LIVING WITH YOUR MEDTRONIC INFUSION SYSTEM
Living with your Medtronic Infusion System

For more than 50 years, Medtronic has pioneered the development of implantable products and therapies designed to restore life and hope to patients. Every 15 seconds around the world, a Medtronic device is used to treat people with a chronic disease or condition.

Medtronic made its debut in implantable drug delivery systems in 1982 with the Medtronic SynchroMed® Infusion System. The SynchroMed system is the only fully implantable, programmable system on the market. It established Medtronic as the leader in site specific drug delivery for the treatment of chronic pain, severe spasticity and cancer. Today, the new Medtronic IsoMed® Constant-Flow Infusion System complements the SynchroMed line of products in the management of chronic pain and cancer. Physicians examine therapy requirements to determine which system is the most appropriate for individual people.
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How to Use This Booklet

Throughout the first section of this booklet, you will receive information that applies to all Medtronic infusion systems, regardless of how the system is used. However, in several sections, there is additional information that applies to a specific therapy. In those areas, the booklet will direct you to a section in the back where you can find additional information that relates to your condition.

Throughout this booklet, you will see this symbol: (!). This symbol indicates that the information you are about to read is critical to your care. Please read these sections carefully.

Words that appear in bold type are defined in the glossary at the back of this booklet.

This booklet is not meant to cover all aspects of the product, your surgery or therapy. Talk with your doctor before making any decisions about your treatment options.

Site Specific Drug Delivery

Medtronic drug delivery systems consist of a pump and catheter, both of which are surgically placed under the skin. The pump is implanted in the abdominal area, just above or below the beltline. A small, flexible tube, called a catheter, connects to the pump and is tunneled under the skin to the site where medication is to be delivered (see below). The pump releases the medication at a set rate, and the medication flows from the pump, through the catheter to the site of delivery.

Medtronic drug delivery systems deliver medication to specific locations within the body, including:

- The area that surrounds the spinal cord. For the treatment of chronic pain or severe spasticity, medications can be delivered to the intrathecal space, which is the fluid-filled area that surrounds the spinal cord. The epidural space – which is the spinal area just outside of the intrathecal space – is an alternate drug delivery site used in the treatment of chronic pain. The intrathecal and epidural spaces are known collectively as the intraspinal space (see Figure 1).

- Specific sites in the body through a vein or artery. This is called intravascular delivery, and is used to deliver chemotherapy for the treatment of cancer (see Figure 2).

![Figure 1: Pump and catheter placement for intraspinal drug delivery](image1)

![Figure 2: Pump and catheter placement for intravascular infusion of chemotherapy](image2)
SynchroMed® Infusion System

Overview
The SynchroMed System offers a fully implantable and programmable method of continuous drug delivery. In use clinically since 1982, and commercially since 1988, the programmability of the SynchroMed system allows:

- Dosages to be varied throughout the day and tailored to match your individual medication needs.
- The potential for a lower dose, which may result in reduced side effects.
- Non-invasive dose changes.

Conditions Managed by the SynchroMed System
The SynchroMed Infusion System is used to treat chronic pain, severe spasticity and cancer. Specifically, the system is approved for:

- Continuous delivery of morphine into the intraspinal space for the treatment of chronic pain.
- Continuous delivery of antispasticity medication into the intrathecal space for the management of severe spasticity.
- Continuous delivery of chemotherapy drugs into a blood vessel for the treatment of certain types of cancer.*

* Because programmability typically is not necessary for chemotherapy treatments, people with cancer usually receive the Medtronic IsoMed Infusion System. This system is described on pages 9-11.

Patient Profile
Programmability allows for different doses to be given throughout the day. It also allows dose changes to be made non-invasively. As a result, the programmability feature makes the SynchroMed system an ideal choice for:

- People who experience variable patterns of pain or spasticity.
- People who require dose adjustments.
- People with progressive diseases.
- People receiving their first implantable drug delivery system.

When selecting a pump for you, your doctor will consider your specific therapy, as well as your individual needs.
**Equipment Overview**

The SynchroMed system consists of:

- Implantable pump
- Implantable catheter
- External physician programmer

**SynchroMed Pump**

SynchroMed pumps are implantable, battery-powered devices that store and dispense drugs according to instructions received from the Medtronic physician programmer.

The pump includes the reservoir, reservoir fill port, and an optional catheter access port.

- **Reservoir** – The reservoir is the cavity inside the pump where the medication is stored.

- **Reservoir Fill Port** – In the center of the pump is a raised area (called a ‘port’) that is used for filling and emptying the pump. In the middle of this port is a self-sealing, silicone septum that is used during your pump refill procedure. (For more information, see the “refill procedure” section on pages 14-15 of this booklet.)

- **Catheter Access Port** – Most pumps feature a catheter access port. The catheter access port allows doctors to bypass the pump reservoir and send medications or sterile solutions directly into the implanted catheter. Doctors also may use the catheter access port for some diagnostic purposes, such as testing to ensure medication is able to flow through the length of the catheter.
**Catheter**

The catheter is a flexible, silicone tube that connects to your pump and delivers medication from the pump to a specific site in your body. Your doctor trims the catheter to the appropriate length for your body size.

**Physician Programmer**

Your doctor or nurse will use a programmer during your refill and checkup sessions. The Medtronic SynchroMed Programmer is the external component of the SynchroMed Infusion System. The physician programmer allows your doctor or nurse to communicate with and program your SynchroMed pump.

Attached to the programmer is a component known as the “programming head.” The programming head looks similar to a computer mouse. Instructions for rate and dose adjustments are transmitted through the programming head to the pump by radio signals. The two-way radio-frequency link also allows the programmer to receive information from the pump. This painless interchange of information between the programmer and pump is called **telemetry**.

**How the SynchroMed Pump Works**

The pump has three sealed chambers. One contains an electronic module and battery; another contains a peristaltic pump and drug reservoir; and the third contains an inert gas. The gas provides the pressure that is used to force the medication into the peristaltic pump (see below).

![Catheters used with the SynchroMed pump.](image)

**Figure 4:** Internal components of the SynchroMed pump
To fill the pump, medication is injected through the reservoir fill port, and into the expandable reservoir. An inert gas puts pressure on the reservoir. The pressure forces the medication through a bacterial-retentive filter and into the pump chamber. From the pump chamber, the medication is pumped out of the device and into the catheter.

A microprocessor controls the rate at which the pump delivers medication. Your doctor may program the pump to deliver different amounts of medication at different times of the day, depending on your individual needs.

**Product Attributes**

- The programmability of the SynchroMed system enables your clinician to tailor your therapy and dosing to best meet your needs.

Examples of programming modes include:

**Figure 5:** Programmable dosing modes offered by the SynchroMed pump

- Programming technology allows dosing changes between refills to be made non-invasively.
- Two reservoir sizes – 18 ml and 10 ml – provide flexibility in meeting your preferences of size and refill schedules.
- The SynchroMed infusion system offers precise, accurate dosing.
SynchroMed System FAQ

Q: How will I know when the battery in my pump is about to run out?

A: Your pump is equipped with an alarm that beeps when the battery is near depletion. The alarm is a soft, high-pitched beep. The beeps may occur several times a minute. A low-battery alarm may go on and off intermittently. The alarm is designed to tell you and your doctor that the pump should be checked.

Your doctor can program an alarm “test” during an office visit so that you can hear what an alarm sounds like. You’ll notice that the pump alarm is relatively soft; as a result, some people have trouble hearing it when the pump is implanted. Because you may not be able to hear the soft alarm, contact your doctor if you notice any change in your condition.

In addition to the low battery alarm, at the time your pump is implanted, your physician may also calculate the estimated battery life of your pump based on the average daily infusion volume your pump is programmed to deliver. Rather than rely solely on the low battery alarm in the pump to tell you when your pump may need to be replaced, it is important that you keep all of your refill appointments with your physician. During your refill appointment, your physician may also use the Medtronic programmer to check on the status of your pump’s battery life and can compare this information with the calculation he or she did at the time your pump was implanted.

Q: Does the alarm always indicate a battery nearing depletion?

A: No. The pump alarm may indicate that the pump needs refilling. This is known as a “low-reservoir” alarm and sounds as a single beep. If you hear any alarm, contact your doctor. If you hear the alarm for more than a few minutes, call your doctor to identify and correct the situation. During the clinic visit, your doctor will check the pump and manage any problems. The alarm also may temporarily sound if the drug was not warmed to body temperature before the pump was filled.

Q: Is there an alarm to indicate that there is a problem with the pump?

A: Yes. There is a pump memory alarm. If there is a pump memory error, the pump will sound a double-beep alarm. A pump memory error may occur if the pump memory is compromised by a strong magnetic force or other circumstances (see section on EMI/RFI on page 20).

Once activated, each alarm occurs at specific intervals (between 4 and 16 seconds) until your doctor shuts the alarm off with the physician programmer.

Q: If the low-battery alarm is sounding, how long do I have before the battery is fully depleted?

A: Many people are surprised at how soft the alarm is and may not hear it when it initially starts. Other times, the person does not hear it at all. For this reason, we recommend scheduling a pump replacement as soon as a low-battery alarm is confirmed by your doctor. If this is not possible, your doctor may prescribe oral medications as a precaution. The oral medication may supplement your other medical treatment and is meant to help prevent withdrawal symptoms in the event that your pump stops working before it is replaced.

For more detailed information on the SynchroMed pump, please refer to Appendix A.
IsoMed Constant-Flow Infusion System

Overview

The IsoMed Constant-Flow Infusion System is Medtronic’s newest fully implantable drug infusion system. Used clinically since 1997, the system was released for commercial use in the U.S. in 2000. The system offers:

• Constant-flow infusion
• Accurate delivery
• Thin design
• Low doses of medication

Conditions Managed by the IsoMed System

The IsoMed system is used to treat chronic pain and cancer. Specifically, the system is approved for:

• Continuous delivery of morphine into an intraspinal space for the treatment of chronic pain.
• Continuous delivery of chemotherapy drugs into a blood vessel for the treatment of certain types of cancer.

Patient Profile

The features of the IsoMed system make it an ideal selection for:

• People who benefit from receiving a constant amount of medication throughout the day.
• People requiring a thinner pump design.
• People with long-term implant needs.
• People whose programmable pumps need to be replaced, and who no longer require programmable drug dosing.
• People who live long distances from a refill clinic.

When selecting a pump for you, your doctor will consider your specific therapy, as well as your individual needs.
Equipment Overview
The IsoMed system consists of:
• Implantable pump
• Implantable catheter

Pump
IsoMed pumps are implantable devices that store and dispense drugs at a fixed flow rate set during the manufacturing process. The delivery rate and the drug concentration determine the drug dose.

The pump includes the reservoir, reservoir fill port, and catheter access port.

• Reservoir — The reservoir is the cavity inside the pump where the medication is stored.
• Reservoir Fill Port — In the center of the pump is a raised area (called a ‘port’) that is used for filling and emptying the pump. In the middle of this port is a self-sealing, silicone septum that is used during your pump refill procedure. (For more information, see the “refill procedure” section on page 14 of this booklet.)
• Catheter Access Port — Near the edge of every IsoMed pump is a raised catheter access port. The catheter access port allows doctors to bypass the pump reservoir and send medications or sterile solutions directly into the implanted catheter. Doctors also may use the catheter access port for some diagnostic purposes, such as testing to ensure medication is able to flow through the length of the catheter.

Catheter
The catheter is a flexible, silicone tube that connects to your pump and delivers medication from the pump to a specific site in your body. Your doctor trims the catheter to the appropriate length for your body size and therapy requirements.

Implantable catheter that may be used with the IsoMed pump.
How the IsoMed Pump Works

The inside of the pump contains two sealed chambers. One chamber contains the reservoir and capillary tubing. The length of capillary tubing determines the amount of medication the pump dispenses each day. The longer the tubing, the smaller the daily volume of medication delivered.

The second sealed chamber contains an inert gas. The gas provides the pressure that forces the medication through the pump.

Medication is injected into the expandable reservoir through the reservoir fill port. The gas in the sealed chamber puts pressure on the reservoir. The pressure forces the medication through a bacterial-retentive filter and into the capillary tubing and implanted catheter.

Product Attributes

- Fixed drug delivery rates meet the needs of people who require a constant amount of medication throughout the day.
- Requires no programming.
- Choice of three reservoir sizes (20 ml, 35 ml, or 60 ml) provides flexibility in meeting your preferences of size and refill schedules.
- Low-profile design meets the needs of a wide range of body types.
- The IsoMed system offers precise, accurate dosing.
- Long implant life may mean fewer pump replacement surgeries.

IsoMed System FAQ

Q: How will I know when the battery in my pump is about to expire?

A: The IsoMed pump does not have a battery to wear out. It is powered by an inert gas. Unless there are complications with the pump mechanism or your medical condition, this pump may never need to be replaced. However, problems with the catheter could result in the need for surgery to replace or repair the catheter. If you experience a change in your condition before your next scheduled refill, contact your doctor.

For more information about the IsoMed pump, please refer to Appendix B.
Patient Selection for Implantable Infusion Systems

Your doctor will explain the factors that are considered in the patient selection process. Depending on your specific condition or disease, your doctor will consider such things as:

- The effectiveness of your current treatment program.
- Your response to traditional medications.
- The level of side effects you have experienced with traditional treatments.
- The progression or current state of your condition.
- Whether your body size and weight will accommodate the pump.
- Your current emotional and psychological well-being.

For additional information on the patient selection process for:

- Chronic pain, see page 27
- Severe spasticity, see page 29
- Chemotherapy, see page 32

Implant Procedure

Overview

The pump is implanted during a surgical procedure that may require a brief hospital stay. Before the surgery, you and your doctor will decide where to best position the pump for your comfort.

During the surgical procedure, your surgeon will form a pocket under your skin that is large enough to hold the pump. This incision is usually in the lower abdominal area. A second incision is made over the area where one end of the catheter will be placed. The other end of the catheter is tunneled under the skin and attached to the pump. Once the pump and catheter are in place, the incisions are closed and the surgery is complete.
**Surgery and Drug-Related Events**

Because the pump and catheter are surgically placed, surgical complications, such as infections, are possible. Other potential surgical complications include bleeding, pain and discomfort around the implant site, and blood (known as ‘*hematoma*’) or fluid (known as ‘*seroma*’) in the pocket where the pump is implanted.

In addition to surgical complications, there is the potential that you may experience:

- Side effects caused by the medications used in the pump.
- Symptoms of drug overdose.
- Symptoms of drug underdose.

Talk with your doctor about the potential side effects and complications associated with your medication(s) and surgical procedure.

For more information on complications of surgery and drug-related events for:

- Chronic pain, see page 28
- Severe spasticity, see page 30, and Appendix C
- Chemotherapy, see page 32

**Implant Procedure FAQ**

**Q: What type of anesthesia is used?**

*A:* Typically, the implant is performed under general anesthesia. However, you may wish to talk with your doctor about other options.

**Q: Can a previous abdominal incision be used to implant the pump?**

*A:* Usually not. The incision needs to be made where the pump will be implanted to help properly anchor the pump. Proper anchoring helps keep the pump in place. This also will help minimize your discomfort and will speed your recovery.

For additional implant procedure FAQ for:

- Chronic pain, see page 27
- Severe spasticity, see page 29
- Chemotherapy, see page 31
Post-Surgery Care

Overview
After surgery, there will be some discomfort and tenderness where your pump and catheter are implanted. Your doctor may prescribe medication to relieve the pain caused by surgery and antibiotics to prevent infection. If you notice any swelling, pain, or redness near your incision, notify your doctor or nurse.

After the implant, your doctor may recommend that you restrict your activity for 6 to 8 weeks. Once your incision has healed, the pump site requires no special care. However, you should talk with your doctor if you perform any excessive or repetitive activities that may damage your pump or catheter.

Post-Surgery FAQ

Q: Will my pump be filled with medication immediately following the implant procedure?
A: Depending on your doctor’s preference, your pump may be filled immediately following surgery. However, some doctors recommend a short waiting period to allow you to recover from surgery and get adjusted to your pump.

For additional post-surgery FAQ for:
• Chronic pain, see page 28
• Severe spasticity, see page 30

Refill Procedure

Overview
The key to effective therapy management is active involvement and cooperation with your health care team. One of your most important responsibilities is to ensure the maintenance of the pump by making regular return visits to your clinic for follow-up care.

The frequency of follow-up visits varies from weeks to months, depending on the type and amount of medication you receive. These short visits are necessary for refills and prescription adjustments. Your doctor or nurse will check the pump to make sure it is working properly. During a typical session, the pump will be emptied and refilled by an injection through the skin. The clinician inserts a needle through your skin and into the pump’s self-sealing silicone septum and removes any medication that remains in the pump. The syringe is removed from the needle and the medication is discarded. A new syringe filled with your prescribed medication is attached to the needle. The new medication is injected into the pump.

This is a relatively short and painless procedure.

(!) It is very important to keep and attend all of your refill appointments in order to maintain the level of medication you need for continuous and effective therapy.
Refill Procedure FAQ

Q: What happens if the pump runs out of medication?
(A) Depending on the drug used in the pump, the withdrawal symptoms can range from fairly minor to very serious. Ask your doctor what symptoms you can expect if your pump runs out of medication, or if you stop receiving medication from the pump for any other reason. Also, talk with your doctor about the immediate steps you should take if you stop receiving drug from the pump.

In addition to the potential for withdrawal symptoms, the pump may become damaged if it is allowed to run dry. If this occurs, a surgical procedure will be required to replace the damaged pump.

It is very important that you do not miss a refill. This may require some planning prior to traveling.

Q: How long does a refill procedure take?
(A) The average time varies from clinic to clinic, depending on their procedures. However, on average, a refill appointment lasts about 30-45 minutes.

Q: How often does my pump need to be refilled?
(A) Refill dates are scheduled based on:
• The amount of medication your pump holds.
• The rate at which the pump delivers medication.
• The frequency of dosing changes required by your particular treatment plan.
• The concentration of the medication you are receiving.

Q: Are there other clinics that can refill the pump if I’m traveling or moving to a new location?
(A) Check with your doctor for direct referrals to other clinics in the area where you will be traveling or moving.

For additional information on the refill procedure for:
• Chronic pain, see page 28
• Severe spasticity, see page 30
• Chemotherapy, see page 32
Activities

Overview

As you begin to receive your therapy, you will be able to resume your daily activities. Your awareness of the pump will lessen. Since there are no external parts, you may often forget it’s there.

You may find that wearing loose clothing over the implanted pump is most comfortable. Depending on your size and shape and where the pump is placed, it may not show at all under regular clothes.

Your doctor will prescribe and adjust the amount of medication to best meet your needs and will inform you of any potential side effects you may experience. As you become more active, you should discuss your level and type of activity with your doctor. Follow your doctor’s suggestions about work, sexual activity, travel, recreation, hobbies, and exercise.

Activities FAQ

The answers to these questions comment about the device itself, not about the medication inside the pump. You will need to check with your doctor regarding any applicable warnings for the specific medication in your pump.

Q: Will I be able to take hot baths or showers?

A: Talk with your doctor to find out if you may shower immediately following surgery. You should not soak in a hot bath until after your stitches are removed and your incisions are well-healed. After the incisions are completely healed, a hot bath – that is less than 102°F – will not interfere with the pump’s operation. You should talk with your doctor about other activities that may greatly affect the temperature of the pump.

Q: Can I go in a hot tub, steam room, sauna or tanning bed?

A: If the temperature of the hot tub, steam room, sauna or tanning bed is above 102°F, it is not recommended that you use it. The pressure in your pump’s reservoir is sensitive to temperature. At a temperature higher than 102°F, the reservoir pressure increases. If the increase is significant, the pressure can cause the pump to over dispense. This may lead to a drug overdose.
**Q: Can I travel?**

**A:** Notify your clinic of your travel plans. Your doctor will tell you about any necessary prescription adjustments or when you must return to the clinic. If you will not return prior to your next refill appointment, your doctor will need to make a referral before your departure.

If you plan to travel to a high-altitude destination, talk with your doctor about adjusting your pump to accommodate for the change in air pressure.

**Q: Will my pump set off the metal detector at the airport?**

**A:** It might. If necessary, present your patient identification card to airport security personnel for clearance. The metal detector will not interfere with your pump or therapy.

**Q: Should I avoid long-duration airplane flights?**

**A:** Generally, SynchroMed and IsoMed pumps are not significantly affected by flights in pressurized aircraft. Commercial aircraft are pressurized to an approximate altitude of 5,000 to 8,000 feet. The pressure at this equivalent altitude is typically less than the pressure to which you are normally exposed. As a result, the pump may deliver more than the prescribed amount under certain conditions. However, this pressure range will not affect most people with pumps.

In rare instances, if a person lived at sea level and was in an aircraft pressurized to the maximum allowable equivalent of 8,000 feet, the pump could deliver up to 15% more medication during the flight. However, most people live at an altitude somewhat above sea level, and most aircraft are pressurized to an equivalent altitude of less than 8,000 feet. Therefore, the potential increase is usually much less than 15%. You should check with your doctor prior to a long-duration flight to see whether this potential rate increase could have a significant effect.

**Q: Can I SCUBA dive?**

**A:** If you have an IsoMed pump or a SynchroMed pump without a catheter access port (model numbers 8611, 8616, 8626), Medtronic does not recommend that you be exposed to greater than 2.3 atmospheres absolute (ATA). This is the equivalent of approximately 43 feet of seawater. Too much pressure could damage the catheter, pump tubing or cause the outer metal shield of the pump to deform. You should talk with your doctor prior to SCUBA diving because the pump flow rate may be affected while under water. This would most likely result in a decrease in medication or no medication being delivered while diving. Your doctor will be able to discuss how a decrease in medication and the physical effects of SCUBA diving may affect you.

If you have a SynchroMed pump with a catheter access port (model numbers 8615, 8617, 8627), Medtronic does not recommend that you be exposed to greater than 3 atmospheres absolute (ATA). This is the equivalent of approximately 66 feet of seawater. The catheter access port contains a valve that minimizes damage to the pump tubing from fluid pushing against the pump. However, if the pump is exposed to significant
pressure, the outer metal shield of the pump may deform or damage could occur to the catheter. You should talk with your doctor prior to SCUBA diving because the pump flow rate may be affected while under water. This would most likely result in a decrease in medication or no medication being delivered while diving. Your doctor will be able to discuss how a decrease in medication and the physical effects of SCUBA diving may affect you.

Q: Can I skydive or participate in other high-altitude activities, such as skiing, hiking in the mountains, or flying in a non-commercial aircraft?

A: If you have an implantable pump, you should not go above 8,000 feet. This will ensure accurate drug delivery. If you plan to engage in activities above this altitude you should talk with your doctor to determine the effects of receiving more than the prescribed amount of medication. Your doctor can help determine whether you should receive a dose adjustment prior to spending time in a high-altitude environment. At high altitudes, the atmospheric pressure is less than at sea level. If the atmospheric pressure decreases significantly, it could cause the pump to temporarily dispense more medication. This may cause an overdose.

You also should be aware that skydiving might cause catheter dislodgement, tear, or disconnection from the pump. These complications may result from movements during the dive, such as when the parachute opens and when landing. The complications also may result in the need for surgery to repair or replace the catheter.

Device-Related Events

Overview

The pump is designed to automatically deliver your medication at the rates and amounts you and your doctor determine best meet your needs.

(!) Device-Related Complications

The catheter could tear, become dislodged or blocked, or in rare cases, the pump could stop working. These complications could cause a reduction in or a loss of therapeutic effect.

Pump complications or failure may result in:

- Increase in signs of your underlying condition.
- Drug withdrawal symptoms.
- Need for surgical removal of the pump.

If the catheter becomes kinked, dislodged, blocked, or torn, it may result in:

- Delivery of medication into the area under your skin where the pump is implanted or along the catheter path.
- Drug withdrawal symptoms.
- Increase in signs of your underlying condition.
- Need for surgical replacement or repair of the catheter.

Talk with your doctor about any additional complications associated with your treatment.
Device-Related FAQ

Q: What can cause catheter dislodgement or tear?

A: You should know where your catheter is implanted and keep in mind which movements may stretch or put strain on the catheter or on the stitches that hold your pump in place. Catheters become dislodged primarily because of certain motions or sudden or repetitive movements. Exercise and other activities should be approached with caution. Excessive or repetitive bending, twisting, bouncing or stretching can move or stretch the catheter. This may eventually dislocate or tear the catheter.

A catheter can tear because of a nick caused by a suture during surgery or by rubbing on the skeletal bones.

Although the catheter is made of flexible and durable materials, it is still subject to wear. Therefore, seemingly harmless or repetitive movements can cause unseen damage over time, eventually causing a tear or dislodgement. This damage or failure may require surgery to replace the catheter.

Q: Will the pump or catheter need to be replaced?

A: The SynchroMed pump is a battery-operated device. Once the battery wears out, the pump will need to be surgically removed and replaced. Battery life depends on the model number, programming parameters, and flow rate. If you hear your pump alarm, notify your doctor immediately and have your pump checked to determine if the pump needs to be replaced. For more information on battery life, see Appendix A. For more information on battery alarms, see page 8.

The IsoMed pump is powered by an inert gas and does not have a battery to wear out.

SynchroMed and IsoMed pumps also may need to be replaced if there are problems with the pumps’ mechanical components.

Regardless of which pump you have, complications with the catheter could result in the need for surgery to replace or repair the catheter. The catheter will need to be replaced or repaired if it is torn, blocked, or damaged. If the catheter becomes disconnected from the pump or dislodged from the area where it is implanted, surgery will be required to fix the problem.

Q: Is the pump a new device?

A: The Medtronic SynchroMed infusion system has been commercially available in the U.S. since 1988. The IsoMed infusion system was commercially released in 2000.

Q: Will people be able to see that I have a pump?

A: On occasion, someone might notice it because it may bulge under fitted clothes. Depending on your size and shape, where the pump is implanted, and the size of your pump, it may not show at all under your clothes. Your pump is placed near the surface of your skin for easy refill access and for easy programming of the SynchroMed pump. The pump may be visible if not covered with clothes.
Contact With Electrical Devices

Overview
Because the IsoMed pump does not contain electronic circuitry, electrical devices will not affect it.

The SynchroMed pump has built-in features to protect it from interference produced by electrical devices. Under normal conditions, the household appliances you use in your daily activities will not affect the pump.

Be sure to keep all your household appliances in good working condition. If you suspect interference with your SynchroMed pump, move away from, or turn off, the electrical device. Your pump will not be permanently affected.

If you have a SynchroMed pump, you should try to avoid high-current industrial equipment, powerful magnets and transmitting towers and antennas. Large amounts of electromagnetic interference (EMI) could potentially alter information stored in the pump’s memory. It also could directly affect operations of one or more of the pump’s internal components. However, EMI will not permanently damage the pump. In rare cases, too much EMI could temporarily stop the pump or cause a pump memory error. If a pump memory error occurs, a double-beep alarm will sound and the pump will need to be reprogrammed by your doctor.

If exposed to a large magnetic field, it is possible that the pump could temporarily stop without affecting the pump memory. If this occurs, no alarm will sound to alert you and the pump may remain stopped until the magnetic field subsides. You could notice an increase in the signs of your underlying condition for a period of time after the magnetic field ends.

Electrical Devices FAQ

The answers to these questions comment about the device itself, not about the medication inside the pump. You will need to check with your doctor regarding any applicable warnings for the specific medication in your pump.

Q: What is EMI/RFI?

A: EMI stands for electromagnetic interference. RFI stands for radio frequency interference. EMI includes all forms of magnetic and electric (known as electromagnetic) fields and RFI includes electromagnetic fields within a specific range of the electromagnetic spectrum. RFI generally consists of higher-frequency EMI (i.e. RFI is a subset of EMI).

Any electrical device can potentially generate and/or be affected by EMI or RFI. The allowable levels of EMI/RFI that a product can generate are controlled by regulatory agencies. Examples of products that generate EMI are motors from power tools, arc welding, cell phones, security systems found in retail stores, libraries, airports, etc. Examples of products that generate RFI are garage-door openers, ham and C.B. radios, microwave ovens, cell phones, radio transmitting towers, radios, speakers, antennae, and television dish systems.
Q: How can EMI/RFI affect my pump?

A: An electronic circuit controls the SynchroMed pump. Large amounts of EMI/RFI could potentially alter information stored in the pump’s memory. It also may directly affect operation of one or more of the pump’s internal components, but it will not damage the device.

The microprocessor inside the SynchroMed pump contains a self test that checks the pump program a few times a minute. If the pump memory is compromised, this self test will turn the pump off and sound a memory error alarm. The memory error alarm is a soft, double-beep that sounds a few times a minute. If a memory error occurs, the pump will need to be reprogrammed before it will start again. If you hear a memory alarm, see your doctor.

The SynchroMed pump also has an internal switch that is activated by a very strong magnet located in the programming head. This switch activates the pump’s antenna. The antenna must be activated in order to program the pump. As a result, the switch minimizes the possibility of EMI/RFI affecting the pump’s memory.

EMI/RFI does not affect the IsoMed pump.

Q: Can I arc weld?

A: If you have a SynchroMed pump, you should use caution because arc welders emit large amounts of EMI (see the overview to this section, and “What is EMI/RFI?” and “How will EMI/RFI affect my pump?” questions above). In theory, the pump memory could be affected if the pump is exposed to a very high amount of EMI.

Arc welding does not affect the IsoMed pump.

Q: Can I work on an automobile?

A: Should you experience any discomfort or problems in the area of your implanted pump while you are working on an automobile, you should immediately discontinue the activity. Then, call your doctor for a visit to make sure the pump does not require reprogramming. Experience to date indicates that automobiles do not produce strong enough EMI fields to affect the pump. (See “What is EMI/RFI?” and “How will EMI/RFI affect my pump?” questions above.)

If you are working on an automobile, excessive or repetitive bending, twisting, or stretching can cause the catheter to dislodge or tear. You should talk with your doctor to find out what type of movements could cause catheter damage, dislodgement or disconnection.
**Q: Can I be near an electric substation?**

A: Electric substations can produce large amounts of EMI/RFI. (See “What is EMI/RFI?” and “How will EMI/RFI affect my pump?” questions above.) It is virtually impossible to know the amounts of interference present at a particular substation. To minimize the potential for adverse effects, you should stay as far away as possible from a substation.

Although remote, there is the potential for this interference to temporarily stop the pump until the interference subsides. In extreme cases, the interference may cause a pump memory error, which would stop the pump and require the pump to be reprogrammed. If you hear a pump memory alarm (a soft, double-beep that sounds a few times a minute), see your doctor.

Electric substations do not affect the IsoMed pump.

**Q: Can I be around industrial equipment?**

A: If you have a SynchroMed pump, your pump may be affected by industrial equipment. Some heavy industrial equipment, such as large motors, magnets, and transformers might produce EMI. EMI may cause the pump to temporarily stop. (See the overview to this section and “What is EMI/RFI?” and “How will EMI/RFI affect my pump?” questions above.)

The IsoMed pump is not affected by industrial equipment.

**Q: Can I use power tools?**

A: Experience to date indicates that typical home power tools do not produce strong enough EMI/RFI to affect the operation of implantable pumps. Contact your physician before operating any potentially dangerous equipment.

**Q: Can I go through theft/security detectors?**

A: Theft/security detectors will not affect the operation of your pump. It is possible for the metal in your implanted pump to set off a metal detector, such as the ones found at airports and some malls. You should carry your patient identification card with you at all times. If you know you will be in an area protected by metal detectors, inform the security personnel that you may set off the detector.

**Q: Will the use of a cellular phone affect my pump?**

A: No. Your pump is protected from low-powered stray electromagnetic interference (EMI) that is present in a typical cellular phone.

**Q: Will a microwave oven affect my pump?**

A: Because microwaves must be shielded, the amount of interference they give off is quite low and will not affect your pump.
Medical Procedures

Overview
Diagnostic X-rays or CT scans will not affect your pump. Before you undergo any other medical procedure, check with your doctor about potential effects on pump operation.

Medical Procedures FAQ
The answers to these questions comment about the device itself, not about the medication inside the pump. You will need to check with your doctor regarding any applicable warnings for the specific medication in your pump.

Q: Can I undergo MRI testing?
A: Contact your doctor before having MRI performed. Your doctor should discuss the procedure with the MRI staff to determine if it is safe and appropriate for you.

Magnetic Resonance Imaging (MRI) will cause the SynchroMed pump to temporarily stop and suspend drug infusion during the MRI procedure. Your pump should return to normal operation after the MRI procedure is complete. Your doctor may check your pump prior to scheduling an MRI and shortly after having an MRI to confirm proper operation of the pump.

During MRI, you may experience a slight tugging sensation of the pump or warmth in the area directly surrounding the pump. An elastic garment or wrap will reduce the tugging sensation you may feel. If the warming sensation is uncomfortable for you, the MRI settings can be adjusted to reduce or eliminate the warming sensation.

**SynchroMed pump** performance has not been established in greater than 2.0 T(Tesla) MR scanners, and it is not recommended that people with SynchroMed pumps have MRI scans using those scanners.

**IsoMed pump** performance has not been established in greater than 1.5 T(Tesla) MR scanners, and it is not recommended that people with IsoMed pumps have MRI scans using those scanners.

Q: Can I have radiation therapy?
A: Radiation therapy will not affect the IsoMed pump.

If you have a SynchroMed pump, you should not be subjected to cumulative radiation therapy in excess of 500 rads. The electronic control circuit in the SynchroMed pump can be damaged by exposure to high-level radiation requiring removal and replacement of the pump.

Talk with your doctor about whether radiation therapy is appropriate for you.

Q: Can I undergo hyperbaric chamber treatment?
A: If you have an IsoMed pump or a SynchroMed pump without a catheter access port (model numbers 8611, 8616, 8626), Medtronic does not recommend that you be exposed to greater than 2.3 atmospheres absolute (ATA). Too much pressure could damage the catheter, pump tubing or cause the outer metal shield of the pump to deform. You should talk with your doctor before having hyperbaric chamber therapy because the pump flow
rate may be affected while in this environment. This would most likely result in a
decrease in medication or no medication being delivered while in the hyperbaric chamber.
Your doctor will be able to discuss how the decrease in the medication and the physical
effects from exposure to high pressure may affect you.

**If you have a SynchroMed pump with a catheter access port (model numbers 8615, 8617, 8627),** Medtronic does not recommend that you be exposed to greater than 3
atmospheres absolute (ATA). The catheter access port contains a valve that minimizes
damage to the pump tubing from fluid pushing against the pump. However, if the pump
is exposed to significant pressure, the outer metal shield of the pump may deform, or
damage could occur to the catheter.

You should talk with your doctor before having hyperbaric chamber therapy because the
pump flow rate may be affected while in this high-pressure chamber. This would most
likely result in a decrease in medication or no medication being delivered while in this
environment. Your doctor will be able to discuss how the decrease in the medication and
the physical effects of hyperbaric treatment may affect you. If you hear a pump memory
alarm, see your doctor.

**Q: Can I use a bone growth stimulator?**

**A:** There are two basic types of bone growth stimulators – external and implantable—
which may use several different types of fields (electric, magnetic, and/or ultrasonic).
If you have an implantable bone growth stimulator and a SynchroMed infusion system,
Medtronic recommends that your doctor hold the programming head for the bone
growth stimulator at least four inches away from the SynchroMed pump. This will
minimize any potential interference.

An electronic circuit controls the SynchroMed pump. The EMI/RFI emitted from the
programmer for a bone growth stimulator could potentially alter information stored in
the pump’s memory. It also may directly affect the operation of one or more of the
pump’s internal components. However, it will not damage the pump.

The microprocessor inside the pump contains a self test that checks the pump program
a few times a minute. If the pump memory is affected, this self test will turn the pump
off and sound a memory error alarm. The memory error alarm is a soft, double-beep
that sounds a few times a minute. If a memory error occurs, the pump will need to
be reprogrammed before it will start again. If you hear a pump memory alarm, see
your doctor.

Your doctor also should verify that the bone growth stimulator will not respond
to the SynchroMed programmer.

The IsoMed pump should not be affected by a bone growth stimulator.

**Q: If I have a pump, can I also have a pacemaker or an implantable cardioverter defibrillator (ICD)?**

**A:** The SynchroMed pump will not be damaged by therapy pulses from the pacemaker or
ICD. However, Medtronic recommends keeping the programming head for the pacemaker
or ICD at least four inches away from the SynchroMed pump to minimize any potential
interference. It also is important to keep the programming head of the SynchroMed pump
programmer away from the pacemaker or ICD because the programming head contains a
large magnet. Most pacemakers and some ICDs respond to a magnet and will change modes if the programming head is placed near the pacemaker or ICD.

An electronic circuit controls the SynchroMed pump. The EMI/RFI emitted from the programmer of the pacemaker or ICD could potentially alter information stored in the pump’s memory or directly affect operation of one or more of the pump’s internal components. However, it will not damage the device.

The microprocessor inside the pump contains a self test that checks the pump program a few times a minute. If the pump memory is compromised, this self test will turn the pump off and sound a memory error alarm. The memory error alarm is a soft, double-beep that sounds a few times a minute. If a memory error occurs, the pump will need to be reprogrammed before it will start again. If you hear a memory alarm, see your doctor.

Neither a pacemaker nor an ICD will affect the IsoMed pump.

**Q: Can I have defibrillation/be defibrillated?**

**A:** The term ‘defibrillation’ describes a method used to restore normal heart rhythm when a person experiences ventricular fibrillation. Ventricular fibrillation is a twitching of the heart ventricle(s).

When ventricular fibrillation occurs, the person loses consciousness because the heart is not pumping blood normally. Immediate medical intervention is required to prevent death. In an attempt to restore the heart to a normal rhythm, medical personnel will use a device called a ‘defibrillator.’ The defibrillator delivers a strong electrical shock. Since death typically occurs without immediate care, ventricular defibrillation is usually performed without regard for its potential effects on a medical device or other lasting effects on the person. Defibrillation has the potential to damage a pump. When defibrillation is neccessary, doctors should minimize the current flowing through the pump by positioning the defibrillation paddles as far from the pump as possible and by using the lowest, clinically appropriate energy output (watt seconds). If you have been defibrillated, you should have your device checked following the procedure.

**Q: Can I have atrial cardioversion?**

**A:** The term ‘atrial cardioversion’ describes a method used to attempt to restore a normal heart rhythm. The condition is not immediately life threatening. As a result, doctors can usually plan the best approach to limit potential damage to an implanted pump. The paddles used for cardioversion should not be positioned near the pump. When cardioversion is neccessary, doctors should minimize the current flowing through the pump by placing the paddles as far from the pump as possible and by using the lowest, clinically appropriate energy output (watt seconds). After atrial cardioversion, you should have your pump checked to determine whether it is functioning normally.

**Q: Can I have diathermy?**

**A:** Diathermy is a treatment that heats tissues to reduce pain.

It is recommended that shortwave (RF) diathermy not be used within 12 inches of the pump or catheter. The effects of other types of diathermy (microwave, ultrasonic, etc.) on the pump and catheter are unknown. If overheated, a pump may deliver more than the prescribed amount of medication, which may result in overdose. Diathermy may produce
significant temperature increases in the area of the pump and catheter tip. This may cause the area around your pump and catheter tip to feel warm after you complete a diathermy session.

**Q: Can I have electrocautery?**

**A:** Electrocautery is a surgical procedure that uses electric current to generate heat. It is used to cut through tissue and to remove lesions. Electrocautery immediately cauterizes capillaries and other blood vessels, thereby limiting the amount of bleeding that occurs from the incision. It also minimizes scarring.

Electrocautery devices do not directly affect the pump. However, if electrocautery touches the catheter, it may melt through the catheter. If this occurs, you may need to undergo surgery to replace your catheter.

**Q: Can I have lithotripsy?**

**A:** Lithotripsy is a treatment that uses soundwaves to break up stones in the kidney or gallbladder.

Lithotripsy should not be directed toward the pump. The powerful ultrasonic shock waves could potentially damage components in the pump. If damage occurs, the pump may need to be replaced during a surgical procedure.

**Q: Can I use a TENS unit/sensory-level stimulation?**

**A:** A TENS unit is a Transcutaneous Electrical Nerve Stimulation device that uses electric pulses to treat chronic pain. Sensory-level stimulation is the same type of technology as a TENS unit and is used to manage spasticity, particularly in children with cerebral palsy.

Medtronic pumps should not be affected by therapy pulses from a TENS device.

**Q: Can I have a diagnostic ultrasound?**

**A:** A diagnostic ultrasound should not affect the Medtronic pumps. Ultrasound should not be directed toward the pump.

**Additional FAQ**

**Q: If I have the pump, can I stop taking other medications?**

**A:** Your doctor will determine whether you still need to take additional medications. Do not make any changes in your current medication without your doctor’s knowledge.

**Q: Are there support groups that my family members and I can attend to talk with other people with pumps?**

**A:** There are some support groups online and in some geographical communities. Check with your clinic for possible resources.

**Q: My doctor mentioned something called “Twiddler’s Syndrome.” What is that?**

**A:** Twiddler’s Syndrome is a name given to people’s tendencies to “fiddle” or play with their implanted pumps. It may cause the stitches that hold the pump in place to come loose and allow your pump to flip over under your skin. It is not possible to refill a “flipped” pump. In addition, Twiddler’s Syndrome can cause the catheter to kink, become dislodged or disconnected from the pump.
Chronic Pain (Additional Information)

Patient Selection
After your doctor confirms that you are a candidate for a Medtronic infusion system, you will likely undergo a screening test (also known as a “trial”.) Participation in the trial allows your doctor to evaluate how well the therapy may work for you.

The objective of the trial is to determine your response to medication delivered into the intraspinal space. Successful therapy generally means at least 50% reduction in pain. Your doctor will closely monitor your response to the medication given in this trial. He or she will work with you to determine if you are a candidate for long-term intraspinal therapy with an implantable infusion system. This therapy will not eliminate the primary source of your pain and will not cure your disease.

During this trial, one of two procedures will typically be used.

- **Single injection:** This procedure consists of a single injection of a small amount of medication into your spinal column. The injection is delivered with a needle and syringe and is similar to an epidural injection.

- **Continuous infusion:** With this procedure, a continuous infusion of medication is delivered to the spine through a temporary, implanted catheter. One end of the catheter is placed in your spinal column and the other end attaches to an external pump. This trial takes place over several days and closely resembles the therapy delivered by the fully implantable Medtronic infusion systems.

The trial is usually conducted under local anesthesia.

Implant Procedure FAQ

**Q: How big are the incisions?**

**A:** The abdominal incision is about 6 inches. This is where the pump is placed. There also is an incision made on your back that is about 2-3 inches. This incision is used to place one end of the catheter into the spine. The other end of the catheter is tunneled under the skin and connected to the pump.

**Q: On average, how long does the surgery take?**

**A:** Times vary depending on individual doctor technique. On average, the procedure takes about 1 to 2 hours from start to finish. Talk with your doctor about the specifics and duration of your procedure.

**Q: What is the average length of the hospital stay?**

**A:** Depending on your doctor’s preference and hospital policy, a one to two night hospital stay may be recommended. However, the procedure may be performed on an outpatient basis, which means no overnight stay is required.

**Q: Between which vertebrae is the catheter placed?**

**A:** This depends on your specific condition and the results you received from the trial. Your doctor will advise you of the recommended catheter location.
Q: Is spinal cord damage a possible complication?
A: In rare cases, spinal cord damage may occur from surgical placement of the catheter. Damage also may occur from the formation of a mass at the tip of the catheter, which may require surgery to correct. In some instances, when a mass is left untreated, it may cause paralysis.

Q: Are there other side effects associated with placing the catheter in the intraspinal space?
A: In some cases, you may experience a "spinal headache" as a result of a needle or catheter being placed in the intraspinal space. A spinal headache is caused when cerebrospinal fluid (the fluid that surrounds your spinal cord) leaks out of the intraspinal space. This headache may correct itself, or your doctor may treat it.

A spinal headache may occur following the trial (see ‘patient selection’ above) and/or following the pump implant.

Post-Surgery Care FAQ

Q: How long will it take before I start receiving benefit from my pump?
A: You will begin receiving therapy as soon as your pump is filled with medication. However, depending on your medication, it may take several weeks before you begin to experience benefits from your medication. During this transition period, your doctor may reduce or eliminate your other medication(s).

Q: What if I have no improvement after the pump is implanted?
A: Let your doctor know if you are not receiving adequate control of your condition and/or symptoms. If you have a SynchroMed pump, your doctor can reprogram the pump to adjust the amount of medication it delivers. If you have an IsoMed pump, your doctor may need to remove the medication from the pump and refill the pump with a different concentration.

Refill Procedure FAQ

Q: Will signs of my underlying condition or my symptoms return prior to my refill date?
A: A recurrence of pain is not likely if your refill appointments are scheduled and kept appropriately. However, once the pump gets close to empty, the pressure in the pump decreases and less drug is pushed into the catheter. As a result, if you wait too long to have your pump refilled, signs of your underlying condition may increase or reappear. If you notice any change in your pain prior to your refill appointment, contact your doctor.

Q: What are the most common side effects from the drugs used to treat pain?
A: The most common side effects for intrathecal morphine reported during Medtronic clinical trials were itching, urinary retention and constipation. Other side effects may include nausea/vomiting, depression, euphoria, dizziness, and anxiety. Talk with your doctor about the side effects you may experience.

Q: What are the symptoms of a morphine overdose?
A: Respiratory depression (e.g. dizziness, euphoria, anxiety); seizure and/or respiratory arrest. Talk with your doctor for more information.
Spasticity (Additional Information)

Patient Selection

After your doctor confirms that you are a candidate for a Medtronic infusion system using intrathecal baclofen, you will likely undergo a screening test (also known as a “trial”). Participation in the trial allows your doctor to evaluate how well this therapy may work for you.

The objective of the trial is to determine your response to medication delivered into the intrathecal space. A successful trial generally means a 1-2 point drop in the Ashworth score. (The Ashworth scale is a measurement doctors use to rate muscle tone.) Your doctor will closely monitor your response to medication given in this trial. He or she will work with you to determine if you are a candidate for long-term intrathecal therapy with an implantable infusion system. This therapy will not eliminate the primary source of your spasticity and will not cure your disease.

This procedure consists of a single injection of a small amount of medication into your spinal column. The injection is delivered with a needle and syringe (similar to an epidural injection). Depending on your initial response, this procedure may be repeated the following day with a slightly larger dose. A third injection also may be administered.

The trial is usually conducted under local anesthesia.

Implant Procedure FAQ

Q: How big are the incisions?
A: The abdominal incision is about 6 inches. This is where the pump is placed. There also is a back incision that is about 2-3 inches. This incision is used to place one end of the catheter into the spine. The other end is tunneled under the skin and connected to the pump.

Q: On average, how long does the surgery take?
A: Times vary depending on individual doctor technique. On average, the procedure takes about 1 to 2 hours from start to finish. Talk with your doctor about the specifics and duration of your procedure.

Q: What is the average length of the hospital stay?
A: Depending on your doctor’s internal procedures and practices, a one to two night hospital stay may be recommended. However, the procedure may be performed on an outpatient basis, which means no overnight stay is required.

Q: Between which vertebrae is the catheter placed?
A: Catheter placement depends on your specific condition and the results you received from the trial. Your doctor will advise you of the recommended catheter location.
Q: Is spinal cord damage a possible complication?

A: In rare cases, spinal cord damage may occur from surgical placement of the catheter. Damage also may occur from the formation of a mass at the tip of the catheter (known as “inflammatory mass”), which requires surgery to correct. However, as of January 2001, there were no reports of inflammatory mass occurring with those patients who have only intrathecal baclofen in their pump.

Q: Are there other side effects associated with placing the catheter in the intrathecal space?

A: In some cases, you may experience a “spinal headache” as a result of a needle or catheter being placed in the intraspinal space. A spinal headache is caused when cerebrospinal fluid (the fluid that surrounds your spinal cord) leaks out of the intraspinal space. This headache may correct itself, or your doctor may treat it.

A spinal headache may occur following the trial (see ‘patient selection’ above) and/or following the pump implant.

Post-Surgery Care FAQ

Q: How long will it take before I start receiving benefit from my pump?

A: You will begin receiving therapy as soon as your pump is filled with medication. However, depending on your medication, it may take several weeks before you begin to experience benefits from your medication. During this transition period, your doctor may reduce or eliminate your other medication(s).

Q: What if I have no improvement after the pump is implanted?

A: Let your doctor know if you are not receiving adequate control of your condition and/or symptoms. If you have a SynchroMed pump, your doctor can reprogram the pump to adjust the amount of medication it delivers.

Refill Procedure FAQ

Q: Will signs of my underlying condition return prior to my refill date?

A: A recurrence of spasticity is not likely if your refill appointments are scheduled and kept appropriately. However, once the pump gets close to empty, the pressure in the pump decreases and less drug is pushed into the catheter. As a result, if you wait too long to have your pump refilled, signs of your underlying condition may increase or reappear. If you note any change in your spasticity prior to your refill appointment, contact your doctor, especially if the change is accompanied by other symptoms, such as fever or itching.

Q: What are the most common side effects from the drugs used to manage spasticity?

A: The side effects of intrathecal baclofen include loose muscles, sleepiness, upset stomach and vomiting, headaches, and dizziness. Talk with your doctor about the side effects you may experience from your treatment.
**Q: What are the symptoms of a baclofen overdose?**

**A:** Drowsiness, lightheadedness, dizziness, respiratory depression, seizures, loss of consciousness and coma. Talk with your doctor for more information.

**Q: What are the signs of rapid or abrupt withdrawal from intrathecal baclofen?**

**A:** Increase in spasticity, itching, lightheadedness, and tingling sensation are often early indications of baclofen withdrawal. Talk with your doctor about the symptoms you may experience. In some cases, severe symptoms may occur. These symptoms include high fever, altered mental status, multiple organ failure, and death. If you experience any of these symptoms, contact your doctor immediately.

For more information on the effects of intrathecal baclofen, please refer to Appendix C.
Chemotherapy (Additional Information)

Patient Selection
Infusion systems are primarily used to treat colorectal cancer that has spread to the liver. If you have this type of cancer, your doctor will take several factors into consideration when determining if you are a candidate for an implantable infusion system. Many of those factors appear on page 12. Other major factors your doctor will consider include:

- Whether your tumors are small and few enough to be removed by surgery. The removal of tumors is a process known as ‘resection.’
- The percentage of your liver that is cancer free.
- Whether there is evidence of infection or tumors outside of your liver.
- Whether there is fluid surrounding the tissues and organs in your abdominal cavity.

Implant Procedure FAQ

Q: How big are the incisions?
A: The abdominal incision is about 6 inches. This is where the pump is placed. The procedure also requires an additional, larger abdominal incision over the area where the catheter will be placed. In many cases, doctors may be performing other surgery – such as a surgery to remove cancerous tumors – at the same time they are placing the pump. The type of surgery required will affect the size of the incision. Talk with your doctor about the specifics of your surgery.

Q: On average, how long does the surgery take?
A: Times vary depending on individual doctor technique. The time also depends on additional surgeries – such as removing tumors – that your doctor may perform at the same time he or she is implanting your pump. Talk with your doctor about the specifics and duration of your procedure.

Q: Will I have to have my gallbladder removed?
A: More than likely, your doctor will remove your gallbladder when he or she is implanting the pump. The gallbladder is connected to the liver by blood vessels. As a result, if the gallbladder is not removed, some of the chemotherapy that is delivered to the liver could travel to the gallbladder and may cause toxicity.

Q: What is the average length of the hospital stay?
A: The hospital stay varies depending on the doctor and scope of the surgery. Talk with your doctor about his or her expectations regarding the length of your hospital stay.
Refill Procedure FAQ

Q: Will signs of my underlying condition or my symptoms return prior to my refill date?

A: If your cancer spreads, you may not notice any change in your symptoms, therefore it is critical you keep your refill appointments and do not allow your pump to run out of medication. If the pump runs out of drug, a blood clot may develop at the end of the catheter.

Q: Do I need to come in for refill appointments during periods when I’m on a break from chemotherapy treatments?

A: Yes. It is critical that you do not let your pump run dry. During breaks in your treatment, your doctor will fill your pump with heparinized saline or some other sterile solution.

Q: What are the most common side effects from the chemotherapy drugs used in the pump?

A: The most common reported side effects for flouxuridine (FUDR) are nausea, vomiting, diarrhea, and intestinal inflammation. Talk with your doctor about the side effects you may experience from your treatment.

Q: What are the signs of toxicity from the chemotherapy drug used in the pump?

A: Toxicity is measured primarily by lab tests. If you have toxicity, your doctor will see an elevation in the liver function studies that he or she performs on you during the course of treatment. However, if you have a severe case of toxicity, you may experience jaundice (a yellow coloring of your skin) or abdominal pain.
Glossary of Terms

**Ashworth Scale** — A measurement method used by clinicians to rate muscle tone.

**Baclofen** — A drug often used to manage severe spasticity. A liquid form of the drug is used for injections and infusion into the spine. The brand of liquid baclofen used with Medtronic infusion systems is known as Lioresal® Intrathecal (baclofen injection). For more information, refer to Appendix C.

**Bolus** — An additional dose of drug that is above the constant delivery rate offered by an implantable infusion system. Bolus doses of drugs can be as an injection with a needle and syringe, or programmed into the SynchroMed infusion system (see chart illustrating Infusion modes on page 7: Figure 5.

**Catheter** — A flexible, silicone tube that connects to the pump. The pump delivers medication through the catheter to a specific area in the body.

**Catheter access port** — A pump feature that allows doctors to bypass the pump reservoir and send medications or sterile solutions directly into the implanted catheter.

**Cerebrospinal fluid** — The fluid that surrounds the spinal cord.

**Drug infusion system** — A system consisting of a pump and catheter, both of which are fully implanted and used to deliver medication. Programmable systems also feature an external programmer that is used to adjust the amount of medication the pump delivers.

**Epidural infusion/Epidural drug delivery** — The delivery of medication into the epidural space, which is the area just outside the intrathecal space. This type of therapy can be administered with a fully implantable drug infusion system and is used to treat chronic pain.

**FAQ** — Frequently Asked Questions

**Hematoma** — A collection of blood under the skin that may resemble a bruise.

**Intraspinal infusion/Intraspinal drug delivery** — The delivery of medication directly into either the intrathecal or epidural space.

**Intraspinal space** — Area surrounding the spinal column. The intraspinal space consists of the intrathecal and epidural spaces.

**Intrathecal infusion/Intrathecal drug delivery** — The delivery of medication directly to the intrathecal space. This type of therapy can be administered with a fully implantable drug infusion system and is used to treat chronic pain or manage severe spasticity.

**Intrathecal space** — The fluid-filled area that surrounds your spinal cord.

**Intravascular infusion/Intravascular drug delivery** — The delivery of medication through a vein or artery. This type of therapy can be administered using a fully implantable infusion system and is used to deliver chemotherapy for the treatment of cancer.

**IsoMed Infusion System** — a fully implantable drug infusion system that delivers drug at a fixed flow rate.

**Lioresal® Intrathecal** — The brand of liquid baclofen used with Medtronic infusion systems.
Medtronic – The world’s leading medical technology company, dedicated to providing lifelong solutions for people with chronic disease. Among other products, Medtronic designs and manufactures the SynchroMed and IsoMed infusion systems.

Patient identification card – A wallet-sized card that indicates the type of Medtronic device a person has implanted, the product’s serial number, emergency contact information, and other pertinent data.

Physician programmer – For programmable pumps (SynchroMed pumps), doctors use a programmer to adjust the amount of medication the pump delivers at any given time. The programmer uses radio frequency waves to communicate with the implanted pumps.

Programming head – The “programming head” is part of the physician programmer and looks similar to a computer mouse and is connected to the programmer by a cord. Holding a programming head near the skin over the implanted pump allows messages to be delivered to the pump. Instructions for rate and dose adjustments are transmitted through the programming head to the pump by radio frequency signals.

Reservoir – The cavity inside the pump where the medication is stored.

Reservoir fill port – The raised port in the center of the pump. To fill the pump with medication, a clinician inserts a special needle through the skin and into the reservoir fill port. Once the needle is in the reservoir fill port, the medication from the syringe is injected into the reservoir.

Septum – The self-sealing, silicone rubber part of the pump through which a special needle is inserted to refill the pump.

Seroma – A collection of fluid under the skin that may occur after having a surgical incision.

Site-specific drug delivery – The delivery of medication directly to specific sites in the body. This is in contrast to systemic drug delivery. Implantable infusion systems, such as those discussed in this booklet, offer a form of site-specific drug delivery.

Spinal headache – A severe headache caused by a spinal fluid leak. This complication may arise from placing a catheter in the spine to treat chronic pain or manage severe spasticity.

SynchroMed EL Infusion System – A fully implantable, programmable drug infusion system.

Systemic drug delivery/systemic therapies – Treatments that carry medication throughout the entire body, rather than to a specific location. Some examples of systemic treatments include oral medications, IV treatments and patches. By contrast, site-specific drug delivery delivers the medication only to the site where it is needed most.

Telemetry – The interchange of information, via a two-way radio frequency link, between the SynchroMed pump and the programmer.
Appendix A: SynchroMed Programmable Pump

The following provides more in-depth, detailed information about the SynchroMed infusion system than is provided elsewhere within this booklet. The SynchroMed EL pumps became commercially available in 1999 and are the newest version of the SynchroMed pumps. SynchroMed pumps are no longer manufactured or available for sale. Unless otherwise specified, the terms “SynchroMed pump” or “SynchroMed infusion system” are used to collectively refer to the SynchroMed and SynchroMed EL pumps.

Specifications

The following chart highlights some of the key specifications for components of the SynchroMed EL pump. The specific weights and measures of the pump are dependent upon whether the pump has a 10 ml reservoir or an 18 ml reservoir and whether the pump offers a side catheter access port. Pumps with a 10 ml reservoir and no catheter access port are the smallest pumps. Pumps with an 18 ml reservoir and a catheter access port are the largest pumps.

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
<th>10 milliliters</th>
<th>18 milliliters</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pump</strong></td>
<td>Titanium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reservoir size:</td>
<td>10 milliliters</td>
<td>18 milliliters</td>
<td></td>
</tr>
<tr>
<td>Weight (when empty):</td>
<td>5.8 ounces (165 grams)</td>
<td>7.2 ounces (205 grams)</td>
<td></td>
</tr>
<tr>
<td>Diameter:</td>
<td>2.77 inches (70.4 millimeters)</td>
<td>3.36 inches (85.2 millimeters)</td>
<td></td>
</tr>
<tr>
<td>Thickness:</td>
<td>0.9 inch (22.86 millimeters)</td>
<td>1.08 inches (27.5 millimeters)</td>
<td></td>
</tr>
<tr>
<td><strong>Refill Septum</strong></td>
<td>Silicone rubber</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Battery</strong></td>
<td>Lithium thionyl-chloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Catheter Access Port</strong></td>
<td>Titanium screen and silicone rubber septum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Puncture life:</td>
<td>500 punctures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Puncture life:</td>
<td>2,000 punctures</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Battery Life**

SynchroMed pumps (manufactured before 1999) typically last 3-5 years, depending on the flow rate. The model number of these pumps generally begins with 861x, for example, 8616-18. SynchroMed EL pumps (manufactured after 1999) feature an extended battery life and lower flow rates. The SynchroMed EL pumps are expected to last 5-7 years, depending on the flow rate. The model numbers of these pumps start with 862x, for example, 8626-10.

The expected SynchroMed EL pump service life relative to drug flow rate is shown.

**Drug Indication and Stability Information**

The table below shows the drugs that have been tested for stability and compatibility with the SynchroMed infusion system. The middle column identifies the condition the drugs are used to treat.

This booklet covers the SynchroMed pump as it is used to treat chronic pain, manage severe spasticity, or deliver chemotherapy drugs. However, the pump also is approved to manage a condition known as osteomyelitis, which is a type of bone infection.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Drug stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>Chronic pain (cancer pain or nonmalignant pain)</td>
<td>90 days</td>
</tr>
<tr>
<td>Baclofen injection (Lioresal® Intrathecal)</td>
<td>Severe spasticity</td>
<td>90 days</td>
</tr>
<tr>
<td>Floxuridine (FUDR)</td>
<td>Cancer</td>
<td>27 days</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>Cancer</td>
<td>14 days</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>Cancer</td>
<td>28 days</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>Cancer</td>
<td>7 days</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>Osteomyelitis</td>
<td>28 days</td>
</tr>
</tbody>
</table>

**Limited Warranty**

Medtronic offers a limited warranty on all of the components of its implantable infusion systems. Should you need a copy of the warranty on your SynchroMed pump, please contact Medtronic Neurological.

Medtronic Neurological SynchroMed Models
8626-10; 8626-18; 8626L-10; 8626L-18;
8627-10; 8627-18; 8627L-10; 8626L-18
Programmable Pumps
Limited Warranty®
(U.S. Customers Only)
Appendix B: IsoMed Constant-Flow Pump

The following provides more in-depth, detailed information about the IsoMed infusion system than is provided elsewhere within this booklet. The IsoMed pump became commercially available in 2000 and is the newest infusion pump from Medtronic.

Specifications

The following chart highlights some of the key specifications for components of the IsoMed pump. The specific weights and measures of the pump are dependent upon the pump reservoir size (20 ml, 35 ml, or 60 ml). IsoMed pumps with a 20 ml reservoir are the smallest pumps. IsoMed pumps with a 60 ml reservoir are the largest pumps.

<table>
<thead>
<tr>
<th>Pump</th>
<th>Material:</th>
<th>Titanium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reservoir size:</td>
<td>20 milliliters</td>
<td>35 milliliters</td>
</tr>
<tr>
<td>Weight (when empty):</td>
<td>113 g (4.0 oz.)</td>
<td>116 g (4.1 oz.)</td>
</tr>
<tr>
<td>Diameter:</td>
<td>77 mm (3.0 in.)</td>
<td>77 mm (3.0 in.)</td>
</tr>
<tr>
<td>Thickness:</td>
<td>17 mm (.67 in)</td>
<td>22 mm (.87 in)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Refill Septum</th>
<th>Material:</th>
<th>Silicone rubber</th>
</tr>
</thead>
<tbody>
<tr>
<td>Puncture life:</td>
<td>1,000 punctures</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Catheter Access Port</th>
<th>Material:</th>
<th>Titanium screen and silicone rubber septum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Puncture life:</td>
<td>500 punctures</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Capillary Tubing</th>
<th>Material:</th>
<th>Glass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length:</td>
<td>Varies with flow rate. Generally 1 foot to 31 feet (0.6 to 9.6 meters)</td>
<td></td>
</tr>
</tbody>
</table>

Drug Indication and Stability Information

The table below shows the drugs that have been tested for stability and compatibility with the IsoMed infusion system. The middle column identifies the condition the drugs are used to treat.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Drug stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>Chronic pain (cancer pain or nonmalignant pain)</td>
<td>90 days</td>
</tr>
<tr>
<td>Floxuridine (FUDR)</td>
<td>Cancer</td>
<td>27 days</td>
</tr>
</tbody>
</table>

Limited Warranty

Medtronic offers a limited warranty on all of the components of its implantable infusion systems. Should you need a copy of the warranty on your IsoMed pump, please contact Medtronic Neurological.

Medtronic
IsoMed Model 8472 Pump
Limited Warranty®
(U.S. Customers Only)
**Medtronic® SynchroMed® and IsoMed® Infusion Systems**

**Product technical manual must be reviewed prior to use for complete prescribing information.**

**Indications:** Chronic intrathecal infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain and chronic intravascular infusion of floxuridine (FUDR) for the treatment of primary or metastatic cancer. SynchroMed is also indicated for chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for severe spasticity, chronic epidural infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic intravascular infusion of doxorubicin, cisplatin, or methotrexate for the treatment of primary or metastatic cancer, and chronic intravenous infusion of clindamycin for the treatment of osteomyelitis.

**Contraindications:** When infection is present; when the pump cannot be implanted within 2.5 cm (1 inch) from the surface of the skin; when body size is not sufficient to accept pump bulk and weight; when contraindications exist related to the drug. Blood sampling through the side catheter access port is contraindicated.

**Warnings:** Use only with approved drugs. Improper use, calculation errors, or component failure may result in loss of therapeutic effect, or clinically significant or fatal drug withdrawal or overdose symptoms. Clinically significant or fatal drug overdose may result from overpressurization of the pump reservoir, improper injection of drug through the catheter access port or into the pump pocket, or failure to account for significant amounts of drug residing in the reservoir, pump tubing, catheter access port, or catheter. The effects of mixing drugs are unknown. Flow rate of the IsoMed pump may decrease or stop if drug precipitation occurs. The effects of implanting the SynchroMed pump in patients with other implanted programmable devices are unknown.

**Precautions:** Only qualified personnel should implant, fill and refill the pumps, access the catheter access ports, or program the SynchroMed pump. Maintain strict aseptic techniques during all procedures to prevent infection. Consider use of peri- and postoperative antibiotics for pump implantation and any subsequent surgical procedures. Use caution in selecting an anatomical pump site appropriate to the size and mass of the patient. Initial fill and refill volumes must not exceed levels specified in the technical manuals. Do not expose pumps to temperatures above 43 degrees C (110 degrees F) or below 5 degrees C (40 degrees F). Do not implant a pump that has been dropped onto a hard surface or shows signs of damage. Do not attempt to resterilize the pump. Follow manufacturer's instructions regarding drug preparation, dosage, and administration. FUDR should be used with added caution in patients with impaired hepatic or renal function. Systemic therapy should be considered for patients with known disease extending beyond an area capable of infusion. IsoMed pump flow rate will vary depending on factors such as body temperature, altitude, arterial pressure at the catheter tip, and solution viscosity. In rare instances, an inflammatory mass may develop at the tip of an implanted spinal catheter, which can result in progressive neurological effects.

**Magnetic Resonance Imaging (MRI):** MRI will temporarily stop the SynchroMed pump motor and suspend drug infusion for the duration of MRI exposure. The SynchroMed pump should resume normal operation upon termination of MRI exposure. Exposure of IsoMed pumps to Magnetic Resonance Imaging (MRI) fields of 1.5 T (Tesla) has demonstrated no impact to pump performance and a limited effect on the quality of the diagnostic information. During an MRI scan, the patient may experience heating or peripheral nerve stimulation at or near the pump implant site. In the unlikely event that this happens, the MRI scan parameters should be adjusted to reduce Specific Absorption Rate (SAR) for heating or dB/dt for nerve stimulation or both. Upon completion of an MRI scan, the SynchroMed pump parameters should be confirmed using a SynchroMed® Programmer. SynchroMed pump performance has not been established in >2.0 T (Tesla) MR scanners nor has IsoMed pump performance been established in >1.5 T (Tesla) MR scanners—it is not recommended that patients have MRI scans using these scanners.

**Adverse Events:** Include, but not limited to, cessation or change in therapy, a return of underlying symptoms or drug withdrawal symptoms due to an empty reservoir, component failure or SynchroMed battery depletion; seroma/hematoma, infection, inflammation, tissue erosion, or pain at implant site; complete or partial catheter occlusion, kinking, breakage, leakage or disconnection; catheter dislodgement or migration; CSF leak/accumulation, internal/GI bleeding; arachnoiditis; meningitis; spinal headache; perforation of internal organs; drug toxicity and related side effects; and procedural complications.
Completely read this information before you start using Medtronic ITB™ Therapy (Intrathecal Baclofen Therapy). This information does not take the place of thorough discussions with your doctor. You and your doctor should discuss ITB Therapy before you begin receiving the therapy and at regular refill appointments.

**Q: What is Lioresal® Intrathecal (baclofen injection)?**

A: Lioresal Intrathecal is a liquid form of baclofen, and is commonly used to treat severe spasticity. Liquid baclofen is used for injections and infusion into the intrathecal space (the fluid-filled area surrounding the spinal cord), using an implantable drug delivery system.

**Q: What is severe spasticity?**

A: Severe spasticity is tight, stiff muscles that make movements – especially of the arms and legs – difficult or uncontrollable. Severe spasticity can interfere with an individual’s function and/or comfort.

**Q: Who is a candidate for Lioresal Intrathecal?**

A: People who suffer from severe spasticity resulting from cerebral palsy, multiple sclerosis, stroke, traumatic brain injury, or spinal cord injury, and who suffer intolerable side effects from oral baclofen (pills), may be a candidate for Lioresal Intrathecal. A screening test will help determine if you will respond to the intrathecal medication. Talk with your doctor about whether Lioresal Intrathecal may be an option for you.

**Q: Who is not a candidate for Lioresal Intrathecal?**

A: People who are hypersensitive (extremely sensitive) to oral baclofen should not take Lioresal Intrathecal.

**Q: What are the most common side effects of Lioresal Intrathecal?**

A: The side effects of intrathecal baclofen include loose muscles, sleepiness, upset stomach, vomiting, headaches, and dizziness. As with most medications, overdose (drug dose is too high) or under dose (drug dose is too low) can occur. Talk with your doctor about the side effects you may experience from your treatment.

**Q: What do I need to know if I am using Lioresal Intrathecal?**

A: Abruptly stopping intrathecal baclofen can result in serious medical problems and in rare cases has been fatal.
Q: What are the signs of rapid or abrupt withdrawal from intrathecal baclofen?
A: Increase or return in spasticity, itching, low blood pressure, lightheadedness, and tingling sensation are often early indications of baclofen withdrawal. It is very important that your doctor be called right away if you experience any of the above symptoms.

In rare cases, severe symptoms may occur. These symptoms include high fever, altered mental status, spasticity worse than before you started ITB Therapy, and muscle rigidity. It is very important that your doctor be called right away if you experience any of the above symptoms.

Q: What can I do to prevent baclofen underdose or abrupt discontinuation of intrathecal baclofen?
A: It is very important that you keep all of your refill appointments. This may require some planning prior to traveling. Maintaining a regular refill schedule will ensure the pump does not run out of medication and that any potential problems with the infusion system are diagnosed and corrected. Additionally, you should be aware of what your pump alarms sound like. If you hear an alarm, contact your doctor immediately.

Furthermore, it is very important that you know and understand the signs of baclofen underdose. Also be sure to tell your doctor right away if you experience any unusual symptoms, side effects, or changes in your condition.

Q: What are the symptoms of baclofen overdose?
A: Although rare, it is possible for you to receive too much medication (overdose). A baclofen overdose may cause drowsiness, lightheadedness, respiratory depression (difficulty breathing), seizures, loss of consciousness and coma. If you experience any of the above symptoms, it is very important that you or your caregiver contact your doctor right away.

This provides a summary of the most important information about Lioresal Intrathecal. If you would like more information, talk with your doctor. You can ask for information about Lioresal Intrathecal that is written for healthcare professionals. You also can get more information by visiting www.spasticity.com.

Rx only.

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