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FDA approved labeling dated October 31, 2013



Medtronic

Refill Kit

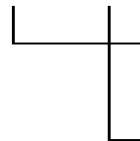
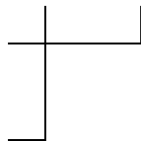
856X

for use with Medtronic Implantable Programmable Infusion
Pumps

Instructions for Use

Rx only

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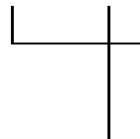
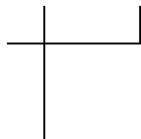


Explanation of symbols on product or package labeling
Refer to the appropriate product for symbols that apply.



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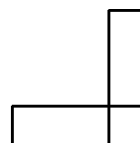


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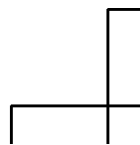
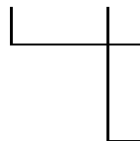
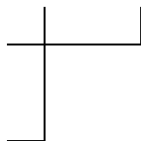
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Refer to the Indications, Drug Stability, and Emergency Procedures reference manual for indications and related information.

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 Lioresal Intrathecal (baclofen injection) drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures.

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Introduction

These instructions include only the procedure for refilling the pump reservoir with Lioresal Intrathecal (baclofen injection). Refer to the appropriate pump technical manual for implanting instructions.

Package contents

The Model 856X Refill Kit contains the following sterile components that are not made with natural rubber latex:

- 20-mL syringe
- Extension set with a clamp
- Template
- 0.22-micron filter
- Two 22-gauge noncoring needles
- Fenestrated drape
- Accessories (povidone iodine swabs, gauze pads, alcohol pads, gloves)

Indications

The Model 856X Refill Kit is intended for use in refilling Medtronic implantable programmable infusion pumps with the exception of Medtronic MiniMed infusion pumps.

Contraindications

Medtronic refill kits are contraindicated for all catheter access port procedures.

Warnings

Withdrawal - Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure and death.

Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g. spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional postimplant clinician and patient information.

User instructions - Comply with all product instructions for initial preparation and filling, implantation, programming, refilling, and accessing the catheter access port (if present) of the pump. Failure to comply with all instructions can lead to technical errors or improper use of implanted infusion pumps and result in additional surgical procedures, a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose.

Implantation and system management - Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the infusion system and must be in compliance with procedures described in the appropriate technical instructions. Inadequate training or failure to follow instructions can require surgical revision or replacement, and result in a clinically significant or fatal drug underdose or overdose.

Calculating catheter volume - Use the catheter length recorded at implant

or catheter revision when calculating catheter volume. The actual implanted catheter length and catheter model number are required to accurately calculate catheter volume. A universal value does not exist that can be used as a substitute for this knowledge. An inaccurate catheter volume calculation can result in a clinically significant or fatal drug underdose or overdose.

Contrast medium (pumps with catheter access port) - Do not inject any contrast medium into the pump reservoir. Injecting contrast medium into the pump reservoir can impair pump operation.

Refill - Patients must return to the clinic for refills at the prescribed times. Failure to return to the clinic for refills at the prescribed times can result in the actual flow rate of the pump being less than expected, resulting in a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose. Failure to return at the prescribed times can also damage the pump, requiring surgical replacement.

Refill kit components – Use the appropriate Medtronic refill kit during all refill procedures for Medtronic implantable infusion pumps. Using components other than Medtronic components or a kit other than the appropriate refill kit can damage Medtronic components, requiring surgical revision or replacement, and allow drug leakage into surrounding tissue, resulting in loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose.

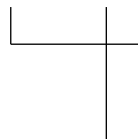
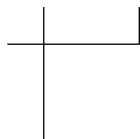
Injection error during a pump refill procedure - Be certain you are accessing the reservoir fill port when injecting fluids into an implanted pump. ALWAYS:

- identify the pump model and reservoir volume.
- identify the location of the reservoir fill port.
- use the instructions, noncoring needles, appropriate template edge, and other accessories provided in the appropriate kit.
- verify the location of the reservoir fill port during needle insertion according to the instructions provided AND using other medical procedures as appropriate.
- refer to the drug labeling for indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.

Pocket fill is the improper injection into the subcutaneous tissue, which includes the pump pocket. Pocket fill can result in a loss of or change in symptom control, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose. Observe the patient after the pump refill procedure for any signs or symptoms that could indicate a pocket fill or any other drug-related adverse event due to the refill procedure. Seek emergency assistance as necessary. Refer to the refill kit manual or the Indications, Drug Stability and Emergency Procedures for SynchroMed and IsoMed Implantable Infusion Systems Reference Manual for emergency procedures associated with drug underdose and overdose. Inadvertent injection into the catheter access port may result in a clinically significant or fatal drug overdose. Observe the patient after the pump refill procedure for any signs or symptoms that could indicate a drug-related adverse event due to the pump refill procedure.

Changing drug or decreasing drug concentrations - Rinse the reservoir twice between solutions when changing drug or decreasing drug concentrations in the pump reservoir. A significant amount of drug may be present in the pump reservoir after emptying the pump. This residual volume cannot be removed by emptying the pump. Rinsing the reservoir between solutions minimizes the amount of drug in this residual volume but does not eliminate it. Failure to account for residual drug in the pump reservoir can result in a concentration that is different than intended and a clinically significant or fatal drug underdose or overdose. For programmable infusion pumps, program a Bridge Bolus after rinsing the reservoir twice. The Bridge Bolus advances the remaining old drug (the drug left in the pump tubing, catheter access port, and catheter after emptying and refilling the pump) to the catheter tip at the prior flow rate.

Refer to "Performing a reservoir rinse" on page 16 of this manual. Refer to



the Programming Guide for bridge bolus procedures.

Connections - Firmly secure all connections. Failure to secure connections can allow drug to leak onto the surrounding skin and may result in inadequate therapy or infection.

Reservoir fill port injections - Do not use excessive force when accessing the reservoir fill port. Excessive force can result in damage to the needle or pump requiring surgical revision or replacement, and leakage into surrounding tissue, resulting in loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose.

Intrathecal therapy - For intrathecal therapy, use ONLY a preservative-free sterile solution indicated for intrathecal use. Nonindicated fluids containing preservatives or endotoxins can be neurotoxic in intrathecal applications. Using nonindicated fluids can result in adverse events including, but not limited to, extreme pain, cramps, seizures, and death.

Drug information - Refer to the drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures. Refer to the drug labeling for specific drug underdose or overdose symptoms and methods of management. Failure to refer to the drug labeling can result in inappropriate patient selection and management, inadequate therapy, intolerable side effects, or a clinically significant or fatal drug underdose or overdose. Consider the possibility of a drug error if the patient experiences unusual side effects. Failure to do so can result in misdiagnosis of patient symptoms.

Mixing drugs - The effects that drug mixtures have on pump operation are unknown. Drugs can precipitate when mixed. These precipitates can inhibit pump flow or block the catheter, resulting in loss of therapy or a clinically significant or fatal drug underdose.

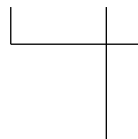
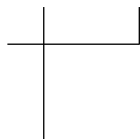
Drug interaction and side effects - Inform patients of the appropriate warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention, including prodromal signs and symptoms of inflammatory mass. Failure to recognize the signs and symptoms and to seek appropriate medical intervention can result in serious patient injury or death.

Drug overdose symptoms and management - Refer to the emergency procedures included at the end of this manual and the drug labeling for specific drug overdose symptoms and methods of management.

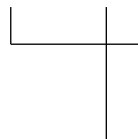
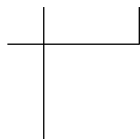
Pocket fill - If it is suspected or known that all or part of the drug was injected into the pocket during the refill procedure, monitor the patient closely for signs and symptoms of overdose in an appropriate facility for a sufficient amount of time or until the symptoms have resolved. Refer to "Emergency Procedures" in the Indications, Drug Stability, and Emergency Procedures manual, the refill instructions for use, and the drug labeling for specific drug underdose and overdose symptoms and methods of management.

Drug underdose/overdose - Inform patients and caregivers of the signs and symptoms of a drug underdose and overdose. Inform patients and caregivers:

- to be aware and report any unusual signs or symptoms at anytime during or after a refill or catheter access port procedure.
- to be alert for any burning sensations in the area of the pump pocket during their refill or catheter access port procedure.
- to especially watch for signs of underdose and overdose.
- to stay alert for signs or symptoms that may indicate changes to their prescribed drug concentration or programmed dose.
- to seek emergency assistance as necessary. Refer to the refill kit or catheter access port kit manual or the Indications, Drug Stability and Emergency Procedures for SynchroMed and IsoMed Implantable Infusion Systems Reference Manual for emergency procedures associated with drug underdose and overdose.



Failure to recognize these signs and symptoms and to seek appropriate medical intervention can result in serious patient injury or death.



Patient travel - Patients should notify their clinicians of any travel plans. Clinicians need this information to coordinate patient care and pump refills and help prevent a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Precautions

Compatibility, all components - Follow these guidelines when selecting system components:

- Medtronic components: For proper therapy, use only components that are compatible with the appropriate indication.
- Non-Medtronic components: No claims of safety, efficacy, or compatibility are made with regard to the use of non-Medtronic components with Medtronic components. Refer to the non-Medtronic documentation for information.

Component packaging - Before shipment the components in the sterile package were sterilized by the process indicated on the package label. Do not use or implant a component if the following circumstances have occurred:

- The storage package or sterile seal has been pierced or altered because component sterility cannot be guaranteed and infection may occur.
- The component shows signs of damage because the component may not function properly.
- The use-by date has expired because component sterility cannot be guaranteed and infection may occur; also, device battery longevity may be reduced and may require early replacement.

Storage temperature: kits and accessories - Do not store or transport the kit device components or accessories above 57 °C (135 °F) or below -34 °C (-30 °F). Temperatures outside this range can damage device components.

Aseptic technique - Use strict aseptic technique when accessing the reservoir fill port or the catheter access port of an implanted pump. Failure to use aseptic technique can contaminate fluids or tissues and result in local or systemic infection.

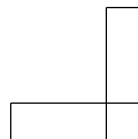
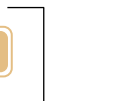
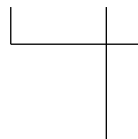
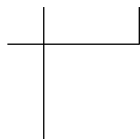
Infection - Use extreme caution when accessing the reservoir fill port or catheter access port of the implanted pump if local or systemic infection is suspected. Avoid contaminating the system or further spreading the infection. Local or systemic infection may require pump revision or removal.

Therapy discontinuance - If therapy is discontinued for an extended period, fill the pump reservoir with preservative-free saline. Program the pump to infuse at the minimum flow rate. Refill the pump as needed to ensure the pump always contains fluid in the reservoir and fluid pathway. Stopping the pump for extended periods or allowing the pump reservoir to empty completely can damage the system and require surgical replacement.

Single use only - Do not reuse any component. Components are intended for single use only. Reusing components can result in inadequate therapy and an increased risk of infection.

Reservoir valve activation (programmable pumps) - Do not prematurely activate the pump reservoir valve. Activation of the pump reservoir valve seals the pump reservoir valve closed. Unusual resistance or the inability to inject the entire fill volume may indicate activation of the pump reservoir valve. If the valve closes, a portion of the reservoir contents must be delivered or removed before filling can be completed, and procedural delays can occur. To prevent activation of the pump reservoir valve during emptying and filling procedures:

- completely aspirate all contents of the pump reservoir before filling;
- do not allow air into the pump reservoir through an open needle in the septum or an unclamped extension; and
- do not exceed the maximum reservoir volume indicated in the pump labeling.



Adverse events

The adverse events associated with the use of this device may include, but may not be limited to, the following:

- Meningitis
- Infection
- Reservoir contamination
- Overpressurization of the reservoir
- Injection into pocket or subcutaneous tissue
- Activation of reservoir valve

Instructions for use

Become thoroughly familiar with all product literature before using this refill kit.

Sterilization

All components of the kit are sterile. Do not resterilize. Should sterility of the kit be in question, discard and use a new kit.

Preliminary procedures

1. Gather the following sterile equipment:
 - Syringe(s) containing prescribed fluid

From the refill kit:

- 20-mL empty syringe
- Extension set with a clamp
- Template
- 0.22-micron filter
- 22-gauge noncoring needle
- Fenestrated drape
- Cleansing agent
- Alcohol pads
- Sterile gloves (not made with natural rubber latex)

Locally supplied:

- Adhesive bandage, optional
2. Refer to the drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures.
 3. Prepare the programmer for use. Refer to the appropriate programming guide for instructions.
 4. Confirm the:
 - pump model
 - reservoir volume
 - location of the pump

Note: The model and reservoir volume can be confirmed by the programmer. Alternatively, a radiopaque identifier in the pump shows

the pump model and identifies Medtronic as the pump manufacturer on a standard x-ray (Figure 1). A three-letter code designates the pump model.

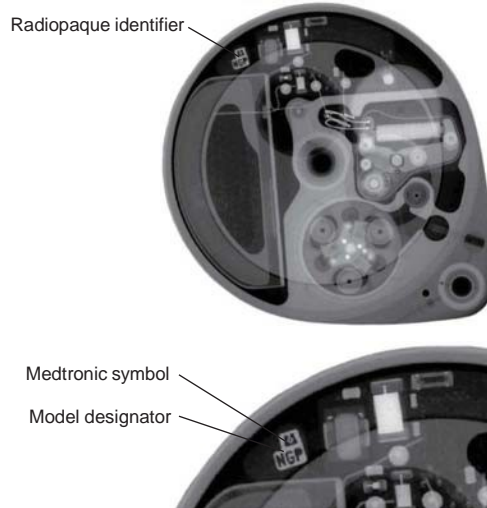


Figure 1. A radiopaque identifier on a SynchroMed II pump.

5. Confirm that the volume of the prescribed fluid does not exceed the reservoir volume of the pump.

Emptying the SynchroMed pump

1. Prepare the injection site by cleansing the area.
2. Open the kit. Put on sterile gloves.
3. Place the drape, exposing the pump site.
4. Using sterile procedures, assemble the needle, extension set, and empty syringe as follows:
 - a. Connect the empty syringe to the extension set.
 - b. Connect the needle to the extension set.
5. Palpate the pump and identify the location of the catheter access port and the edges of pump.

Factors that may make it difficult to locate the pump include, but are not limited to:

 - deep implant
 - patient position (eg, a seated patient)
 - scar tissue at the pump implant site
 - seroma
 - the pump is tilted in the pocket
 - obesity
 - pump movement within the pocket
 - weight gain after implant
 - weight loss after implant

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.

6. Place the template on the skin over the pump, and align the refill template correctly based on the model of the pump that is being refilled (Figure 2). Align the edges of the template with the edges of the pump.

Use the center circle of the template to insert the needle into the reservoir fill port.

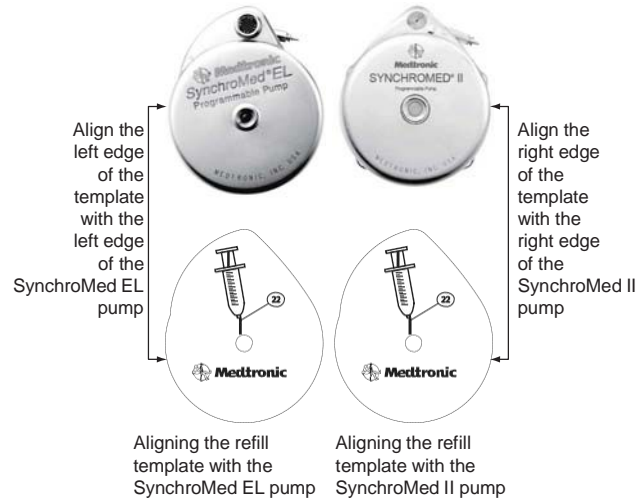


Figure 2. Aligning the refill template according to the pump model.

7. Close the clamp.
8. Gently insert the 22-gauge needle perpendicular to the surface of the pump through the center of the template and into the center of the reservoir fill port until the needle touches the bottom of the reservoir fill port (Figures: 3 – 4).

Note: The pump may be tilted within the pocket and therefore the needle angle may not be perpendicular to the patient's body.

During proper needle insertion, you will feel the needle:

- 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.

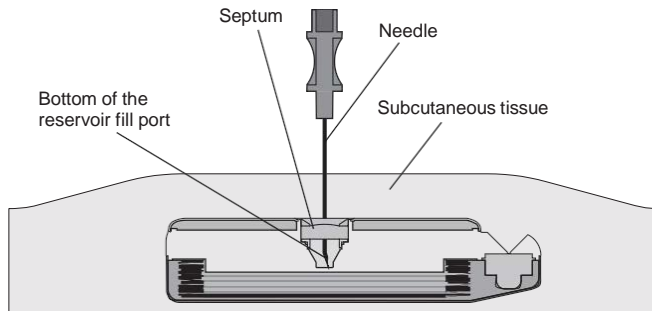


Figure 3. View inside of a SynchroMed programmable pump while the needle is fully and properly inserted.

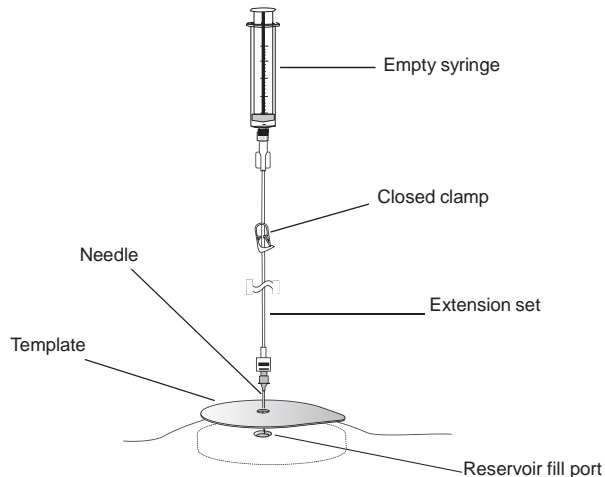


Figure 4. Close the clamp and insert the needle into the reservoir fill port.

Note: At any point during the procedure, if in doubt about the needle location, reassess its position. Factors that may contribute to difficulty inserting the needle into the reservoir fill port include, but are not limited to:

- the pump is flipped in the pocket
- deep implant
- patient position (eg, a seated patient)
- patient movement (eg, spasticity, difficulty hold still)
- localized muscle spasms at the pump implant site
- scar tissue at the pump implant site
- seroma
- the pump is tilted in the pocket
- obesity
- pump movement within the pocket
- weight gain after implant

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- weight loss after implant
9. Open the clamp and slowly withdraw the fluid from the reservoir into the empty syringe.
Note: If the withdrawn fluid has an unexpected appearance (eg, evidence of blood), this may indicate that the needle is not properly inserted into the pump.
 10. If the syringe maximum capacity is reached before the reservoir is completely empty, more than one syringe will be needed to empty the pump.
 - a. Close the clamp.
 - b. Remove the full syringe.
 - c. Attach an empty syringe.
 - d. Verify that the needle is in the pump reservoir fill port.
 - e. Repeat step 9, then continue to step 11.
 11. Completely empty the pump. When the pump is empty, the bubbles will stop forming, and negative pressure in the syringe can be felt.
 12. Close the clamp and remove the syringe from the extension set.
Note: Keep the needle in the reservoir fill port and the clamp closed for the pump refill procedure that follows.
 13. Note the amount withdrawn from the pump for entry in the patient's record.
 14. Compare the amount withdrawn from the pump to the expected volume. See the pump programmer for the expected volume. The amount withdrawn should approximately equal the expected volume.
 15. Discard the fluid and syringe as appropriate for the fluid content in accordance with institutional policies and applicable regulations.

Refilling the SynchroMed pump



Warning:

Pocket fill is the improper injection into the subcutaneous tissue, which includes the pump pocket. Pocket fill can result in a loss of or change in symptom control, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose. Observe the patient after the pump refill procedure for any signs or symptoms that could indicate a pocket fill or any other drug-related adverse event due to the refill procedure.

Inadvertent injection into the catheter access port may result in a clinically significant or fatal drug overdose. Observe the patient after the pump refill procedure for any signs or symptoms that could indicate a drug-related adverse event due to the pump refill procedure.



Warning: If it is suspected or known that all or part of the drug was injected into the pocket during the refill procedure, monitor the patient closely for signs and symptoms of overdose in an appropriate facility for a sufficient amount of time or until the symptoms have resolved. Refer to "Emergency Procedures" in the Indications, Drug Stability, and Emergency Procedures manual, the refill instructions for use, and the drug labeling for specific drug underdose and overdose symptoms and methods of management.



Warning: Swelling at the injection site may indicate that the needle tip is not properly located within the pump reservoir, and the result could be pocket fill. Pocket fill can result in a loss of or change in symptom control, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose. Absence of swelling does not in all cases demonstrate that the needle tip is properly located. If swelling is present, stop injecting and observe the patient for any signs or symptoms that could indicate a pocket fill or any other drug-related adverse event.

1. If changing drug or drug concentrations, refer to "Performing a reservoir rinse" on page 16. Otherwise, proceed to the next step.

2. Confirm that the refill volume of the prescribed fluid does not exceed the reservoir volume of the pump.
3. Purge the air from the syringe containing the prescribed fluid.
4. Attach the filter to the syringe with the prescribed fluid.
5. Purge all air from the filter.
6. Attach the syringe with the prescribed fluid and filter to the extension set (Figure 5).
7. Before and during injection, verify that the needle remains fully inserted to the bottom of the reservoir fill port. Do not apply tension to the extension tubing because the needle may be pulled out from the reservoir.
8. Open the clamp and as the clamp is opened, observe the following indications that the needle continues to be properly positioned:
 - The bubbles in the extension set are immediately drawn into the pump.
 - The plunger may move slightly when the drug is initially drawn into the pump.
9. Slowly depress the plunger on the syringe to inject the prescribed fluid into the pump reservoir. While injecting the prescribed fluid, verify that the needle remains properly located within the reservoir (Figure 5).
 - a. Periodically withdraw and observe a portion of the drug to confirm that the drug has the expected appearance.
 - b. After confirming that the needle remains in the reservoir, resume injecting fluid.

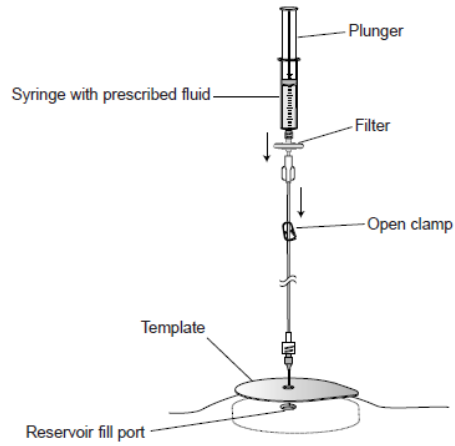


Figure 5. Open the clamp and inject into the pump reservoir.

⚠ Caution: If you encounter unusual resistance before the maximum reservoir volume is injected or you are unable to inject fluid, the reservoir valve may have been activated. Activation of the pump reservoir valve seals the pump reservoir valve closed. If the valve closes, a portion of the reservoir contents must be delivered or removed before filling can be completed, and procedural delays can occur.

To prevent activation of the pump reservoir valve during emptying and filling procedures:

- completely aspirate all contents of the pump reservoir before filling;
 - do not allow air into the pump reservoir through an open needle in the septum or an unclamped extension; and
 - do not exceed the maximum reservoir volume indicated in the pump labeling.
10. If you have activated the reservoir valve, complete steps a – g below. Otherwise, proceed to step 11.
 - a. Discontinue injection.
 - b. Close the clamp.
 - c. Remove the syringe with prescribed fluid and attached filter.
 - d. Attach an empty 20-mL syringe to the extension set.
 - e. Open the clamp, and aspirate until all fluid/air is removed.
 - f. Close the clamp and remove the syringe containing the aspirate from the extension set and discard the syringe.
 - g. Repeat steps 2 – 10.
- Note: For pumps with a reservoir valve, the amount of time before the valve will release is dependent on the duration and the amount of pressure applied after the valve is first activated. The more pressure exerted, the longer it may take to release the valve.
11. If more than one syringe of prescribed fluid is needed to fill the pump reservoir, complete steps a – d below. Otherwise, proceed to step 12.
 - a. Close the clamp.
 - b. Keep the filter from the extension set in place, and remove the first syringe from the filter.



Caution: Do not remove the filter from the extension set. Removal of the filter could compromise the sterile barrier, which could result in an infection for the patient.

- c. Purge the air from the second syringe, and attach the second syringe to the filter (Figure 5).
 - d. With the second syringe in a vertical position, open the clamp and slowly depress the plunger on the syringe to inject the prescribed fluid into the pump reservoir.
12. When filling is complete, close the clamp and carefully remove the needle from the reservoir fill port.

Note: If you are unsure whether drug was injected correctly into the pump, completely aspirate the pump to verify that all of the injected drug can be removed.
13. Remove the cleansing agent from the patient's skin using an alcohol pad.
14. Apply an adhesive bandage, if desired.
15. Discard all components of the kit.

Programming the SynchroMed pump

1. If the drug concentration or drug has been changed, program a bridge bolus. Refer to the programming guide for the pump software.
2. If any prescription information has changed, enter the changed information into the clinician programmer: for example drug name, drug concentration, infusion information, or volume of prescribed fluid in the pump reservoir.
3. Update the pump.

After the refill procedure

1. Print out the desired refill-related reports, and place the final pump settings in the patient file.

2. Determine the refill date from the printout, and schedule a refill appointment.

Reservoir rinse procedure

Performing a reservoir rinse

To prevent drug overdose or underdose when changing concentrations or changing solutions in the pump reservoir, always rinse the reservoir twice between solutions to remove the drug that remains in the reservoir after emptying the pump. This remaining volume is known as the residual volume.

The procedure for performing a reservoir rinse is outlined below. Use the components of the appropriate refill kit to perform the rinse and follow the applicable empty and refill procedures for that kit.

1. Empty the pump completely.
2. Fill the pump with 10 mL of sterile preservative-free Sodium Chloride Injection, USP.
3. Empty the pump completely.
4. Repeat steps 2 and 3.
5. Fill the pump to capacity with the prescribed fluid.
6. For programmable infusion pumps, program a bridge bolus. Refer to the programming guide for the pump software.

Technical support

A toll-free technical support service is available 24 hours a day for clinicians managing patients with Medtronic implantable infusion pumps. Telephone Customer Service at: 1-800-707-0933.

Emergency procedures

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 intrathecal baclofen injection.

Actions

See table on following page.

Table 1. Intrathecal baclofen injection overdose emergency procedures

Maintain airway/breathing/circulation. Intubation and respiratory support may be necessary.	
↓	
Empty pump reservoir to stop drug flow. Record Amount withdrawn.	
↓	
FOR INTRATHECAL OVERDOSE:	FOR SUBCUTANEOUS OVERDOSE: (eg, pocket fill)
↓	↓
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	Proceed immediately to the next step.
↓	↓
Notify patient's physician managing intrathecal baclofen injection therapy.	
↓	
Continue to monitor closely for symptom recurrence.	
↓	
Report incident to Medtronic, Inc.	

^a Use a 25-gauge needle for withdrawal from a SynchroMed or SynchroMed EL catheter access port. Use a 24- or 25-gauge needle for withdrawal from a SynchroMed II catheter access port.

Lioresal Intrathecal (baclofen injection) underdose/withdrawal

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

Symptoms of underdose

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

Symptoms of withdrawal

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

Actions:

See table on following page.

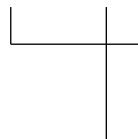
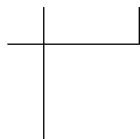
Table 2. Intrathecal baclofen injection underdose/
 withdrawal emergency procedures

Initiate life-sustaining measures if indicated.
↓
<p>If a patient receiving intrathecal baclofen injection presents with the signs and symptoms suggestive of withdrawal (see previous page, the following is consistent with that suggested by a panel of therapy-experienced clinicians convened to explore this issue. ^{a,b}</p> <ol style="list-style-type: none"> 1. Immediately contact a physician experienced in 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. 2. If a physician experienced in intrathecal baclofen injection is unavailable, consider instituting one or more of the following options, unless otherwise contraindicated: <ul style="list-style-type: none"> • high-dose oral* or enteral baclofen • restoration of intrathecal baclofen injection infusion • intravenous benzodiazepines by continuous or intermittent infusion, titrating the dosage until the desired therapeutic effect is achieved <p>* Note: Oral baclofen should not be relied upon as the sole treatment for intrathecal baclofen injection withdrawal syndrome.</p>
↓
Report incident to Medtronic, Inc.

^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.

^b Coffey R.J, Edgar TS, Francisco GE, et al. Abrupt withdrawal from the intrathecal baclofen: recognition and management of a potentially life-threatening syndrome. Arch Phys Med Rehabil. 2002;83:735-741.

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Emergency procedure to empty pump reservoir

Equipment

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

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 6).

During proper needle insertion, you will feel the needle:

- 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.

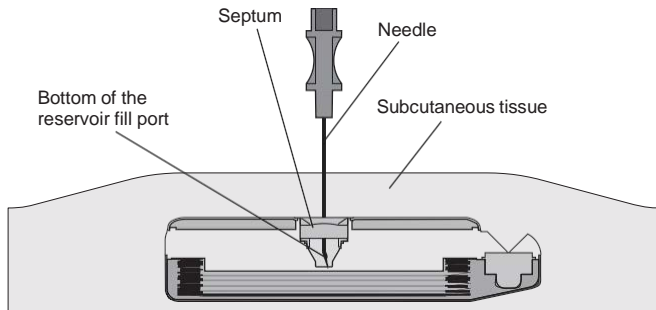


Figure 6. View inside of a SynchroMed programmable pump while the needle is fully and properly inserted.

5. Open the clamp or stopcock and slowly withdraw the fluid from the reservoir into the empty syringe.
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. When the pump is empty, the bubbles will stop forming, and negative pressure in the syringe can be felt.
8. Remove the needle from the reservoir fill port.
9. Record in patient chart the amount of fluid emptied from the pump reservoir.

Special notice

The Medtronic 856X Refill Kit is designed to be used for refilling Medtronic implantable programmable infusion pumps with the exception of Medtronic MiniMed infusion pumps. Medtronic cannot warrant or guarantee the refill kit because, despite the exercise of all due care in design, component selection, manufacture, and testing prior to sale, the components of the refill kit may be easily damaged before or during use by improper handling or other intervening acts.

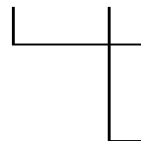
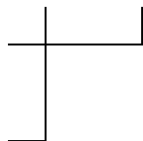
Limited Warranty

Medtronic® Neuromodulation MODEL 856X REFILL KIT LIMITED WARRANTY¹

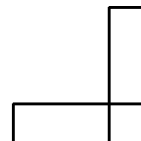
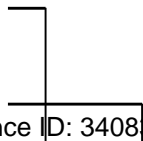
- A. This Limited Warranty provides the following assurance to the purchaser of the Medtronic Model 856X packaged herein, hereafter referred to as the "Product":
- (1) Should the Product fail to function within normal tolerances due to a defect in materials or workmanship prior to its "Use By" date, Medtronic will at its option: (a) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement Product or provide a functionally comparable replacement Product at no charge.
 - (2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement Product.
- B. To qualify for the Limited Warranty set forth in Section A(1), the following conditions must be met:
- (1) The Product must be used prior to its "Use By" date.
 - (2) The unused portion of the Product must be returned to Medtronic within thirty (30) days after discovery of the defect and shall be the Property of Medtronic.
 - (3) The Product must not have been altered or subjected to misuse, abuse or accident.
 - (4) The Product must be used in accordance with the labeling and instructions for use provided with the Product.
- C. This Limited Warranty is limited to its express terms. In particular:
- (1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.
 - (2) This Limited Warranty is made only to the purchaser who uses the Product. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.
 - (3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the patient specific legal rights. The patient may also have other rights which vary from state to state.

¹ This Limited Warranty is provided by Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432-5604. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

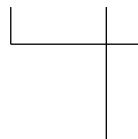
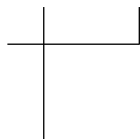
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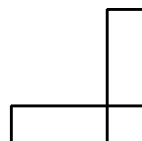
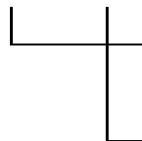
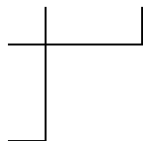
- (4) No person has any authority to bind Medtronic to any representation, condition or warranty except this Limited Warranty.



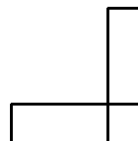
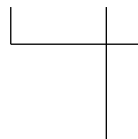
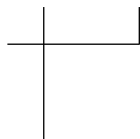
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Medtronic

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