned about motor stalls in implanted devices, please consider Medtronic's patient management recommendations below.

1. Pump Stall Troubleshooting

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). If a pump motor stall is confirmed, immediate replacement of this pump is necessary for continued intrathecal therapy.

2. Educate Patients on Risks of Pump Stalls

Discuss the risks of this system failure with your patients and caregivers. Remind them that their implanted drug delivery system can fail without warning due to gear shaft wear, 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.

3. Educate Patients on Underdose/Withdrawal

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

4. Educate Patients on How to Seek Care in Case of Underdose/Withdrawal

⁶ For a list of drugs approved for use with SynchroMed EL see the pump's instructions for use



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Instruct patients where and how to receive immediate medical assistance in the event that signs or symptoms of drug underdose or withdrawal appear.

Recommendations for Specific Therapy and Pump Populations

For ITB patient management information, please refer to the enclosed “Lioresal® Intrathecal (Baclofen Injection) Emergency Procedures Sheet”

Note: 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).

In addition, please consider the following recommendations for the two pump populations:

- **Pre September 1999:** For ITB therapy, use your professional medical judgment in considering early pump replacement due to the potentially severe medical consequences of ITB withdrawal. For intrathecal pain therapy or chemotherapy, 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.
- **During and After September 1999:** For ITB and pain therapy, remind your patient and their caregivers to be observant for early symptoms of treatment withdrawal. For chemotherapy, determine whether alternative treatment is appropriate based on your medical judgment and your specific patient condition.

Next Steps

1. **Should you decide to replace any pumps in the pre-99 population, please return the explanted SynchroMed EL pumps to Medtronic Returned Products Analysis. Please contact your local Medtronic representative to facilitate the device return procedure, if you need assistance.**
2. **Please maintain a copy of this notification in your SynchroMed EL User Manual.**

Physician Support

The following resources are available for additional assistance.

- Physicians may contact Medtronic Technical Services at (insert [REDACTED]) or your local Medtronic representative for additional support.
- Report any malfunction or adverse event related to this device to Medtronic Technical Services or local Medtronic Representative.

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.

Sincerely,

Country Manager

Enclosures:

- Pump Stall Troubleshooting Procedure
- Pump Serial Number Listing
- Figure 1: “SynchroMed EL Survival Plot – ITB Therapy”



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- Figure 2: "SynchroMed EL Survival Plot – Pain Therapy"
- Lioresal Intrathecal (baclofen injection) underdose/withdrawal procedure sheet

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