

## Important Patient Management Information

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# SynchroMed<sup>®</sup> 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<sup>®</sup> 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.<sup>1,2</sup>

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

<sup>2</sup> 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/](http://www.merck.com/pubs/mmanual/)

## **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<sup>3</sup>. 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**

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

(\*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<sup>4</sup>).

<sup>3</sup> 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.

<sup>4</sup> Medtronic ITB Clinical Reference Guide; UC199601184b EN NP2584b

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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<sup>5</sup>.

## **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<sup>6</sup>). 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.

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<sup>5</sup> Note that the SynchroMed EL pump is approved for use with Lioresal and morphine.

<sup>6</sup> Medtronic ITB Clinical Reference Guide; UC199601184b EN NP2584b

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### **Pumps with Motors Manufactured Beginning September 1999**

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#### **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](http://www.fda.gov/medwatch/how.htm).

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**Pumps with Motors Manufactured Beginning September 1999**

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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](http://www.medtronic.com) Tel. 763-505-5000 Fax 763-505-1000

**Figure 1**

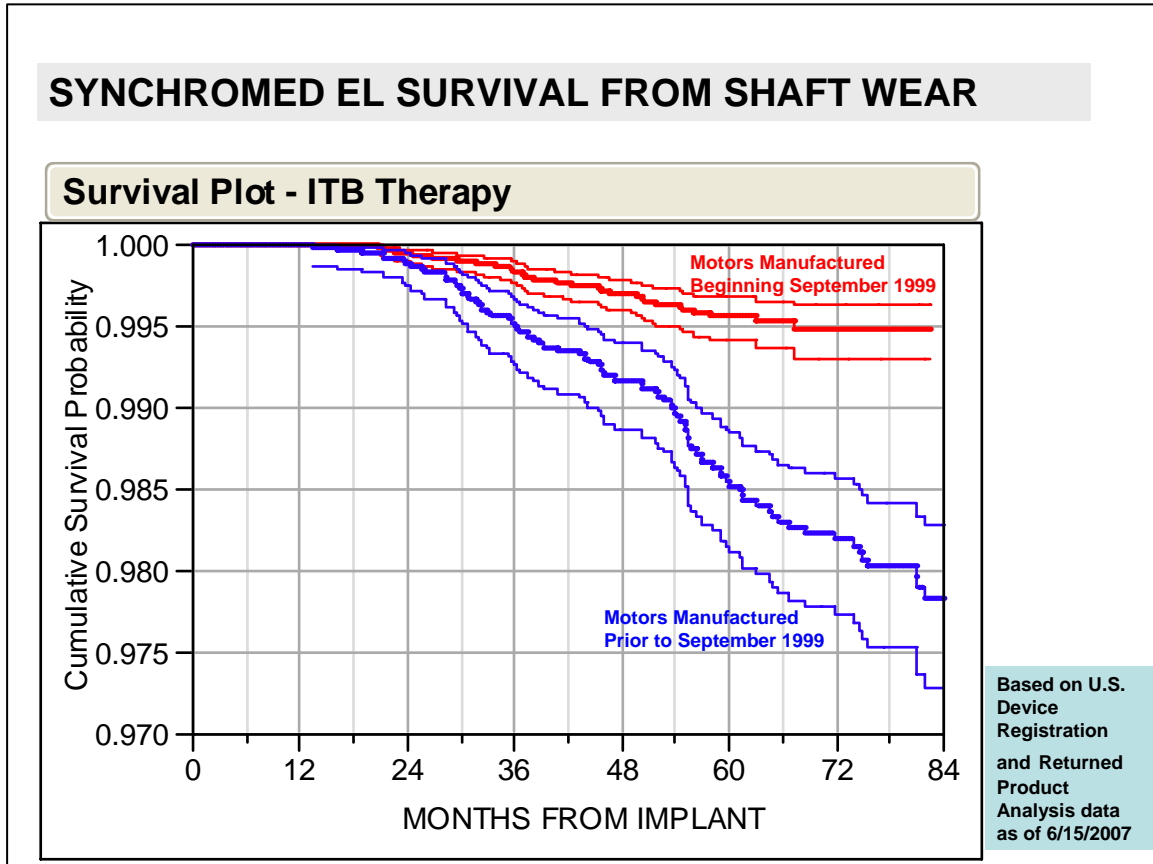


Figure 1 provides cumulative survival curves for the gear shaft wear failure mode with 95% confidence bounds for two pump populations (those that contain motors manufactured prior to September 1999 vs. those containing motors manufactured beginning September 1999 and beyond).

The cumulative survival estimate for motors manufactured prior to September 1999 is 97.8% at 7 years (84 months) post implant. This equates to a cumulative failure rate of 2.2% at 7 years.

The cumulative survival estimate for motors manufactured beginning September 1999 and beyond is 99.5% at 7 years (84 months) post implant. This equates to a cumulative failure rate of 0.5% at 7 years.

**Figure 2**

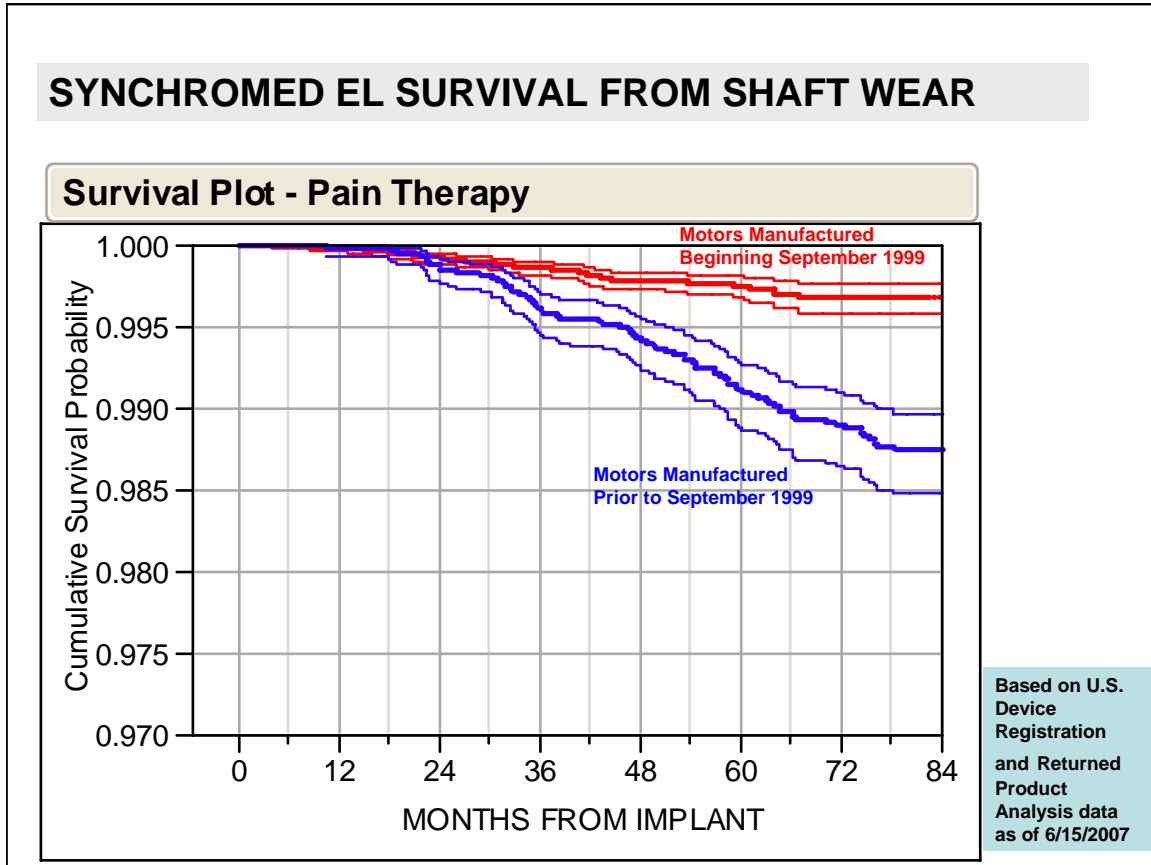


Figure 2 provides cumulative survival curves for the gear shaft wear failure mode for pain patients with 95% confidence bounds for two pump populations (those that contain motors manufactured prior to September 1999 vs. those containing motors manufactured beginning September 1999 and beyond).

The cumulative survival estimate for motors manufactured prior to September 1999 is 98.7% at 7 years (84 months) post implant. This equates to a cumulative failure rate of 1.3% at 7 years.

The cumulative survival estimate for motors manufactured beginning September 1999 and beyond is 99.7% at 7 years (84 months) post implant. This equates to a cumulative failure rate of 0.3% at 7 years.

**- Sample -**

**Pain Patient Letter  
Pumps with Motors Manufactured Prior to September 1999**

Dear [Patient Name]:

Medtronic, Inc., the manufacturer of your implantable pump, has recently informed us of a pump reliability concern. The motor component within your pump may stall and could result in decreased amount of the drug being delivered or not being delivered at all 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 underinfusion or 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, you may wish to consider having the pump replaced now. Please contact our office at XXX-XXX-XXXX, to discuss your options. As always, if you have any question or concerns, please contact our office.

To address the impact of any inconvenience that you may experience related to early replacement surgery, Medtronic will reimburse you 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. In addition, Medtronic recognizes that you may incur additional non-reimbursed expenses that are unique to your situation, and will work with you accordingly.

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 statement, or parking receipts related to the surgery). For assistance or questions related to reimbursement, contact Medtronic Patient Services at 1-800-510-6735.

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

Sincerely,

[Physician name]

- Sample -

**Baclofen Patient Letter  
Pumps with Motors Manufactured Prior to September 1999**

Dear [Patient Name]:

Medtronic, Inc., the manufacturer of your implantable pump, has recently informed us of a pump reliability concern. The motor component within your pump may stall and could result in decreased amount of the drug being delivered or not being delivered at all 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 underinfusion or withdrawal which can in the most severe cases be fatal if not treated promptly and effectively.**

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, you may wish to consider having the pump replaced now. Please contact our office at XXX-XXX-XXXX. As always, if you have any question or concerns, please contact our office.

To address the impact of any inconvenience that you may experience related to early replacement surgery, Medtronic will reimburse you 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. In addition, Medtronic recognizes that you may incur additional non-reimbursed expenses that are unique to your situation, and will work with you accordingly.

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 statement, or parking receipts related to the surgery). For assistance or questions related to reimbursement, contact Medtronic Patient Services at 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]

### Procedure 8.4: Suspected Pump Underinfusion

*Patient Symptom  
and Possible Cause*

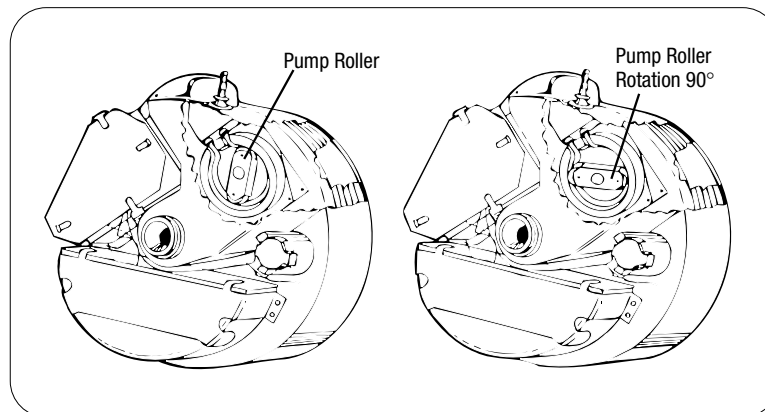
If the pump has underinfused by more than 25% of the expected volume (there is **more** drug in the reservoir than expected), and possible occlusion of implanted system components has been eliminated, the pump may not be operating properly. To confirm pump function, conduct a roller study using this procedure.

*Troubleshooting Procedure*

Review the following procedure carefully.

1. X-ray the pump to determine the location of the pump roller (overexposing the film will make the roller more visible). Several attempts may be necessary to visualize the roller (**Figure 8-1**).

**Figure 8-1**  
Pump Roller Rotation



**Figure 8-2**  
X-Ray of Pump



2. Calculate the amount of a bolus, in microliters ( $\mu\text{L}$ ), that will move the roller  $90^\circ$ . Use the formula in **Table 8-7**.

**Table 8-7**  
Calculation for Moving  
Pump Roller  $90^\circ$

a.	<b>Determine the calibration constant from the Pump Status Screen or patient's <i>Implanted Device Identification</i> card.</b>
b.	<b>Divide 1800 by the calibration constant.</b> The result is the volume in $\mu\text{L}$ required to move the roller $90^\circ$ . $1800 \div \text{Cal Constant} = \text{_____ } \mu\text{L}$
c.	<b>Program the amount calculated (<math>\mu\text{L}</math>) using the above formula; OR</b>
d.	To obtain the bolus dose expressed in the present metrology, <b>multiply the formula's result (in <math>\mu\text{L}</math>) by the concentration, divided by 1000.</b> $\frac{\mu\text{L} \times (\text{drug concentration}/\text{mL})}{1000 \mu\text{L}/\text{mL}} = \text{Dose in Present Metrology}$
e.	The pump will operate for approximately 45 seconds to deliver a bolus that will turn the roller $90^\circ$ .

3. X-ray the pump and determine the new position of the pump's roller. The pump's roller should have moved  $90^\circ$ . Fluoroscopy can be used to visualize the pump as it moves to its new position (**Figure 8-2**).
4. If there is no roller movement, or less than  $90^\circ$  of movement, the device may be stalled. Contact Medtronic Technical Services or your local Medtronic Sales Specialist.
5. If the roller shows proper movement, make certain there are no occlusions in the catheter system. Refer to **Procedure 8.2** or **8.3**.

**WARNING**

Programming a bolus could lead to drug overdose. Therefore, caution must be used when calculating and programming all bolus doses.

# Lioresal® Intrathecal (baclofen injection) Underdose/Withdrawal

In the U.S. emergency technical support is available 24 hours/day for clinicians managing patients with Medtronic SynchroMed® Infusion System implants: 800-707-0933. In other world areas contact your Medtronic representative.

## EMERGENCY PROCEDURE

### Symptoms of Underdose

Pruritus, hypotension, paresthesias, fever, and altered mental state.

### Symptoms of Intrathecal Baclofen Withdrawal

High fever, altered mental status, exaggerated rebound spasticity and muscle rigidity that in rare cases has advanced to rhabdomyolysis, multiple organ system failure and death. The condition may resemble autonomic dysreflexia, sepsis, malignant hyperthermia, and neuroleptic-malignant syndrome.

### Medtronic SynchroMed Infusion System

The SynchroMed Infusion System consists of an implantable programmable pump, intraspinal catheter and pump programmer. The pump is implanted in the lower abdomen and dispenses medication from the pump's reservoir through the catheter to the intrathecal or epidural space. Some pumps are equipped with a catheter access port that bypasses the pump reservoir, permitting direct catheter access to the intrathecal or epidural space.

### Suggested Treatment for Intrathecal Baclofen Underdose/Withdrawal

Initiate life-sustaining measures if indicated.

If a patient receiving ITB™ Therapy (Intrathecal Baclofen Therapy) presents with the signs and symptoms suggestive of baclofen withdrawal (above), the following approach is consistent with that suggested by a panel of therapy-experienced clinicians convened to explore this issue:

1. Immediately contact a physician experienced in ITB Therapy, preferably the physician managing the therapy for the patient in question; follow the recommendations of this physician. This step is important even if the patient's signs and symptoms seem mild.
2. If an ITB Therapy physician is unavailable, consider instituting one or more of the following options, unless otherwise contraindicated:
  - high-dose oral\* or enteral baclofen
  - restoration of intrathecal baclofen infusion
  - intravenous benzodiazepines by continuous or intermittent infusion, titrating the dosage until the desired therapeutic effect is achieved

\*Note: Oral baclofen should not be relied upon as the sole treatment for intrathecal baclofen withdrawal syndrome.

Report incident to Medtronic, Inc. In the U.S. call 1-800-328-0810.  
In other world areas contact your Medtronic representative.

The physician experienced with ITB Therapy should expeditiously attempt device troubleshooting. This may include, but is not limited to:

- interrogation of the pump status using the Medtronic pump programmer
- radiologic examination of the pump and catheter system
- a pump refill procedure with the appropriate concentration of baclofen
- system troubleshooting procedures to determine the cause of ITB Therapy interruption
- surgical repair, revision, or replacement of system components

Baclofen withdrawal has been identified during post-approval use of Lioresal Intrathecal. Because this reaction is reported spontaneously from a population of uncertain size, it is not possible to reliably estimate the frequency.

Abrupt withdrawal of intrathecal baclofen, regardless of the cause, has, in rare cases, resulted in a life-threatening syndrome that included high fever, altered mental status, exaggerated rebound spasticity and muscle rigidity that progressed to rhabdomyolysis, multiple organ-system failure, and death.

All patients receiving ITB Therapy are potentially at risk. Some clinical characteristics of the advanced intrathecal baclofen withdrawal syndrome may resemble autonomic dysreflexia, or infection (sepsis), malignant hyperthermia, neuroleptic-malignant syndrome, and other conditions associated with a hypermetabolic state or widespread rhabdomyolysis. **A rapid and accurate diagnosis is important in an emergency room or intensive care setting before initiating treatment in order to prevent the potentially life-threatening central nervous and systemic effects of intrathecal baclofen withdrawal.**

### Contact Information

ITB Therapy Physician

Name: \_\_\_\_\_ Phone: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.

\*Coffey RJ, Edgar TS, Francisco GE, et al. Abrupt withdrawal from intrathecal baclofen: recognition and management of a potentially life-threatening syndrome. *Arch Phys Med Rehabil*. Vol. 83, June, 2002. pp735-41

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UC200303503 EN NPS676EN PN221500-101

# Lioresal® Intrathecal (baclofen injection) Overdose

In the U.S. emergency technical support is available 24 hours/day for clinicians managing patients with Medtronic SynchroMed® Infusion System implants: 800-707-0933. In other world areas contact your Medtronic representative.

## EMERGENCY PROCEDURE

### Symptoms of Overdose

Drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia and loss of consciousness progressing to coma.

There is no specific antidote for treating overdoses of Lioresal Intrathecal. However, anecdotal reports suggest that intravenous physostigmine may reverse central side effects, notably drowsiness and respiratory depression.<sup>2</sup>

### Medtronic SynchroMed Infusion System

The SynchroMed Infusion System consists of an implantable programmable pump, intraspinal catheter and pump programmer. The pump is implanted in the lower abdomen and dispenses medication from the pump's reservoir through the catheter to the intrathecal or epidural space. Some pumps are equipped with a catheter access port that bypasses the pump reservoir, permitting direct catheter access to the intrathecal or epidural space.

### Suggested Treatment for Intrathecal Baclofen Overdose

Maintain Airway/Breathing/Circulation.  
Intubation and respiratory support may be necessary.

Empty pump reservoir to stop drug flow (see right).  
Record amount withdrawn.

Administer physostigmine if not contraindicated.  
Adult Dosage: 0.5 to 1.0 mg IM or IV @ slow controlled rate of not > 1mg/min.  
(May repeat every 10-30 min. if desired patient response is not obtained.)  
Pediatric Dosage: 0.02 mg/kg IM or IV, not >0.5 mg/min. May repeat every 5-10 min. up to 2 mg max.

If not contraindicated, withdraw 30-40 mL CSF by lumbar puncture or through the catheter access port to reduce baclofen concentration in the CSF.  
For instructions on how to withdraw CSF through the catheter access port, please contact Medtronic Technical Services. In the U.S. call 1-800-707-0933.  
In other world areas contact your Medtronic representative.

Notify patient's ITB™ Therapy Physician (see right).

Continue to monitor closely for symptom recurrence.

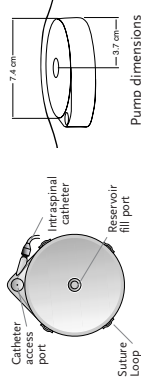
Report incident to Medtronic, Inc. In the U.S. call 1-800-328-0810.  
In other world areas contact your Medtronic representative.

## Medtronic SynchroMed Pump Descriptions

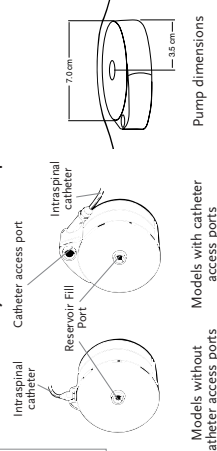
Pump Name	Model	Catheter Access Port?	Reservoir Size
SynchroMed II	8637-40	Yes, funnel-shaped	40 mL
SynchroMed II	8637-20	Yes, funnel-shaped	20 mL
SynchroMed EL	8627-18, 8627L-18*	Yes, screened	18 mL
SynchroMed EL	8627-10, 8627L-10*	Yes, screened	10 mL
SynchroMed EL	8626-18, 8626L-18*	No	18 mL
SynchroMed EL	8626-10, 8626L-10*	No	10 mL
SynchroMed	8618-18, 8618L-18*	Yes, not screened	18 mL
SynchroMed	8617-18, 8617L-18*	Yes, screened	18 mL
SynchroMed	8617-10	Yes, screened	10 mL
SynchroMed	8616-18	No	18 mL
SynchroMed	8616-10	No	10 mL

\*L=pump contains suture loops

### SynchroMed II Pumps

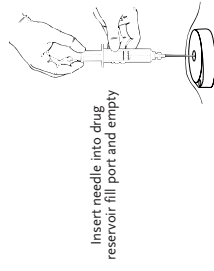


### SynchroMed EL Pumps



Models without catheter access ports

Models with catheter access ports



Insert needle into drug reservoir fill port and empty

## Emergency Procedure to Empty the Pump Reservoir

Equipment:

- 22-gauge or smaller needle (1.5 in./3.8 cm or 2 in./5.1 cm)
- 20 mL luer-lock syringe
- antiseptic agent

1. Locate the pump (right or left abdomen) by palpation.

Pump diameter is approximately 3 in./7 cm.

The reservoir fill port is located in the CENTER of the pump.

2. Prepare injection site by cleansing area using an antiseptic agent; allow skin to dry.

3. Locate reservoir fill port and insert needle through skin. Enter the port's septum until the needle touches the metal needle stop. If you encounter resistance during needle insertion, reassess placement. Do not force the needle; use of excessive force may damage the needle.

4. Withdraw fluid from reservoir using negative pressure. Empty reservoir until large air bubbles are apparent in syringe.

5. Maintain negative pressure while removing needle and attached syringe together from port septum and skin.

6. Record amount of fluid emptied from reservoir in patient chart.

## Contact Information

ITB Therapy Physician

Name: \_\_\_\_\_ Phone: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.

<sup>2</sup>Müller-Schwefe G., Penn R.D. Physostigmine in the treatment of intrathecal baclofen overdose: report of three cases. *J Neurosurg.* August, 1989; 71:273-5.

Lioresal® is a registered trademark of Novartis Pharmaceuticals Corporation.



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# Medtronic

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## INDICATIONS, DRUG STABILITY, AND EMERGENCY PROCEDURES

SynchroMed® and IsoMed® implantable infusion systems

Reference manual

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Rx only

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Infumorph™ is a trademark of Wyeth-Ayerst.

Narcan® is a registered trademark of DuPont.

Lioresal® is a registered trademark of Novartis Pharma, AG.

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**Technical Services 12**

**Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, and component disposal.**

**Refer to the device implant manual for device description, package contents, device specifications, and instructions for use.**



# Indications

Physicians prescribing the SynchroMed II, SynchroMed, or SynchroMed EL Infusion Systems or the IsoMed Constant-Flow Infusion System for use with the drugs listed in Table 1 must be familiar with the indications, contraindications, warnings, precautions, adverse events, dosage and administration information, and screening procedures described in the drug labeling. Each system includes (at a minimum) a pump and a catheter.

**Table 1. Drug indications for Medtronic implantable infusion systems.**

<b>Drugs approved for use with infusion system<sup>a</sup></b>	<b>SynchroMed II</b>	<b>SynchroMed and SynchroMed EL</b>	<b>IsoMed</b>
<b>The chronic epidural/intrathecal infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain.</b> A 0.9% solution of preservative-free sodium chloride injection, USP, can be used to achieve the physician-prescribed concentration of preservative-free morphine sulfate sterile solution.	X	X	X <sup>b</sup>
<b>The chronic intravascular infusion of floxuridine (FUDR) for the treatment of primary or metastatic cancer.</b> Bacteriostatic water or preservative-free sterile saline (USP) can be used to achieve the physician prescribed concentration of chemotherapy drugs or to flush the pump reservoir. Saline or heparinized physiological saline (unless contraindicated) may be used during an interruption in chemotherapy to maintain pump and catheter patency.	X	X	X

**Table 1. Drug indications for Medtronic implantable infusion systems.**

<b>Drugs approved for use with infusion system<sup>a</sup></b>	<b>SynchroMed II</b>	<b>SynchroMed and SynchroMed EL</b>	<b>IsoMed</b>
<b>The chronic intravascular infusion of methotrexate for the treatment of primary or metastatic cancer.</b> Bacteriostatic water or preservative-free sterile saline (USP) can be used to achieve the physician prescribed concentration of chemotherapy drugs or to flush the pump reservoir. Saline or heparinized physiological saline (unless contraindicated) may be used during an interruption in chemotherapy to maintain pump and catheter patency.	X	X	—
<b>The chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain.</b> A 0.9% solution of preservative-free sodium chloride injection, USP, can only be used with preservative-free ziconotide sterile solution after the initial fill of the pump with this drug.	X	X	—
<b>The chronic intrathecal infusion of Lioresal Intrathecal (baclofen injection) in the management of severe spasticity.</b> A 0.9% solution of preservative-free sodium chloride injection, USP, can be used to achieve the physician-prescribed concentration of Lioresal Intrathecal (baclofen injection).	X	X	—

**Table 1. Drug indications for Medtronic implantable infusion systems.**

<b>Drugs approved for use with infusion system<sup>a</sup></b>	<b>SynchroMed II</b>	<b>SynchroMed and SynchroMed EL</b>	<b>IsoMed</b>
<b>The chronic intravascular infusion of doxorubicin or cisplatin for the treatment of primary or metastatic cancer.</b> Bacteriostatic water or preservative-free sterile saline (USP) can be used to achieve the physician prescribed concentration of chemotherapy drugs or to flush the pump reservoir. Saline or heparinized physiological saline (unless contraindicated) may be used during an interruption in chemotherapy to maintain pump and catheter patency.	—	X	—
<b>The intravenous infusion of clindamycin for the treatment of osteomyelitis.</b>	—	X	—

<sup>a</sup> Refer to the appropriate drug labeling for a complete list of indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures.

<sup>b</sup> IsoMed is approved only for intrathecal infusion of preservative-free morphine sulfate sterile solution.

X Specific pump is approved for use with drug.

— Specific pump is not approved for use with drug.

## Drug stability

Testing has indicated that the drugs in Table 2 are stable and compatible with the infusion systems listed in the table. Refer to the appropriate drug labeling for complete prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

**Table 2. Stability<sup>a</sup> of drugs approved for use with Medtronic implantable infusion systems.**

	SynchroMed II		SynchroMed and SynchroMed EL		IsoMed
	Initial fill <sup>b</sup>	Refill	Initial fill <sup>b</sup>	Refill	
Cisplatin (1 mg/mL)	—		7 days		—
Clindamycin (70 mg/mL)	—		28 days		—
Doxorubicin (5 mg/mL)	—		14 days		—
Floxuridine (FUDR) (20 mg/mL)	56 days		28 days		27 days
Lioresal Intrathecal (baclofen injection) (0.5 mg/mL) (2 mg/mL)	180 days		90 days		—
Methotrexate (5 mg/mL)	56 days		28 days		—
Morphine sulfate sterile solution (preservative-free) (25 mg/mL)	180 days		90 days		90 days
Ziconotide sterile solution (preservative-free)	<b>Initial fill<sup>b</sup></b>	<b>Refill</b>	<b>Initial fill<sup>b</sup></b>	<b>Refill</b>	—
25 µg/mL, undiluted	14 days	60 days	14 days	60 days	—
100 µg/mL, undiluted	*	60 days	*	60 days	—
100 µg/mL, diluted	*	40 days	*	40 days	—

<sup>a</sup> Stability is defined as 90% of initial concentration.

<sup>b</sup> For a pump that has not been previously filled with preservative-free ziconotide sterile solution, only the undiluted 25 µg/mL formulation of preservative-free ziconotide sterile solution can be used for the initial pump fill. Refill of the pump with this drug should be completed within 14 days to avoid underdosing the patient. At initial fill of a new pump, some of the drug is lost due to two factors that do not occur upon subsequent refills: adsorption on internal device surfaces, such as titanium, and by dilution in the residual space of the device. Refer to the drug labeling for additional information.

— Drug is not approved for use with this specific pump.

\* Formulation is not applicable for the initial pump fill.

# Emergency procedures

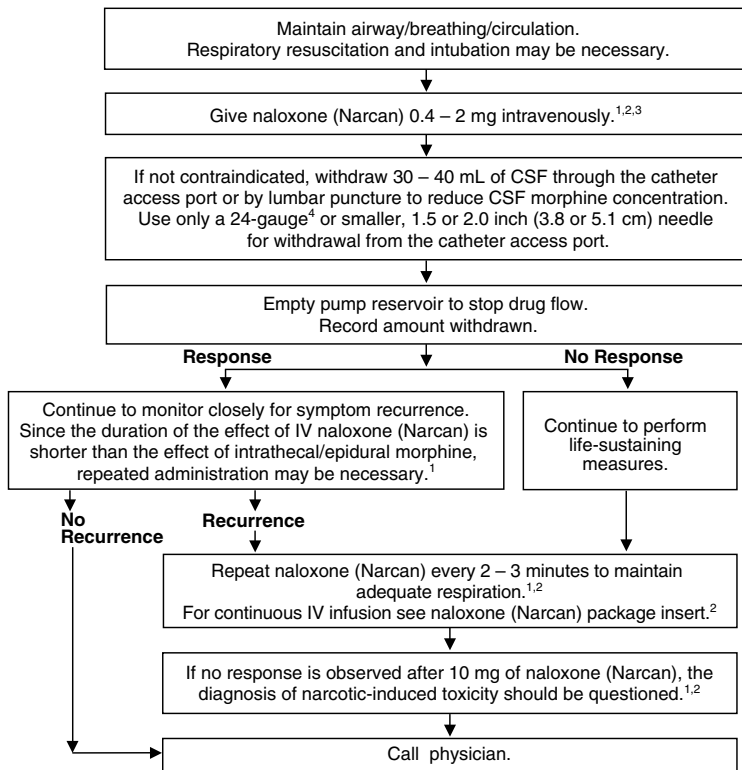
## Morphine intrathecal/epidural overdose

Consult the patient's medical record or with the patient's physician to confirm the drug or drug concentration within the pump reservoir.

### Symptoms

Respiratory depression with or without concomitant central nervous system depression (ie, dizziness, sedation, euphoria, anxiety, seizures, respiratory arrest).

## Actions



**Figure 1.** Morphine intrathecal/epidural overdose emergency procedures.

- 1 Infumorph (Preservative-free morphine sulfate sterile solution) manufacturer's package insert (Wyeth-Ayerst).
- 2 Narcan (naloxone hydrochloride) manufacturer's package insert (DuPont).
- 3 Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.
- 4 Use a 25-gauge needle for withdrawal from a SynchroMed or SynchroMed EL catheter access port. Use a 24- or 25-gauge needle for withdrawal from a SynchroMed II or IsoMed catheter access port.

## **Lioresal Intrathecal (baclofen injection) overdose**

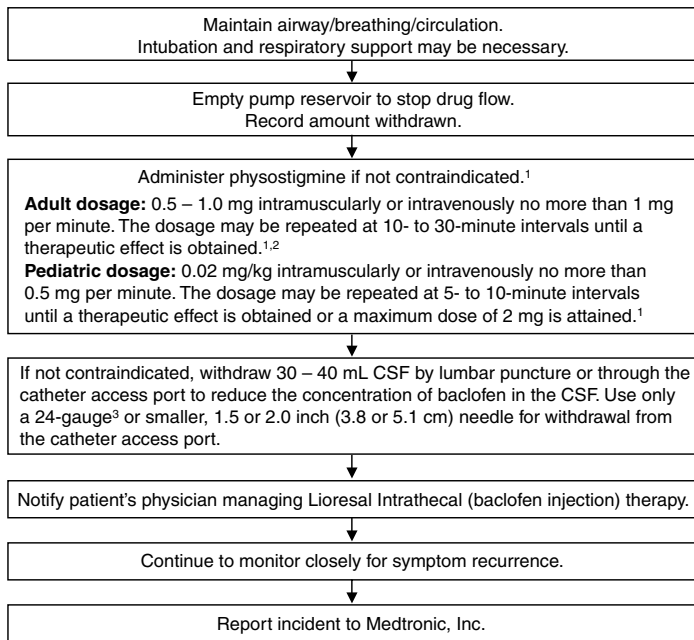
Consult the patient's medical record or with the patient's physician to confirm the drug or drug concentration within the pump reservoir.

### **Symptoms**

Drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia, and loss of consciousness progressing to coma.

There is no specific antidote for treating overdoses of Lioresal Intrathecal (baclofen injection). However, anecdotal reports suggest that intravenous physostigmine may reverse central side effects, notably drowsiness and respiratory depression.

## Actions



**Figure 2.** Lioresal Intrathecal (baclofen injection) overdose emergency procedures.

- 1 Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.
- 2 Müller-Schwefe G, Penn RD. Physostigmine in the treatment of intrathecal baclofen overdose: report of three cases. *J Neurosurg.* August 1989;71:273-275.
- 3 Use a 25-gauge needle for withdrawal from a SynchroMed or SynchroMed EL catheter access port. Use a 24- or 25-gauge needle for withdrawal from a SynchroMed II or IsoMed catheter access port.

## Lioresal Intrathecal (baclofen injection) underdose/withdrawal

Consult the patient's medical record or with the patient's physician to confirm the drug or drug concentration within the pump reservoir.

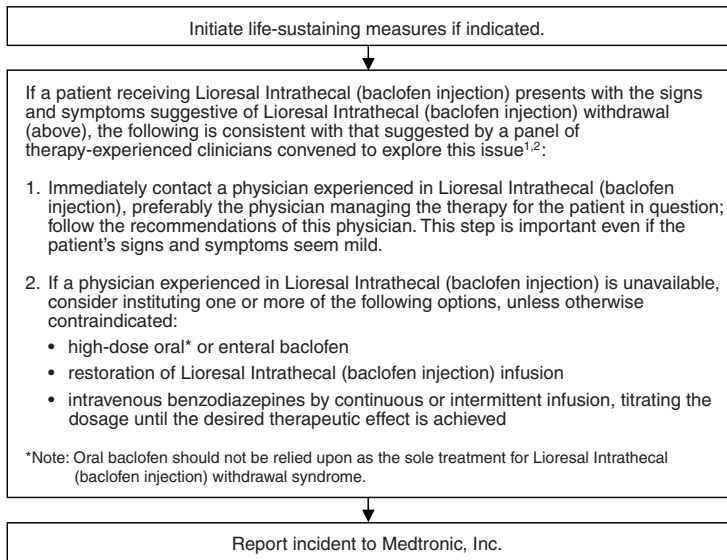
### Symptoms of underdose

Pruritus without rash, hypotension, paresthesia, fever, and altered mental state.

### Symptoms of withdrawal

Exaggerated rebound spasticity and muscle rigidity, rhabdomyolysis, and multiple organ failure. The condition may resemble autonomic dysreflexia, sepsis, malignant hyperthermia, and neuroleptic-malignant syndrome.

### Actions



**Figure 3.** Lioresal Intrathecal (baclofen injection) underdose/withdrawal emergency procedures.

- 1 Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.
- 2 Coffey RJ, Edgar TS, Francisco GE, et al. Abrupt withdrawal from intrathecal baclofen: recognition and management of a potentially life-threatening syndrome. *Arch Phys Med Rehabil.* 2002;83:735-741.

## Emergency procedure to empty the pump reservoir

### Equipment

- 22-gauge needle
  - 20-mL syringe(s)
  - 3-way stopcock
  - Antiseptic agent
1. Locate the pump by palpation. The reservoir fill port is located in the CENTER of the pump.
  2. Prepare the injection site by cleansing the area using antiseptic agent.
  3. Gently insert the 22-gauge needle into the center of the reservoir fill port septum until the needle touches the needle stop. If the clinician encounters resistance during needle insertion, the clinician should reassess placement. Do not force the needle. Hitting metal or the feel of abnormal resistance during the procedure may be an indication that the needle is not in the center of the reservoir fill port septum.



### Cautions:

- The IsoMed pump reservoir contents are under significant pressure. To prevent the reservoir contents from being ejected, do not use an open syringe when emptying the pump.
  - When removing a vesicant or cytotoxic drug, care must be taken to prevent spillage or leakage of the drug into adjacent tissue.
4. If desired, use a 3-way stopcock. Withdraw fluid from the pump reservoir using passive backflow and gentle negative pressure. Empty the pump reservoir until back-flow has stopped and wait five seconds to ensure all fluid is removed and the pump reservoir is empty. Depending on pump reservoir volume, more than one syringe may be needed to empty the pump.
  5. Remove the needle from the reservoir fill port.
  6. Record in the patient chart the amount of fluid emptied from the pump reservoir.

## Technical Services

For additional information, contact Medtronic Technical Services at 1-800-328-0810.





# Medtronic

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