Indications, drug stability, and emergency procedures
SynchroMed® and IsoMed® implantable infusion systems

Reference manual
Rx only
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 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.

⚠️ Warning: Medtronic SynchroMed and IsoMed infusion systems are approved for use with the drugs identified in Table 1. Nonindicated formulations (including admixtures, compounded drugs, and unapproved drug concentrations) have not been tested with the SynchroMed / IsoMed infusion system. Use of nonindicated drugs or fluids can result in increased risks to the patient, damage to the infusion system requiring surgical replacement, and a loss or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Table 1. Medtronic implantable infusion systems are approved for use with the following:

<table>
<thead>
<tr>
<th>Infusion System</th>
<th>SynchroMed II</th>
<th>SynchroMed EL</th>
<th>IsoMed</th>
</tr>
</thead>
<tbody>
<tr>
<td>The chronic intrathecal infusion of Infumorph (preservative-free morphine sulfate sterile solution) in the treatment of chronic intractable pain. The maximum approved concentration is 25 mg/mL. 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.</td>
<td>⬗</td>
<td>⬗</td>
<td>⬗</td>
</tr>
</tbody>
</table>

1 Please review the drug labeling to ensure that it is indicated for intrathecal delivery through the SynchroMed and/or IsoMed infusion systems. Except as stated in Table 1, Medtronic has not tested other drugs for use in the SynchroMed or IsoMed infusion system. Medtronic is not responsible for the accuracy of any drug manufacturer's representations regarding formulation testing of any drugs not listed in Table 1. Medtronic is not responsible for any harm to a patient or damage to a Medtronic infusion system caused by use of such drugs. Medtronic’s warranty will not apply when the infusion system is used with drugs not listed in Table 1.
Table 1. Medtronic implantable infusion systems are approved for use with the following: (continued)

<table>
<thead>
<tr>
<th>Infusion System is specifically approved for a</th>
<th>SynchroMed II</th>
<th>SynchroMed EL</th>
<th>IsoMed</th>
</tr>
</thead>
<tbody>
<tr>
<td>The chronic intrathecal infusion of Prialt (preservative-free ziconotide sterile solution) for the management of severe chronic pain. The maximum approved concentration is 100 µg/mL. 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.</td>
<td>X</td>
<td>X</td>
<td>—</td>
</tr>
<tr>
<td>The chronic intrathecal infusion of Lioresal Intrathecal (baclofen injection) in the management of severe spasticity. The maximum approved concentration is 2 mg/mL. 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).</td>
<td>X</td>
<td>X</td>
<td>—</td>
</tr>
</tbody>
</table>

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

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 of drugs approved for use with Medtronic implantable infusion systems

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>SynchroMed II</th>
<th>SynchroMed EL</th>
<th>IsoMed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lioresal Intrathecal (baclofen injection) (0.5 mg/mL)</td>
<td>180 days</td>
<td>90 days</td>
<td>—</td>
</tr>
<tr>
<td>Infumorph (preservative-free morphine sulfate sterile solution; 25 mg/mL)</td>
<td>180 days</td>
<td>90 days</td>
<td>90 days</td>
</tr>
<tr>
<td>Prialt (preservative-free ziconotide sterile solution)</td>
<td>Initial fill&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Refill</td>
<td>Initial fill&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>25 µg/mL, undiluted</td>
<td>14 days</td>
<td>84 days</td>
<td>14 days</td>
</tr>
<tr>
<td>100 µg/mL, undiluted</td>
<td>*</td>
<td>84 days</td>
<td>*</td>
</tr>
<tr>
<td>100 µg/mL, diluted</td>
<td>*</td>
<td>40 days</td>
<td>*</td>
</tr>
</tbody>
</table>

<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. The pump reservoir should be refilled within 14 days of the initial fill to ensure appropriate dose administration. 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 dosing information.

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

* Formulation is not applicable for the initial pump fill.

### Emergency procedures

#### Morphine 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

See the following figure (Figure 1).
Maintain airway/breathing/circulation. Respiratory resuscitation and intubation may be necessary.

Give naloxone (Narcan) 0.4 – 2 mg intravenously.\textsuperscript{a,b,c}

**FOR INTRATELIAL OVERDOSE:**

If not contraindicated, withdraw 30 – 40 mL of CSF through the catheter access port or by lumbar puncture to reduce CSF morphine concentration. Use only a 24-gauge\textsuperscript{d} or smaller, 1.5 or 2.0 inch (3.8 or 5.1 cm), needle for withdrawal from the catheter access port.

Empty pump reservoir to stop drug flow. Record amount withdrawn.

Response

- Continue to monitor closely for symptom recurrence. Since the duration of the effect of IV naloxone (Narcan) is shorter than the effect of intrathecal and subcutaneous morphine, repeated administration may be necessary.\textsuperscript{a}

No Recurrence

- Repeat naloxone (Narcan) every 2 – 3 minutes to maintain adequate respiration.\textsuperscript{a,b} For continuous IV infusion, see naloxone (Narcan) package insert.\textsuperscript{b}

No Response

- Continue to perform life-sustaining measures

Recurrence

- If no response is observed after 10 mg of naloxone (Narcan), the diagnosis of narcotic-induced toxicity should be questioned.\textsuperscript{a,b}

Notify patient’s physician managing intrathecal pain therapy.

**Figure 1. Morphine overdose emergency procedures.**

\textsuperscript{a} Infumorph (Preservative-free morphine sulfate sterile solution) manufacturer's package insert (West-Ward Pharmaceuticals Corp).

\textsuperscript{b} Narcan (naloxone hydrochloride) manufacturer's package insert (Adapt Pharma Operations Limited).

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

\textsuperscript{d} Use a 25-gauge needle for withdrawal from a 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, hypothermia, 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).

**Actions**

See the following table (Table 3).
### Table 3. Lioresal Intrathecal (baclofen injection) overdose emergency procedures

<table>
<thead>
<tr>
<th>FOR INTRATHECAL OVERDOSE:</th>
<th>FOR SUBCUTANEOUS OVERDOSE: (eg, pocket fill)</th>
</tr>
</thead>
<tbody>
<tr>
<td>If not contraindicated, withdraw 30 – 40 mL CSF by lumbar puncture or through the catheter access port to reduce the concentration of baclofen in the CSF. Use only a 24-gauge or smaller, 1.5- or 2.0-inch (3.8- or 5.1-cm), needle for withdrawal from the catheter access port.(^a)</td>
<td>Proceed immediately to the next step.</td>
</tr>
<tr>
<td>Notify patient’s physician managing Lioresal Intrathecal (baclofen injection) therapy.</td>
<td></td>
</tr>
<tr>
<td>Continue to monitor closely for symptom recurrence.</td>
<td></td>
</tr>
<tr>
<td>Report incident to Medtronic, Inc.</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) Use a 25-gauge needle for withdrawal from a 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. Priapism may develop or recur if treatment with intrathecal baclofen is interrupted.

**Symptoms of withdrawal**

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

**Actions**

See the following table (Table 4).
**Table 4. Lioresal Intrathecal (baclofen injection) underdose/withdrawal emergency procedures**

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Immediately contact a physician experienced in Lioresal Intrathecal (baclofen injection), 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.</td>
</tr>
</tbody>
</table>
| 2.   | If a physician experienced in Lioresal Intrathecal (baclofen injection) is unavailable, consider instituting one or more of the following options, unless otherwise contraindicated:  
• high-dose oral* or enteral baclofen  
• restoration of Lioresal Intrathecal (baclofen injection) 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 Lioresal Intrathecal (baclofen injection) withdrawal syndrome.*

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**Report incident to Medtronic, Inc.**

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

Emergency procedure to empty pump reservoir

Equipment

- 22-gauge noncoring needle
- 20-mL syringe
- 3-way stopcock or extension set with clamp
- Antiseptic agent

⚠️ Caution:

- Do not use an open syringe when emptying the IsoMed Pump. The pump reservoir contents are under significant pressure and can eject through an open syringe when emptying the pump. Ejection of pump contents under pressure can result in procedural delays and a potential risk to the clinician or patient.

1. Assemble the needle, syringe, and stopcock or extension set.

2. Locate the pump by palpation. The reservoir fill port is located in the CENTER of the pump.

   If you have difficulty identifying the pump features, you may seek assistance from another clinician. If deemed necessary by the clinician, x-ray and fluoroscopy can be used to assist in locating or determining the orientation of the pump.

3. Prepare the injection site by cleansing the area using an antiseptic agent.

4. Gently insert the 22-gauge noncoring needle into the center of the reservoir fill port until the needle touches the bottom of the reservoir fill port (Figure 2).

   During proper needle insertion, the needle will:
   - pass through the patient's skin and subcutaneous tissue,
   - hit the silicone septum,
     (Scar tissue, if present, can feel similar to the septum.)
   - pass through the septum, and
   - hit the metal bottom of the reservoir fill port.
     (The top of the pump is metal and hitting the top of the pump can feel similar to hitting the bottom of the reservoir fill port.)

   If excessive resistance is encountered during needle insertion, reassess placement. Do not force the needle. 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.
5. For SynchroMed programmable pumps: Open the clamp or stopcock and slowly withdraw the fluid from the reservoir into the empty syringe.

For IsoMed nonprogrammable pumps: Maintain light pressure on the syringe plunger when emptying the pump. Open the clamp or stopcock and slowly withdraw the fluid from the reservoir into the empty syringe. If backflow is not observed, remove the needle from the reservoir fill port and repeat steps 2 – 5. If backflow still does not occur, and the Expected Volume is greater than 2 mL, contact your Medtronic representative.

6. Depending on pump reservoir volume, more than one syringe may be needed to empty the pump. Close the clamp or stopcock when changing syringes.

7. Completely empty the pump.

For SynchroMed programmable pumps: When the pump is empty, the bubbles will stop forming, and negative pressure in the syringe can be felt.

For IsoMed nonprogrammable pumps: Wait approximately 5 seconds after fluid stops flowing into the syringe to ensure that all fluid is removed and the pump is empty.

8. Remove the needle from the reservoir fill port.

9. Record in 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.