

SYNCHROMED® II

Programmable Infusion System Clinical Reference Guide



Surgical Procedures

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Surgical Procedures

The following instructions give an overview of the pump and catheter implant procedures for the Medtronic SynchroMed® II Programmable Infusion System. These instructions are not intended to address all of the surgical options, complications, or special needs of patients; however, techniques that may reduce complications are recommended. **Before implanting a SynchroMed II Infusion System, please review the technical manuals, this module, and other educational information available through your Medtronic representative.**

Contraindications for Pump Implant

Implantation of the programmable pump is contraindicated:

- In the presence of infection
- When the pump cannot be implanted 2.5 cm or less from the surface of the skin
- In patients whose body size is not sufficient to accept the pump bulk and weight

Contraindications relating to the use of the prescribed drug must be observed. See the *Contraindications* sections of the [Intrathecal Morphine for Pain Management](#) module and the [ITB TherapySM for the Management of Severe Spasticity](#) module.

Overview of Implant

The SynchroMed II Programmable Infusion System is implanted in a sterile surgical procedure performed under general, regional, or local anesthesia. In addition to the pump, a Medtronic intrathecal catheter is also required to complete the system for intrathecal drug delivery. Key tasks for the implant procedure are divided into three primary categories:

Preoperative Tasks

- Conduct patient and caregiver education
- Determine initial dose
- Assemble equipment and supplies
- Check initial pump status

- Prepare drugs and solutions
- Identify pump site

Intraoperative Tasks

- Prepare the patient
- Prepare the pump for implant
- Implant the intrathecal catheter and pump
- Record patient information

Postoperative Tasks

- Program the pump
- Complete pump and catheter registration
- Manage and prevent postoperative complications
- Conduct patient and caregiver education
- Schedule the first refill appointment

Pump Implant: Preoperative Tasks

Conduct Patient and Caregiver Education

During preoperative care, the patient should be instructed on his or her treatment and personal responsibilities.

Review the Patient Informed Consent Form with the patient and caregiver. The Appendix of this module has samples of the [Patient Informed Consent Form for Intrathecal Morphine Therapy](#) and the [Patient Informed Consent Form for ITB TherapySM](#).

Primary topics to be covered during preoperative education and the informed consent process include:

- Preoperative procedures
- Implant procedure
- Postoperative procedures
- Postoperative pain or discomfort
- Postoperative precautions and self-care responsibilities
- Refill schedules and procedures
- Follow-up care

A [Preoperative Patient Education Checklist](#) is provided in the Appendix of this module.

Determine Initial Dose

The patient's initial dose should be determined by monitoring his or her response to the trial. For information about trialing and initial dosing of intrathecal morphine, refer to the [Patient Selection and Trials](#) and [Dosing/Titration Guidelines](#) sections of the *Intrathecal Morphine for Pain Management* module. The [Morphine Equivalence Chart](#) in the *Intrathecal Morphine for Pain Management* module may also be helpful. For information about screening and initial dosing of intrathecal baclofen, refer to the [Patient Selection and Screening](#) and [Dosing and Titration Guidelines](#) sections of the *ITB TherapySM for the Management of Severe Spasticity* module.

Assemble Equipment and Supplies

Supplies required for implant include the following:

STERILE ITEMS

- Medtronic SynchroMed II pump package which includes:
 - Implantable drug pump
 - 22-gauge non-coring needle (for filling the pump)
 - 24-gauge non-coring needle (for flushing the catheter access port)
- Medtronic intrathecal catheter and catheter accessories
- Medtronic catheter passer (appropriate for catheter diameter)
- Mesh pouch (if suture loops will not be used to secure the pump in the subcutaneous pocket)
- Clinician-supplied items:
 - Empty 20-mL syringe (for emptying the pump)
 - Syringe containing the prescribed fluid drawn up through a filter needle or straw (volume not to exceed the reservoir volume of the pump)
 - 0.22-micron filter
 - 10-mL syringe with 1-2 mL of sterile, preservative-free 0.9% normal saline (for flushing the catheter access port)

NONSTERILE ITEMS

- Medtronic N'Vision® programmer

Check Initial Pump Status

A fully-trained clinician must coordinate pump preparation for implantation. The circulating nurse may perform the interrogation of the pump before it is removed from its package.

1. Set up the N'Vision programmer according to instructions provided in the *8870 SynchroMed II Programming Guide*.
2. Using the programmer, interrogate the pump to check the current pump status (**Figure 1**). Confirm that there are no active alarm events. If the pump is still in Shelf State, audible alarms are silenced. The pump must be interrogated to determine if an alarm has been activated.

Figure 1
Pump Status



3. After checking the pump status, confirm that the pump calibration constant displayed on the programmer screen matches the pump calibration constant printed on the shelf package.



WARNING

If calibration constants differ, contact Medtronic, Inc. Using an incorrect calibration constant can result in a clinically significant or fatal drug underdose or overdose.

Prepare Drugs and Solutions

Some drugs and solutions need to be ordered in advance from the pharmacy (**Table 1**). Others are prepared in the operating room by a trained clinician using sterile technique. Correct calculation of the infusion solution concentration is of critical importance in preventing over- or underdosing. The SynchroMed II pump can be programmed to vary the dose being delivered at any given time during the day. Depending on the concentration of the drug in the reservoir, and the drug dose desired for a specific period of time, the programmer will calculate the appropriate flow rate for the pump. Therapeutic settings can be made between 48 μL per day (or 2 μL per hour) up to 24,000 μL per day (or 1 mL per hour). A minimum rate of 6 μL per day can also be programmed.

Table 1
Prepare or Order
from Pharmacy

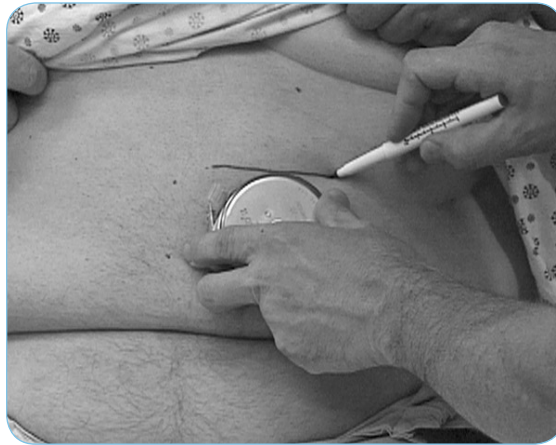
| Order from Pharmacy | | |
|--|---------------------------|--------------------------------|
| Fluid | Volume | Purpose |
| Prescribed medication in syringe(s) equal to the pump volume | Pump volume (20 or 40 mL) | Fill the pump reservoir |
| Sterile, preservative-free 0.9% normal saline in a 10 mL syringe | 1-2 mL | Flush the catheter access port |

Identify Pump Site

1. Prior to surgery, the patient should be consulted to determine the most appropriate pump pocket site. The implant site should be clearly marked with the patient in a sitting position (**Figure 2**). The following guidelines should be used in making that determination:
 - The pump should be placed where restrictive clothing, braces, orthotics, and/or the sides of a wheelchair will not irritate it.
 - The pump should not be placed:
 - On the belt line
 - In an area where the patient receives radiation or may receive radiation in the future

- Near the pelvic bone or rib cage
- Near ostomies, tubes, or other implanted devices

Figure 2
Mark the
Pump Site



Pump Implant: Intraoperative Tasks

Prep the Patient

1. The pump pocket site should have been identified and marked while the patient was in a sitting position.
2. Once the anesthesia is administered, place the patient in a right or left lateral recumbent position with the lumbar region slightly flexed. The side where the pump will be placed should be up from the table and the patient's back should be perpendicular to the floor. A baseline fluoroscopy image should be taken to confirm proper positioning.
3. Prep axilla to pubis, table-to-table and drape the area widely, leaving both the pump and the catheter insertion sites exposed. Then cover the skin with a surgical drape (**Figure 3**).

Figure 3
Position Patient



4. A paramedian oblique needle insertion technique is recommended for catheter placement. Using sterile technique, mark the needle entry location parallel to the vertebral pedicle approximately 1 to 2 cm off of the midline and 1 to 1 ½ vertebral levels below the interlaminar space through which the needle will pass.
5. Administer the appropriate anesthesia. If the procedure is not done under general anesthesia, administer a local anesthetic as necessary (e.g., preparing the subcutaneous pocket, tunneling the catheter, etc.).
6. Consider peri-operative antibiotics. The hospital's antibiotic regimen for CSF shunts can be used as a guide.

Prepare the Pump for Implant

OPEN THE SHELF PACKAGE

1. Before opening the shelf package, verify that the intrathecal catheter can be placed and the pump can be implanted. After opening the shelf package, save all the paperwork including:
 - Registration form
 - "For Your Records" label
 - Patient manual
 - Pump technical manual
 - Patient temporary ID card

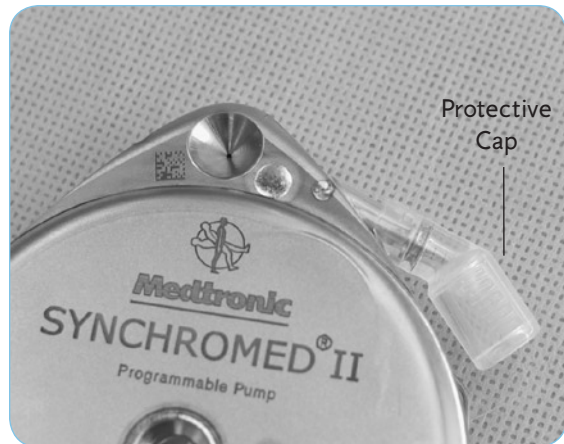
Do not remove the pump from its sterile plastic tray.

2. Attach a "For Your Records" label (enclosed in the shelf package) to the patient's record. This label displays the pump model, reservoir size, calibration constant and serial number.

EMPTY THE PUMP

1. Carefully examine the sealed pump tray. If contamination is suspected for any reason, do not use it. Using sterile technique, open the sterile plastic tray and remove the pump. (The pump should be passed to the sterile field. Do not drop the pump from the tray to the table.)
2. Remove the protective cap from the catheter port by pulling it away from the pump. Be aware that a small amount of sterile water may splash from the cap (**Figure 4**).

Figure 4
Protective Cap



3. Assemble the 22-gauge non-coring needle and the empty syringe.
4. Insert the needle into the reservoir fill port septum until the needle touches the metal needle stop. Maintain negative pressure to withdraw the sterile water from the pump into the empty syringe (**Figure 5**).

NOTE:

If the volume of fluid in the pump reservoir exceeds the volume of the syringe used for emptying, remove the filled syringe and needle, attach an empty syringe to the needle, and repeat until the reservoir is empty.

Figure 5
Empty the Pump



PRECAUTION

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 reservoir fill port septum.
- Do not exceed the maximum pump reservoir volume.

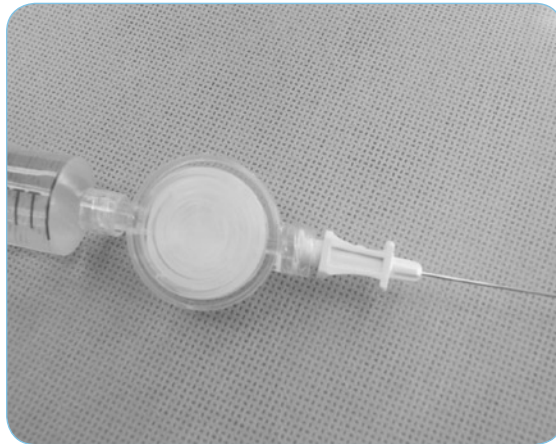
See the [Reservoir Valve Activation](#) section of the *Therapy Maintenance* module for more information.

5. Empty the reservoir completely, until air bubbles stop flowing into the syringe.
6. Maintain negative pressure on the syringe as you remove the needle from the septum.

FILL THE PUMP

1. Attach a 0.22-micron filter to the syringe containing the prescribed fluid and purge the air from the fluid pathway.
2. Attach the 22-gauge non-coring needle to the syringe containing the prescribed fluid and filter (**Figure 6**).

Figure 6
Syringe with
Filter



NOTE:

Because some sterile water remains in the drug chamber, the final concentration of the drug will vary based on the following fill methods:

- Filling the pump to capacity will bring the expected concentration to about 93%.
- Rinsing the pump with 3 mL of the drug will result in a concentration of about 98%. Rinsing the pump with 10 mL of the drug will result in a concentration of about 99%. Discard the 3 mL or 10 mL of the drug used to flush the pump, and fill the pump with the remaining drug. Use the actual fill volume (initial volume in the syringe less the 3 mL or 10 mL used for rinse) when entering information into the programmer.

3. Insert the needle into the reservoir fill port septum until it touches the metal needle stop. Slowly inject the prescribed fluid into the pump reservoir at a rate of no more than 1 mL per 3 seconds (**Figure 7**).

Figure 7
Fill the Pump



NOTE:

Unusual resistance or the inability to inject the entire fill volume into the pump reservoir may indicate activation of the pump reservoir valve.

4. If you have activated the reservoir valve before completely filling the pump, discontinue injection, remove the needle from the reservoir fill port septum, and return to step #4 of the previous section, [Empty the Pump](#).
5. When filling is complete, remove the needle from the reservoir fill port septum.

FLUSH THE CATHETER ACCESS PORT

1. Flush the catheter access port using the 24-gauge non-coring needle and a 10-mL syringe filled with 1-2 mL sterile, preservative-free 0.9% normal saline. Gently insert the needle into the catheter access port septum until the needle touches the metal needle stop. Inject fluid into the catheter access port septum until fluid is observed at the catheter port (**Figure 8**). Remove the needle from the catheter access port.

Figure 8
Flush the
Catheter Access
Port



INSERT PUMP IN MESH POUCH (OPTIONAL)

1. If a mesh pouch (separate accessory) will be used to secure the pump in the subcutaneous pocket, place the pump in the pouch and tie the pouch strings. Use caution not to damage gloves on the catheter port. Trim the excess pouch strings after placing the knot. The pump is now ready for implantation (**Figure 9**).

Figure 9
Pump in Mesh
Pouch



Implant the Intrathecal Catheter and Pump

This section describes the surgical technique for the SynchroMed II pump and the Models 8709SC and 8731SC intrathecal catheters with sutureless connectors. If a different catheter will be used, consult the technical manual in the catheter package for instructions.

PLACE THE SPINAL CATHETER SEGMENT

NOTE:

A small plastic bag of catheter accessories is included in the catheter packaging. Be careful not to accidentally discard these accessories.

1. Carefully examine the sealed catheter tray. If contamination is suspected for any reason, do not use it. Remove the catheter from its sterile tray to the sterile field.

If using the Model 8731SC Intrathecal Catheter: select the introducer needle of the desired length for the patient's needs.

2. Orient the bevel of the 15-gauge Tuohy spinal needle cephalad or parallel to the dural fibers and insert the needle under fluoroscopy. A shallow, oblique paramedian insertion technique is recommended when inserting the needle. The skin entry point will be parallel to the vertebral pedicle, approximately 1 to 2 cm off of midline and 1 to 1½ vertebral levels below the targeted interlaminar space. For example, using the pedicle of L4 as an entry point, aim the needle towards the midline at the L2-3 interlaminar space (**Figures 10 and 11**).

NOTE:

In retrospective analyses, Medtronic has observed low complication rates associated with the paramedian oblique technique.

Figure 10
Shallow Angle
Paramedian
Oblique
Insertion Side
View

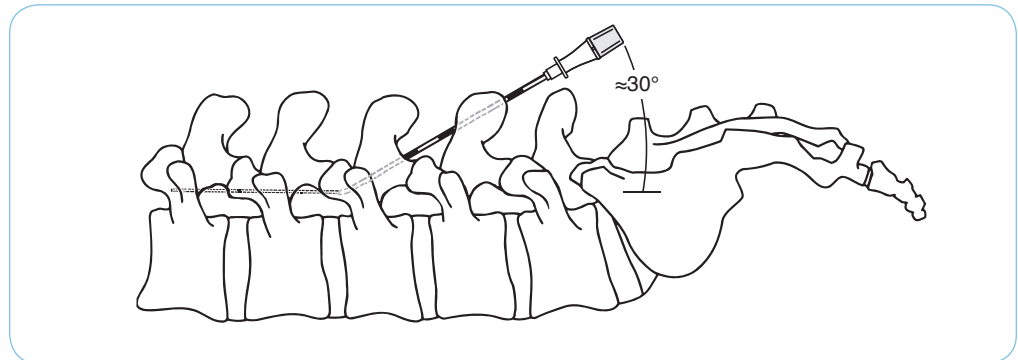
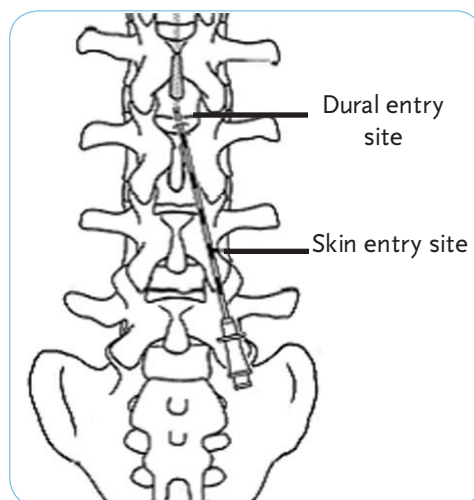
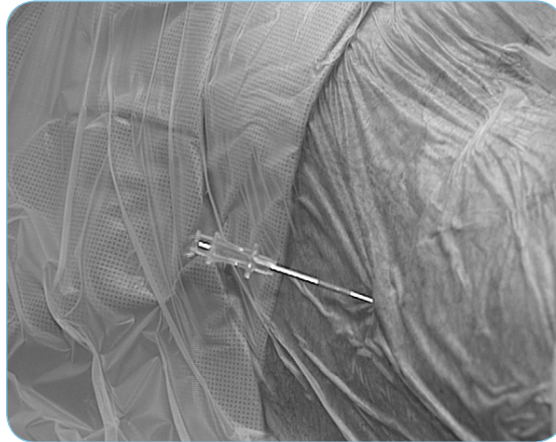


Figure 11
Shallow Angle
Paramedian
Oblique
Insertion Top
View



3. Advance the needle until the dura is penetrated.
4. Remove the needle stylet and confirm needle location by observing cerebrospinal fluid (CSF) backflow. (**Figure 12**).

Figure 12
CSF Backflow



5. Replace the needle stylet to stop CSF flow. Make certain the stylet handle key is properly seated in the slot in the needle hub.
6. Confirm the catheter guidewire is properly seated completely with the hub against the end of the catheter. The guide wire should remain in place during all maneuvers to insert or position the catheter.
7. Verify that the needle has a cephalad orientation by making sure that the stylet handle faces up. Remove the stylet.
8. Advance the catheter as follows:

If using the Model 8709SC Indura 1P Intrathecal Catheter:

Thread the catheter tip through the needle and advance the catheter to the desired location.

NOTE:

When the catheter tip reaches the curved point of the needle, a slight increase in advancement pressure will be noted and the first centimeter marking from the catheter tip will be located at the needle hub.

If using the Model 8731SC Intrathecal Catheter:

Thread the spinal segment tip through the needle and advance the catheter to the desired location.

NOTE:

When the tip of the catheter reaches the curved point of the needle, a slight increase in advancement pressure will be noted.

- If using the 11.4 cm needle: the first centimeter marking from the catheter tip will be located at the needle hub.
- If using the 9.3 cm needle: the first centimeter marking from the catheter tip will be approximately 2.3 cm from the needle hub.

CAUTION

If the catheter must be retracted during positioning, do not withdraw the catheter through the introducer needle. The needle tip can damage the catheter, requiring additional surgery to repair or replace the catheter. Withdraw the introducer needle and catheter together. Then, carefully retract the catheter from the introducer needle. Begin the procedure again.

9. Verify catheter position using fluoroscopy.

10. Prepare the anchor site as follows (**Figure 13**):

If using the Model 8709SC Indura 1P Intrathecal Catheter:

Make an incision at the needle site to expose an area of the fascia that is large enough to place an anchor.

If using the Model 8731SC Intrathecal Catheter:

Make an incision at the needle insertion site to expose an area of the fascia that is large enough to place the v-wing anchor and the catheter connection.

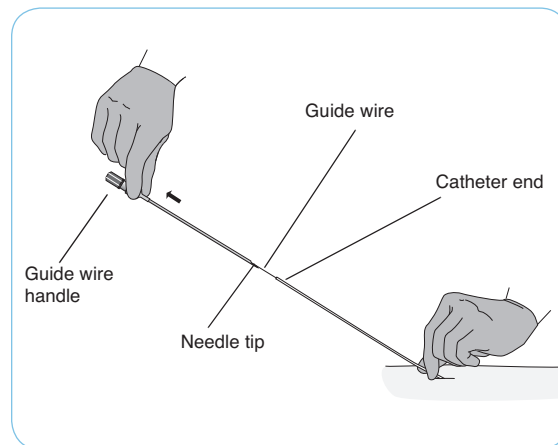
Figure 13
Cut Down to the
Lumbo-dorsal
Fascia

**NOTE:**

- This incision can be made prior to catheter placement and should be long enough to avoid introducing kinks or sharp bends when anchoring the catheter.
- Take special care to avoid cutting or puncturing the catheter during the procedure.
- To protect the catheter, keep the needle in place while the incision is made.
- Undermine the edges of incision to develop a smooth fascial plane for the catheter anchor.

11. Carefully remove the needle from the fascia and grasp the catheter near the fascial exit site to prevent catheter dislodgement.
12. Carefully slide the needle to the end of the catheter to prevent catheter damage from the needle tip during guide wire removal.
13. Hold the catheter securely at the spinal exit site and remove the needle and guide wire from the catheter simultaneously (**Figure 14**).

Figure 14
Guide Wire
Removal



CAUTIONS

- To aid in guide wire removal and avoid catheter damage, **hold the catheter straight** during needle and guide wire removal.
- During needle and guide wire removal, **do not squeeze the catheter**: excessive compression will increase the difficulty of guide wire removal.
- To avoid catheter damage, remove the guide wire slowly.
- If the catheter becomes twisted or if the guide wire seizes up, **stop**. Let the catheter relax and return to its original shape. Then slowly start again. Be sure to grasp the catheter near the exit site.
- If the catheter must be repositioned after the guide wire has been removed, remove the catheter from the patient's body, lay the catheter straight, and then carefully reinsert the guide wire into the catheter, avoiding excessive force. Attempting to reinsert the guide wire while the catheter is in the patient's body can cause injury to the patient or damage the catheter, requiring additional surgery to repair or replace the catheter.

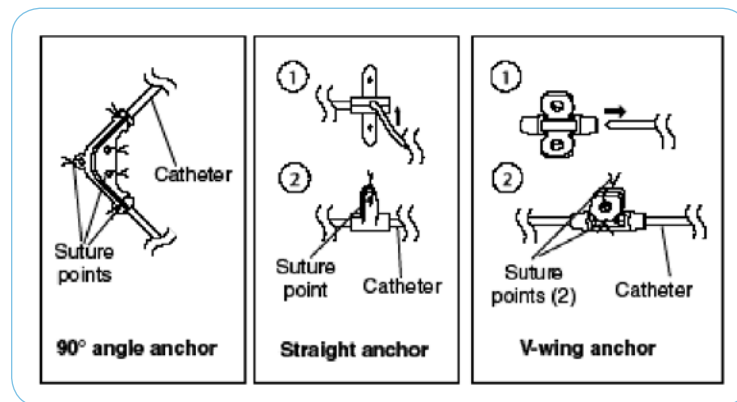
14. Confirm CSF backflow
15. Tie a purse string suture to close the ligament around the catheter to prevent CSF leakage.

16. Attach the anchor to the catheter as follows:

If using the Model 8709SC Indura 1P Intrathecal Catheter:

- Place 1 of the following anchors on the catheter as close as possible to the fascia entry point using the technique described (**Figure 15**):
- 90 degree angle anchor – Place the catheter in the groove of the anchor
- Straight anchor – Place the catheter in the slit of the anchor. If the slit is not visible, pull on the suture tabs of the anchor until the slit opens. A significant amount of force may be required to open the slit.
- V-wing anchor – Attach the v-wing anchor to the catheter by threading onto the end of the catheter (Figure 16).

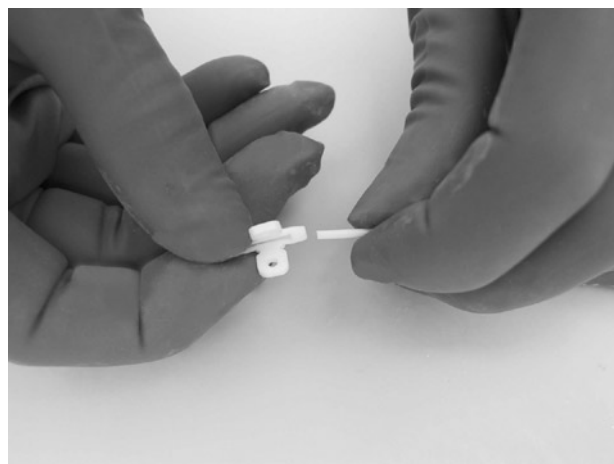
Figure 15
Attach the
Anchor



If using the Model 8731SC Intrathecal Catheter:

- Attach the v-wing anchor to the catheter by threading the anchor onto the end of the catheter (**Figure 16**).
- Place the v-wing anchor as close as possible to the fascia entry point.

Figure 16
Attach the V-wing
Anchor

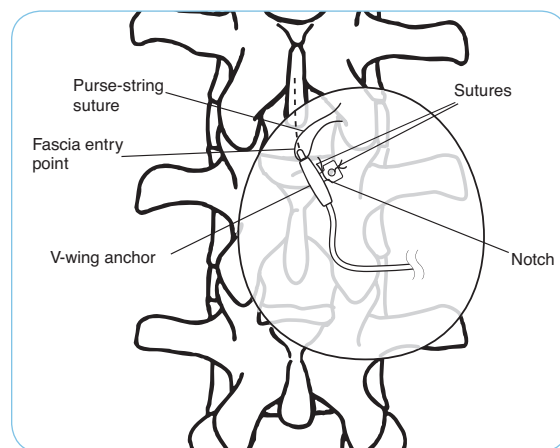


CAUTIONS

- Always use an anchor to secure the catheter to the surrounding tissue to prevent catheter dislodgement or kinking.
- Do not tie sutures directly onto the catheter, which may damage or occlude the catheter.
- Do not overtighten sutures on the anchor, which may damage the component.
- Do not use metallic sutures for ligation, which may damage the component.

17. Using rubber-tipped forceps, clamp the catheter to prevent CSF loss during tunneling and pocket formation.
18. Secure the anchor to the surrounding fascia using heavy nonabsorbable sutures as follows:
 - If using the Model 8709SC Indura 1P Intrathecal Catheter, use the associated technique as described:
 - 90 degree angle anchor – Suture through the suture holes and over the notched ends (**Figure 15**).
 - Straight anchor – Suture the 2 tabs through the suture holes so the tabs are flat against each other (**Figure 15**).
 - V-wing anchor
 - a. Suture the anchor wings together at the notch with the wings flat against each other to properly engage and grasp the catheter (**Figure 15**).
 - b. Suture the anchor wings together through the suture holes and attach to the surrounding fascia (**Figure 17**).

Figure 17
Placing the
V-Wing Anchor



- **If using the Model 8731SC Intrathecal Catheter:**
 - a. Suture the anchor wings together at the notch with the wings flat against each other to properly engage and grasp the catheter (**Figure 17**).
 - b. Suture the anchor wings together through the suture holes and attach to the surrounding fascia (**Figure 17**).
- 19. Unclamp the spinal segment of the catheter and confirm CSF backflow.
- 20. Re-clamp the spinal segment of the catheter.

PREPARE THE PUMP POCKET

Prepare the subcutaneous pocket at the pump site that was identified and marked before surgery. The pocket should be large enough so that the incision does not lie over the pump and should be no more than 2.5 cm beneath the skin. The pocket should be positioned away from:

- The superior iliac crest and rib cage
- The belt line to minimize discomfort
- The site of current or future surgeries or radiation treatments

Because fibrous bands in the pocket can be vascular, meticulously use electrocautery to avoid hematoma or seroma formation after surgery.

When finished, the pocket should be no more than 2.5 centimeters beneath the skin and large enough to easily accommodate the pump, allowing a gradual curve of the catheter.

TUNNEL THE CATHETER

1. Carefully examine the sealed catheter passer package. If contamination is suspected for any reason, do not use it. Remove the catheter passer from its sterile tray to the sterile field.
2. Remove the plastic sheath from the catheter passer.
3. Bend the catheter passer to conform to the patient's contour as needed.
4. Tunnel the catheter as follows:

If using the Model 8709SC Indura 1P Intrathecal Catheter:

- Tunnel subcutaneously from the spinal incision site toward the pump implant site using the appropriate catheter passer.
- Pass the catheter from the spinal incision site to the pump implant site. Pass enough catheter to the pump implant site to allow for 1 or 2 complete catheter coils behind the pump.

NOTE:

If using a catheter passer with a non-removable handle, tunnel from the pump implant site toward the spinal incision site.

If using the Model 8731SC Intrathecal Catheter:

- Tunnel subcutaneously from the spinal incision site toward the pump implant site using the appropriate catheter passer.
 - Pass the pump segment from the pump implant site to the spinal incision site. Leave enough catheter near the pump implant to allow for 1 or 2 complete catheter coils behind the pump.
5. If using the Model 8583/8586 Catheter Passers, unlock the obturator tab from the catheter passer.

CAUTION

Deep tunneling is not desirable.



WARNING

When placing the catheter, avoid making sharp bends or kinks, which may occlude the catheter. Occlusions can result in a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, and may require surgical revision or replacement.

6. At this point, the obturator can be used to carry the catheter through the catheter passer, or it can be removed if the catheter will be suctioned or manually pushed through the catheter passer. The procedure varies, depending on which method is preferred.

| With Obturator | Without Obturator |
|---|--|
| <ol style="list-style-type: none"> 7. Connect the pump segment to the obturator. <ol style="list-style-type: none"> a. Grasp the obturator tip and pull out the obturator approximately 5-7.5 cm from the catheter passer. b. Remove the pointed obturator tip (Figure 18) and discard. c. Insert the end of the catheter with the strain-relief sleeve into the obturator cradle (Figure 19). 8. Push the obturator back into the catheter passer and lock the obturator tab into its original position in the handle. 9. Slowly pull the catheter passer back through the subcutaneous tunnel, making sure the obturator stays within the catheter passer. 10. Once the catheter passer has reached the spinal incision, unlock the obturator tab from the handle of the catheter passer. 11. Grasp the obturator/catheter combination and pull it out of the catheter passer. 12. Remove the catheter from the obturator cradle. | <ol style="list-style-type: none"> 7. Remove the obturator from the passer tube. 8. Insert the catheter connector/anchor into the catheter passer at the pump pocket. 9. Thread the proximal catheter through the catheter passer until it emerges from the handle. Use suction and saline if necessary. 10. Slowly remove the catheter passer, using care to leave the catheter in the subcutaneous tunnel. |

Figure 18
Remove
Obturator Tip

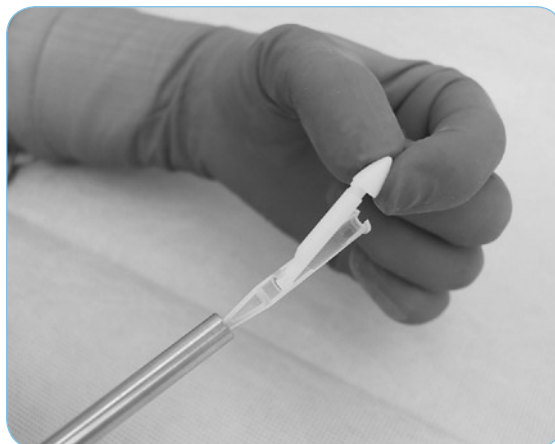
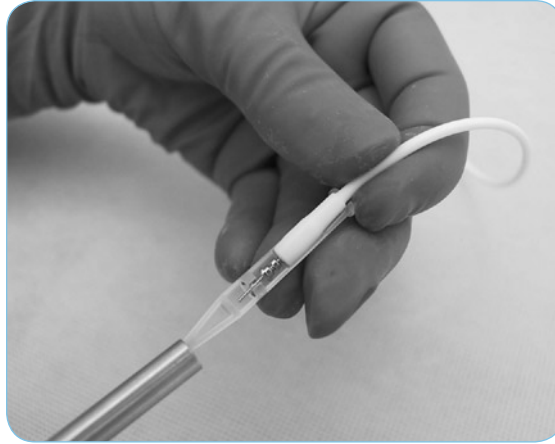


Figure 19
Insert in
Obturator
Cradle



CATHETER CONNECTIONS



WARNING Firmly secure all connections. Failure to secure connections can allow drug or CSF leakage into surrounding tissue resulting in tissue damage or 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 overdose or underdose.

1. Trim the catheter as follows:

If using the Model 8709SC Indura 1P Intrathecal Catheter:

- Trim the pump end of the placed catheter as necessary. Leave enough catheter near the pump pocket to allow for 1 or 2 complete catheter coils behind the pump. Note that the catheter interface will add 7.6 cm of catheter to the catheter length.

If using the Model 8731SC Intrathecal Catheter:

- At the spinal incision site, trim the spinal segment of the catheter as necessary. Leave approximately 5 cm outside the fascia entry point to allow for patient movement and to prevent kinking.

NOTE:

Both the pump and spinal segments of the 8731SC Catheter are trimmable

CAUTION

When trimming, allow enough slack in the catheter to accommodate patient movement. Trimming the catheter too short or pulling the catheter taut may result in catheter damage or dislodgement, requiring additional surgery to repair or replace the catheter.

2. Save the trimmed catheter tubing for information entry into the programmer later in the procedure.
3. Slide the transparent, strain-relief sleeve, small end first, over the previously placed spinal segment (**Figure 20**).

Figure 20
Slide
Transparent
Spinal Segment
Strain-Relief
Sleeve over
Spinal Segment

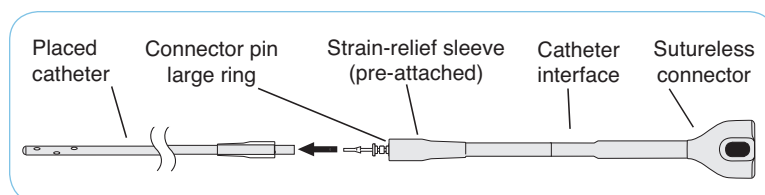


4. Connect the spinal catheter tubing to the pump segment tubing.
5. Insert the connector pin using 1 of the following methods:

If using the 8709SC Indura 1P Intrathecal Catheter:

- On the catheter interface, grasp the pre-attached strain-relief sleeve near the connector pin and insert the connector pin into the placed catheter until the catheter is against the connector pin large ring. Be careful not to disrupt the catheter placement in the spine (**Figure 21**).

Figure 21
Inserting the
Connector Pin
(Model 8709SC)



If using the 8731SC Intrathecal Catheter:

- On the pump segment, grasp the strain-relief sleeve near the connector pin and insert the connector pin into the spinal segment until the spinal segment is against the closest large ring. Be careful not to disrupt the catheter placement in the spine (**Figure 22**).

Figure 22
Inserting the
Connector Pin
(Model 8731SC)



6. Unclamp the spinal segment of the catheter.
7. Confirm catheter patency by verifying CSF flow through the sutureless pump connector.
8. Using rubber-tipped forceps, re-clamp the pump segment of the catheter to prevent CSF loss.

NOTE:

If the catheter must be removed from the connector pin, grasp the catheter next to the connector pin midsection. Then grasp the center hub of the connector pin with a forceps and pull or twist the connector pin off the implanted catheter. **DO NOT pull on the catheter.** Trim the spinal segment of the catheter before reconnecting. Save the trimmed catheter for catheter length measurements and volume calculations.

9. Slide the strain-relief sleeve towards the connector pin using 1 of following methods:

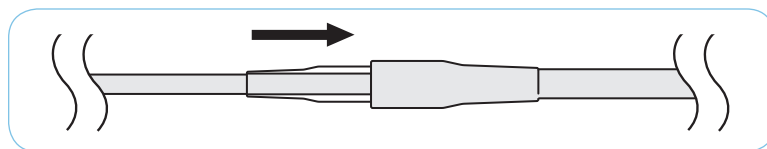
If using the 8709SC Indura 1P Intrathecal Catheter:

- Slide the transparent strain-relief sleeve of the placed catheter towards the connector pin until the sleeve snaps into place (**Figure 23**).

NOTE:

Do not place sutures over the connector pin or strain-relief sleeve.

Figure 23
Sliding the Spinal Segment Strain-Relief Sleeve toward the Connector Pin (Model 8709SC)



If using the 8731SC Intrathecal Catheter:

- Slide the transparent strain-relief sleeve of the spinal segment towards the connector pin until the sleeve of the spinal segment snaps into place (**Figure 24**).
- Place a heavy nonabsorbable suture in each of the 2 grooves in the center of the connector pin and attach to the fascia (**Figure 25**).

NOTE:

Do not cover the center section of the connector pin and do not place sutures over the strain-relief sleeves.

Figure 24
Sliding the Spinal Segment Strain-Relief Sleeve toward the Connector Pin (Model 8731SC)

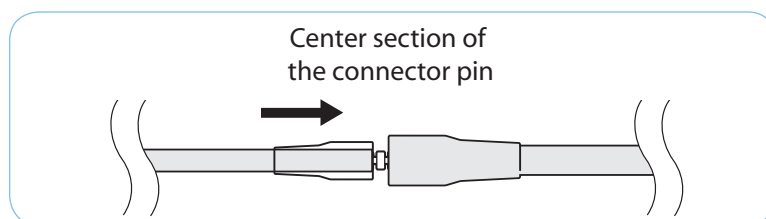
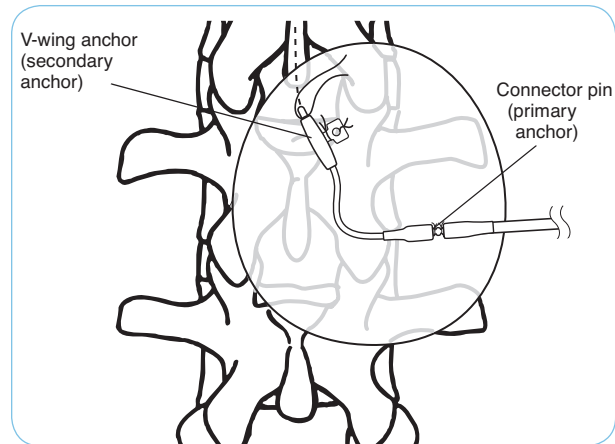


Figure 25
Anchoring the
Model 8731SC
Catheter



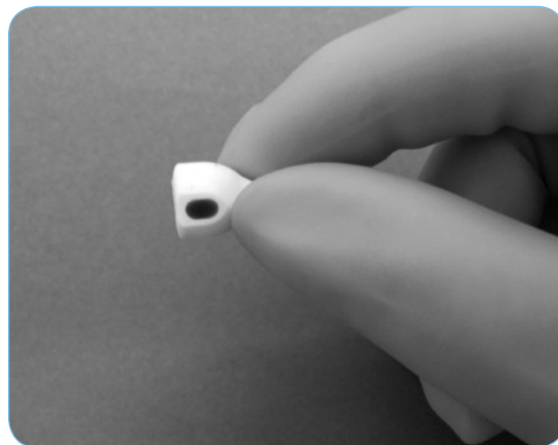
NOTE:

Ensure that the catheter and connector pin (primary anchor) connection are placed in an area that will minimize catheter tension or angulation. At this point in the procedure, make sure the pump has been properly prepared and is ready for implantation.

CONNECTING THE SUTURELESS PUMP CONNECTOR TO THE PUMP

1. With a thumb and forefinger, grasp the tapered portion of the pump connector (**Figure 26**).

Figure 26
Grasp the
Tapered Portion
of the Sutureless
Pump Connector



2. At the pump pocket site, position the catheter port of the pump in line with the opening of the sutureless pump connector.

3. Attach the pump connector using 1 of the following methods (**Figure 27**):
 - Method 1:
Firmly press the sutureless pump connector onto the catheter port until the connector fully covers the catheter port. The connector snaps into place.
 - Method 2:
 - a. Firmly squeeze precisely on the oval marks of the sutureless pump connector.
 - b. While squeezing, carefully press the pump connector onto the catheter port until the connector fully covers the catheter port.

Figure 27
Attaching the
Sutureless Pump
Connector to the
Catheter Port



4. Release the thumb and forefinger.
5. Confirm that the sutureless connector is properly attached by using the following method:
 - a. Grasp the tapered portion of the connector (**Figure 28**).
 - b. Tug as if to remove the connector from the pump. The connector should feel firmly attached.

Figure 28
Checking
for Proper
Attachment



CAUTIONS:

- Exercise care when connecting the catheter or sutureless pump connector to metal connectors or fittings. They can cut or puncture the catheter or pump connector, requiring additional surgery to repair or replace the damaged component.
- When connecting the sutureless pump connector to the pump, do not introduce air bubbles into the catheter, which can lead to spinal headache.

**WARNING**

Firmly secure all connections. Failure to secure connections can allow drug or cerebrospinal fluid (CSF) leakage into surrounding tissue resulting in tissue damage or 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.

NOTES:

- If the sutureless pump connector does not feel firmly attached:
 - a. Place a thumb and forefinger precisely on the oval marks located on the 2 flat portions of the connector (**Figure 28**).
 - b. Firmly squeeze the connector to apply pressure precisely on the oval marks.
 - c. While squeezing on the ovals, pull the connector off the catheter port.
 - d. Repeat steps 1-5 of “Connecting the catheter to the pump”.
- If the sutureless pump connector is difficult to remove, try one or both of the following methods:
 - While squeezing on the ovals, gently rock the connector from side-to-side and slowly pull the connector off the catheter port.
 - If the finger pressure is inadequate, use a hemostat with rubber-tipped forceps to carefully apply pressure precisely on the oval marks. While squeezing, pull the connector off the catheter port. Be careful not to damage the connector.
 - Do not use additional methods to secure the sutureless pump connector.

6. Unclamp the catheter.

7. Coil the excess catheter behind the pump and place the pump in the pocket.

CAUTIONS:

Do not coil excess catheter in front of the pump. Coil excess catheter behind the pump to:

- a. Minimize potential damage during pump replacement surgery.
- b. Minimize potential kinking of the catheter.
- c. Prevent damage to the catheter during refill and catheter access procedures.

PLACE AND SUTURE PUMP IN POCKET

Before securing the pump into the subcutaneous pocket, coil the excess catheter behind the pump. The filled pump should be placed into the subcutaneous pocket so that:

- The pump is no more than 2.5 cm from the surface of the skin.
- The center reservoir fill port is anteriorly oriented and the center reservoir fill port and catheter access port will be easy to access after implantation.

- The catheter is not kinked, is looped at least once under the pump, and is secured well away from pump ports.
 - No skin sutures will be directly overlying the reservoir fill port or the catheter access port.
- 1a. **If using the pump suture loops:** Set 2 non-absorbable sutures in the fascia toward the bottom of the pump pocket. The location of the sutures should roughly correspond to the location of the suture loops on the pump's perimeter. Pull 1 suture through each of the pump's bottom suture loops. Draw the pump into the pocket and tie the sutures. Coil the excess catheter under the pump. Then, place 2 additional sutures in the fascia toward the top of the pump pocket. Pull each of these sutures through 1 of the suture loops toward the top of the pump. Tie the sutures, securing the pump into the pocket. Avoid entangling the pump segment in the pump tie-down sutures.
 - 1b. **If using a mesh pouch:** 2 to 4 sutures should be placed to secure the mesh pouch to the fascia. Coil the excess catheter under the pump before tying knots in the sutures. Avoid entangling the pump segment in the pump tie-down sutures.

CLOSE INCISIONS

1. Irrigate the pump pocket and spinal incision site thoroughly.
 2. Close the incisions using subcutaneous and skin sutures and apply dressing.
1. Measure the trimmed length of catheter tubing and document it in the patient's record.
 2. A "For Your Records" label with the pump model, reservoir size, calibration constant, and serial number should be attached to the patient's record while preparing the pump for implant. Be sure the following information is also recorded in the patient's file:
 - Date of implant
 - Catheter model number
 - Catheter sterile lot number
 - Implanted catheter length
 - Drug name, concentration, and volume
 - Daily drug dose

Record Patient Information

3. Complete the information on the patient identification card from the pump shelf package as required by local regulations. Please be aware that procedures outside the United States may vary.
4. Label the Patient Manual with the patient's name and identification number.
5. Place the Patient Manual and identification card with the patient's chart to accompany the patient into the recovery room.

Pump Implant: Postoperative Tasks

Program the Pump

1. After incisions have been closed and dressed, interrogate the pump with the N'Vision programmer. Use information from the patient's record to enter the following information into the programmer:
 - Patient information
 - Catheter model number
 - Catheter length (implanted length)
 - Drug name and concentration
 - Reservoir volume (volume of drug placed in the pump at implant)

NOTE:

The catheter length recorded at implant or catheter revision will be used by the programmer to calculate catheter volume. The catheter length is essential for accurate dosing calculations.



WARNING

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.

2. Select the Infusion Mode and enter dosing information. After implantation of a new system, the infusion prescription usually includes a postoperative priming bolus that is used to advance the prescribed fluid from the reservoir to the catheter tip. For more information on programming, refer to the *8870 SynchroMed II Programming Guide*.

ATTENTION

To avoid potential overdose for a pump replacement, refer to the procedure for [Pump Replacement](#) in this module before programming a priming bolus.

3. Set the Low Reservoir Alarm (to at least 1 mL). The programmer will automatically calculate the Low Reservoir Alarm Date, which should be used to [schedule the first refill appointment](#).
4. Update the pump with the new parameters.
5. Print out the patient's prescription and save it for the patient's record. (Make a copy of the printout if it is not printed on standard paper because the image on thermal paper fades over time.)

NOTE:

Patients can wear an abdominal binder or a tight foundation garment over the implant site to provide mild compression and reduce the chance of hematoma or seroma.

Complete Pump and Catheter Registration

The pump and catheter registration process varies in different world areas. The process for the United States is given below. For other world areas, please consult your Medtronic representative.

IN THE U.S.

1. Inside the shipping container with each pump and catheter is an implant registration forms that must be used to create a permanent record of the patient's implant. Complete the forms and promptly return the originals to Medtronic, Inc. Two copies are provided for the patient's records.
2. Medtronic will transfer vital information to a wallet-size, plastic-coated Implanted Device Identification Card and will mail it directly to the patient.

Manage and Prevent Postoperative Complications

Following surgery, the patient should be closely monitored for complications. This section contains information on managing selected procedure-related complications. For a complete list of complications and disclosures, refer to the *SynchroMed II Pump Technical Manual*.

PROCEDURE-RELATED COMPLICATIONS

The procedure-related adverse events associated with the use of this system may include, but are not limited to, the events that follow:

- Inaccessible reservoir fill port due to pump being implanted upside down (inverted) or too deep
- Pocket seroma, hematoma, erosion or infection
- Post-lumbar puncture (spinal) headache
- Cerebrospinal fluid (CSF) leak leading to CSF subcutaneous collection or rare central nervous system (CNS) pressure-related problems
- Radiculitis
- Arachnoiditis
- Bleeding
- Spinal cord damage
- Meningitis
- Medical complications
- Anesthesia complications
- Damage to the pump, catheter, and catheter access system due to improper handling and filling before, during, or after implantation
- Infection
- Reservoir contamination

CATHETER-RELATED COMPLICATIONS

- Change in catheter performance due to catheter kinking, catheter disconnection, catheter leakage, catheter breakage, complete or partial catheter occlusion, catheter dislodgement or migration, or catheter fibrosis or hygroma.
- Detached catheter tip or catheter fragment(s) in the intrathecal space

COMPROMISED ANTIBIOTIC EFFECTIVENESS

Residual catheter fragments in the CSF may compromise antibiotic effectiveness in the presence of a concomitant CSF infection.

Table 2 contains information on managing selected postoperative complications.

Table 2
Management of
Postoperative
Complications

| | |
|--|---|
| <p>Seromas</p> | <ul style="list-style-type: none"> ■ Seromas may be evident by the first postoperative day. ■ Signs and symptoms of seromas include swelling over the pump site and/or feeling of tightness over the pump site. ■ Pocket seromas often resolve without treatment, but may persist for days or, in some cases, weeks. Aspiration may be necessary if the seroma is painful or the wound is at risk for dehiscence. Always evaluate the risk of infection. After aspiration, a compression dressing or abdominal binder may decrease the risk of re-accumulation. |
| <p>Spinal Epidural Hematoma</p> | <ul style="list-style-type: none"> ■ For patients with low platelet counts—at high risk for post surgical bleeding—follow standard medical practice for patients on anticoagulant therapy. ■ Epidural hematomas are rare, but could produce severe complications. ■ Watch for signs of epidural hematoma: severe back pain, sudden onset of leg weakness and spasm, loss of reflexes in the distal extremities, and loss of bladder/bowel control. An epidural hematoma is an emergency and must be given immediate attention. |
| <p>Spinal Headaches</p> | <ul style="list-style-type: none"> ■ Watch for subcutaneous cerebrospinal fluid leakage at the incision site, along the catheter, and in the pump pocket site. ■ Surgical re-suturing or revision may be necessary. ■ Spinal headaches may be caused by cerebrospinal fluid leakage around the catheter, or loss of cerebrospinal fluid during the implant procedure. <ul style="list-style-type: none"> ■ A preventive measure includes instructing the patient to lie flat overnight immediately following surgery. This greatly reduces the risk of spinal headache. If a headache still occurs, the patient should continue to lie flat for 1 to 2 days. ■ Consider oral analgesics to reduce the pain. Caffeine in some over-the-counter pain medications may relieve the headache. ■ Check for cerebrospinal fluid leakage if pain persists beyond a few days. ■ If the spinal headache persists, consider performing a blood patch. <ul style="list-style-type: none"> ■ A blood patch involves the injection of 10 to 15 mL of the patient's own venous blood into the epidural space to seal the epidural puncture. ■ The blood patch should be performed under fluoroscopy. ■ CSF leak or drainage from the spinal incision is an emergency and must be given immediate attention. |
| <p>Bleeding</p> | <ul style="list-style-type: none"> ■ For patients at higher risk for post surgical bleeding with low platelet counts, follow standard medical practice for preoperative/ postoperative management of patients on anticoagulant therapy. |

| | |
|-------------------------------------|--|
| Infections | <ul style="list-style-type: none"> ■ Watch for signs and symptoms of infection: redness, pain, and swelling. ■ Any leak from the wound should be closed immediately to avoid contamination of the implanted system. ■ Infections should be treated aggressively with systemic antibiotics. Delay in treatment can lead to meningitis and/or pump explant. ■ Consider IV antibiotics. These antibiotics should differ from the peri-operative antibiotics to ensure that all gram-positive organisms are treated. ■ Purulent drainage from the wound or erythema (redness) of the pump pocket or catheter insertion site should be considered an emergency. The patient should be placed on intravenous antibiotics. ■ If infection persists, the pump and catheter should be removed and the CSF should be evaluated for meningitis. Aggressive treatment of withdrawal should begin prior to pump removal and continue in the postoperative period. |
| Incision Pain and Discomfort | <ul style="list-style-type: none"> ■ Pain and discomfort around the incision sites and the area in which the catheter is tunneled are common complaints following surgery. ■ Observe for bleeding or wetness on incision dressings over the pump and catheter insertion site. ■ Change sterile dressings on both incision sites per hospital policy. ■ The duration and intensity of pain varies by individual. Provide additional analgesia as needed. |
| Spinal Hygromas | <ul style="list-style-type: none"> ■ Spinal hygromas present the following characteristics: <ul style="list-style-type: none"> ■ Swelling typically found under the skin in the lumbar region of the back ■ Result from leakage after the intraspinal catheter implantation ■ Are typically small and self-limiting (tend to disappear on their own without treatment) ■ Consider using an abdominal binder with pressure dressing at the spinal site immediately post-op. ■ Hygromas may be aspirated; evaluate risk of infection before aspirating. |

SYSTEM-RELATED COMPLICATIONS

- Cessation of therapy due to end of device service life or component failure
- Change in flow performance characteristics due to component failure
- Inability to program the device due to clinician programmer failure or loss of telemetry
- Catheter access port failure due to component failure

Refer to the [Troubleshooting System Complications](#) section of the *Therapy Maintenance* module for more information about system-related complications.

DRUG-RELATED COMPLICATIONS

- Local and systemic drug toxicity and related side effects
- Complications due to use of drugs not approved or formulated for intraspinal delivery. Formulations should be sterile and preservative-free.
- Complications due to using drugs not in accordance with drug labeling
- Inflammatory mass formation at the tip of the implanted catheter in patients who receive intraspinal morphine or other opioid drugs

For more information on adverse effects related to intrathecal morphine, refer to the [Potential Adverse Effects](#) section of the *Intrathecal Morphine for Pain Management* module. For more information on adverse effects related to Lioresal® Intrathecal (baclofen injection), refer to the [Potential Adverse Effects](#) section of the *ITB TherapySM for the Management of Severe Spasticity* module.

OTHER COMPLICATIONS

Other complications include:

- Local and systemic drug toxicity and related side effects
- Body rejection phenomena
- Surgical replacement of the pump or catheter due to complications
- Pump inversion (“flipping”)



WARNING

Patients must consult their physician before engaging in activities involving pressure or temperature changes (e.g., scuba diving, saunas, hot tubs, hyperbaric chambers, airline flights, skydiving, non-pressurized aircraft, etc.). Pressure and temperature changes can cause temporary underinfusion or overinfusion and result in a clinically significant or fatal drug underdose or overdose. Refer to the [Flow Rate Accuracy](#) section of the *System Components* module of this guide for more information regarding the effects of temperature and pressure on the SynchroMed II pump.

Conduct Patient and Caregiver Education

The Patient Manual and identification card from the pump shelf package should be discussed and given to the patient to bring home. Patient education is of critical importance to ensure safe and effective intrathecal drug delivery. Properly educating and informing the patient and caregiver will increase the likelihood that complications are recognized should they occur. In addition, an informed patient with realistic expectations is more likely to be satisfied with his or her therapy and in turn, consistently comply with the necessities of treatment. See the [Postoperative Patient Education Checklist](#) in the Appendix of this module.

Schedule the First Refill Appointment

The SynchroMed II pump should always contain at least 1 mL of fluid at the time of refill. The flow rate of the pump decreases rapidly and then stops as the volume in the reservoir decreases from 1 mL to 0 mL. This may result in loss of therapeutic effect or drug withdrawal symptoms.

Determine the refill date based on the Low Reservoir Alarm Date on the programmer. To get the first refill date, set the Low Reservoir Alarm (to at least 1 mL). The programmer then calculates the Low Reservoir Alarm Date based on the reservoir volume entered into the programmer.

If the refill interval exceeds the number of days for drug stability, schedule the refill based on the drug stability. (For drug stability information refer to the [Stability/Compatibility in Pump](#) section of the *ITB TherapySM for the Management of Severe Spasticity* module and the [Drug Stability](#) section of the *Intrathecal Morphine for Pain Management* modules of this guide).

Pump Replacement

Alarms

The SynchroMed II pump has an audible alarm system to alert the patient to a variety of conditions. The following 2 alarms indicate the need for pump replacement:

- **Elective Replacement Indicator (ERI):** This alarm indicates that the pump will stop in approximately 90 days and a pump replacement should be scheduled before that time. The default setting for this single-tone alarm is to sound every hour; however, it can be silenced after its initial sounding.
- **End of Service (EOS):** This 2-tone alarm indicates the pump has stopped because it has reached the end of its service life. Prevent loss of therapeutic effect and/or withdrawal by immediately scheduling a pump replacement. The default setting for this alarm is to sound every hour; however it can be silenced after its initial sounding.

Prior to Pump Replacement

1. Determine the daily dose, assemble equipment and supplies, and prepare drugs and solutions as described in the [Pump Implant: Preoperative Tasks](#) section of this module.
2. Prior to implant, verify the currently implanted catheter length and volume.
3. Interrogate (and print) existing pump status prior to patient preparation in the operating room. Compare the model number and reservoir volume of the currently implanted pump with the new pump.
4. Check the initial status of the new pump, empty and fill the new pump, and flush the catheter access port according to the procedures in the [Prepare the Pump for Implant](#) section of this module.

NOTE:

Because some sterile water remains in the drug chamber, the final concentration of the drug will vary based on the following fill methods:

- Filling a 20-mL pump to capacity will bring the expected concentration to about 93%.
- Rinsing the pump with 3 mL of the drug will result in a concentration of about 98%. Rinsing the pump with 10 mL of the drug will result in a concentration of about 99%. Discard the 3 mL or 10 mL of the drug used to flush the pump, and fill the pump with the remaining drug. Use the actual fill volume (initial volume in the syringe less the 3 mL or 10 mL used for rinse) when entering information into the programmer.


Procedure for Pump Replacement

1. If the presently implanted pump has a mesh pouch, generally the pouch may be reused. Make a small incision into the fibrosed pouch to remove the old pump and suture the pouch closed after the new pump is placed inside.
2. Remove the suture at the connector and disconnect the implanted pump from the implanted catheter. Avoid damage to the pump connector and leave the pump connector attached to the catheter.
3. Slowly aspirate 1 to 2 mL of fluid from the catheter using a 1 mL tuberculin syringe with the needle removed. Leave the syringe in place to avoid CSF loss. Aspirating directly from the catheter clears the catheter of drug and confirms catheter patency. Continue the implant with 1 of the 2 procedures listed below (**Table 3**).

NOTE:

Conditions may exist under which the catheter is not aspirated or is not patent. If the catheter is not patent it must be replaced. Refer to the appropriate catheter technical manual for catheter replacement instructions.

Table 3
Procedure for
Pump Replacement

| If the catheter has been replaced or aspirated: | If the catheter has NOT been replaced and has NOT been aspirated: |
|--|---|
| <ol style="list-style-type: none"> 4. Firmly press the sutureless pump connector onto the catheter port until the connector snaps into place or firmly squeeze on the oval marks of the pump connector and carefully press the pump connector onto the catheter port. Make sure the connector fully covers the catheter port. 5. Check that the connector is properly attached by grasping the tapered portion of the connector or tugging as if to remove the connector from the pump. The connector should feel firmly attached. 6. Place and suture the pump in the pump pocket, as described in the Place and Suture Pump in Pocket section of this module. 7. Close the wound as described in the Close Incisions section of this module. 8. Program the prescribed daily infusion. Then, program a post-operative priming bolus based on the combined volume of the pump tubing and catheter. | <ol style="list-style-type: none"> 4. Program a priming bolus to fill the pump internal tubing volume with the prescribed fluid before connecting the catheter and implanting the pump. Refer to the <i>8870 SynchroMed II Programming Guide</i> and the Priming Bolus section of the <i>Programming Module</i> for information on how to program this bolus. The pump internal tubing prime must be complete before attaching the catheter to the pump. Otherwise, drug present in the catheter will be bolused into the intrathecal space. 5. Firmly press the sutureless pump connector onto the catheter port until the connector snaps into place or firmly squeeze on the oval marks of the pump connector and carefully press the pump connector onto the catheter port. Make sure the connector fully covers the catheter port. 6. Check that the connector is properly attached by grasping the tapered portion of the connector or tugging as if to remove the connector from the pump. The connector should feel firmly attached. 7. Place and suture the pump in the pump pocket, as described in the Place and Suture Pump in Pocket section of this module. 8. Close the wound as described in the Close Incisions section of this module. 9. Program the pump to deliver the prescribed infusion. <div data-bbox="852 1680 1461 1942" style="border: 1px solid #0070C0; border-radius: 10px; padding: 10px; margin-top: 10px;">  <p>WARNING A post-operative Priming Bolus is not necessary and should not be programmed, as it can cause an overdose. Connecting a purging pump to the un aspirated catheter can result in overdose.</p> </div> |

AFTER PUMP REPLACEMENT

- Monitor the patient closely after pump replacement to ensure quick response to any signs of drug withdrawal or overdose.
- Register the new pump as described in the [Complete Pump and Catheter Registration](#) section of this module.

HANDLING THE REPLACED PUMP

- Be sure to remove drug from the old pump reservoir.
For SynchroMed II pumps:
 - If the old pump requires analysis, enter the maximum Reservoir Volume and program the infusion mode to Minimum Rate.
 - If the old pump does not require analysis it should be permanently disabled. For instructions on how to permanently disable a pump, call Medtronic Technical Services at 1-800-707-0933 (U.S.) or your Medtronic Representative (other world areas).
- For SynchroMed EL pumps:
 - Program the infusion mode to Stopped Pump and disable audible alarms.
- Medtronic implantable devices are intended for single use only. Do not re-sterilize and re-implant explanted devices.
- Please return explanted devices to Medtronic for analysis and/or disposal. See the back cover for mailing addresses. In the U.S. return the pump to Medtronic for evaluation and disposal. Call 1-800-328-0810 to obtain a return mailer kit for explanted devices.

Catheter Revision

Considerations for Dosing

Medtronic recommends aspirating drug or CSF from the catheter segment that is distal to the site of the revision. The internal pump tubing already contains drug, so program a Priming Bolus for only the empty portion of the catheter. If the catheter has not been fully functional, the patient's dose may have been escalated over time to maintain therapeutic effect. If the patient has not been on a stable dose over the past few weeks or months, consider significantly reducing the dose or starting the daily dose at the dose programmed at pump implant. Failure to do so may result in a significant overdose.

Surgical Considerations

If replacing the spinal catheter segment an intraoperative blood patch should be considered. The dural hole from the old catheter may not close quickly, resulting in CSF leak and post-operative headache.

Pump Removal

Preoperative Considerations DRUG WITHDRAWAL

Prior to elective pump removal, the patient should be slowly weaned from the pump medication to prevent withdrawal symptoms. The length of time needed to wean the medication depends on the drug and dosage the patient is receiving.

If desired, withdraw drug from the pump reservoir, fill it with preservative-free saline and program the pump to Minimum Rate.

PRECAUTION

If therapy is discontinued for an extended period of time, fill the reservoir with preservative-free saline and program the pump to the Minimum Rate. Stopping the pump for extended periods or allowing the reservoir to run dry can damage the system. A pump alarm will sound if the pump is stopped for 48 hours.

CATHETER REMOVAL

If the intrathecal catheter has been in place for more than several weeks, the established dural hole may not close rapidly. If no infection is present, consider the option of leaving the spinal catheter in place and ligating it after patient discussion.

Postoperative Considerations

- Keep the patient in bed overnight. Staying flat reduces the occurrence of a spinal headache.
- Drug withdrawal should be carefully managed.
- Be sure to remove drug from the pump reservoir.

For SynchroMed II pumps:

- If the pump requires analysis, enter the maximum Reservoir Volume and program the infusion mode to Minimum Rate.
- If the pump does not require analysis it should be permanently disabled. For instructions on how to permanently disable a pump, call Medtronic Technical Services at 1-800-707-0933 (U.S.) or your Medtronic Representative (other world areas).

For SynchroMed EL pumps:

- Program the infusion mode to Stopped Pump and disable audible alarms.
- Please return explanted devices to Medtronic for analysis and/or disposal. See the back cover for mailing addresses. In the U.S. call 1-800-328-0810 to obtain a return mailer kit for explanted devices.

Post Mortem

- Medtronic implantable devices are intended for single use only. Do not re-sterilize and re-implant explanted devices.
- **If subjected to incineration or cremation temperatures, the device could explode.** In addition, explanting battery-operated implantable devices post mortem is mandatory in some countries because of environmental concerns; please check your local regulations.
- Be sure to remove drug from the pump reservoir.
For SynchroMed II pumps:
 - If the pump requires analysis, enter the maximum Reservoir Volume and program the infusion mode to Minimum Rate.
 - If the pump does not require analysis it should be permanently disabled. For instructions on how to permanently disable a pump, call Medtronic Technical Services at 1-800-707-0933 (U.S.) or your Medtronic Representative (other world areas).For SynchroMed EL pumps:
 - Program the infusion mode to Stopped pump and disable audible alarms.
- Please return explanted devices to Medtronic for analysis and/or disposal. See the back cover for mailing addresses. In the U.S. call 1-800-328-0810 to obtain a return mailer kit for explanted devices.
- Medtronic implantable devices are intended for single use only. Do not re-sterilize and re-implant explanted devices.

Appendix

| | |
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Preoperative Patient Education Checklist

SYNCHROMED II PRODUCT DESCRIPTION

- Show patient the SynchroMed II system.**
 - Allow patient to feel the pump's weight and size.
 - Show a diagram of system placement.
- Explain the purpose of the pump reservoir, center reservoir fill port and the catheter access port.**
 - The pump reservoir holds the drug.
 - The gas that pressurizes the pump is located behind the reservoir; the pressure forces the drug through the filter to the pump rollers, which move the drug through the tubing and catheter.
 - The pump is refilled through the center reservoir fill port.
 - The catheter access port allows direct access to the implanted catheter.

SURGICAL OVERVIEW

- Explain the invasive nature of the surgery.**
- Explain (major) components of surgery.**
 - The tip of the catheter is placed in the intrathecal space of the spinal column.
 - The catheter is tunneled under the skin from the pump pocket site, around the flank to the back.
 - The catheter is connected to the pump.
 - The pump is placed in the abdomen, not more than 2.5 cm (1 inch) under the skin.
- Explain the system removal procedure and conditions under which the pump would be removed.**
- Discuss potential surgical complications and their symptoms including:**
 - Pump pocket hematoma/seroma
 - CSF leak/accumulation
 - Infection
 - Catheter cut/kink/dislodgement/break
 - Pump pocket erosion/wound dehiscence

PATIENT RESPONSIBILITIES

- Discuss the role of the patient.**
 - Patient will need to return for pump refill within 180 days, depending on the treatment plan.
 - Patient agrees that he or she will not seek pain medications from any other source.
 - Patient must be able to adhere to pump requirements and guidelines, such as temperature changes, travel precautions, etc.

LIFESTYLE ALTERATIONS

- Discuss mandatory refill appointments.**
 - The pump requires refill every 1-6 months (depending on regimen).
 - These appointments must be planned and adhered to.
 - Patient should have access to the proper clinical team including patient rehabilitation therapists for intrathecal baclofen patients.
- Discuss clothing requirement.**
 - Wear loose clothing to promote comfort and prevent pressure on skin overlying pump.
- Discuss travel/recreation.**
 - Avoid physical activities, which may damage the implant site or device, and restrict activities to reduce catheter movement for six to eight weeks post-implant per my doctor's orders.
 - Patient must consult with the physician before engaging in activities involving pressure or temperature changes, or changes in altitude (e.g., scuba diving, saunas, hot tubs, airline flights, etc.)
 - Patient should discuss travel plans with the physician, (e.g., make arrangements for out-of-town pump refills.)

Postoperative Patient Education Checklist

PATIENT RESPONSIBILITIES

- Discuss the role of the patient.**
 - Patient will need to return for pump refill within 180 days, depending on the treatment plan.
 - Pain patient agrees that he or she will not seek pain medications from any other source.
 - Patient must be able to adhere to pump requirements and guidelines, such as temperature changes, travel precautions, etc.
 - Patient should inform other personal physicians, dentists, and health care professionals about the pump so they can adjust other therapies and medications as needed (e.g., MRI, diathermy, etc.)
 - Patient must always carry his or her Implant Device Identification Card and Emergency Information.

LIFESTYLE ALTERATIONS

- Discuss mandatory refill appointments.**
 - The pump requires refill every 1-6 months (depending on regimen).
 - These appointments must be planned and adhered to.
 - Patient should have access to the proper clinical team including patient rehabilitation therapists for intrathecal baclofen patients.
- Discuss clothing requirement.**
 - Wear loose clothing to promote comfort and prevent pressure on skin overlying pump.
 - Protect pump site from irritation from wheelchair straps, braces, etc.
- Discuss travel/recreation.**
 - Avoid physical activities, which may damage the implant site or device, and restrict my activities to reduce catheter movement for six to eight weeks post-implant per my doctor's orders.
 - Patient must consult with the physician before engaging in activities involving pressure or temperature changes, or changes in altitude (e.g., scuba diving, saunas, hot tubs, airline flights, etc.).
 - Patient should discuss travel plans with the physician, (e.g., make arrangements for out-of-town pump refills).

DRUG-RELATED COMPLICATIONS

- Review and explain the potential for the following drug-related complications:**
 - The most common drug-related side effects.
 - The most serious (but less common) adverse experiences encountered during continuous infusion.
 - Review additional potential adverse events.
 - If the patient misses a refill appointment and the drug is allowed to deplete, loss of therapeutic effect and/or withdrawal symptoms can be serious and even life threatening.

DEVICE-RELATED COMPLICATIONS

- Review and explain the potential for the following device-related complications:**
 - Inability to withdraw/inject into the catheter access port.
 - Pump inversion (“flipped pump”).
 - Catheter cut/kink/dislodgement/break.

OTHER THERAPIES AND MEDICATIONS

- Review the use of concomitant therapies or medications.**
 - DO NOT use diathermy, high-output ultrasonic devices/lithotripsy, or radiation therapies near the implanted pump.
 - Avoid hyperbaric chamber treatment unless approved by a physician. This therapy may affect pump operation.
 - Prescribed and over-the-counter medications should be discussed with the physician before taking them.
 - Inform other personal physicians, dentists and health care professionals about the pump so they can adjust other therapies and medications as needed.

Patient Informed Consent Form for Intrathecal Morphine Therapy

PATIENT INFORMED CONSENT FORM FOR INTRATHECAL MORPHINE THERAPY VIA THE SYNCHROMED II INFUSION SYSTEM (PUMP)

(“Insert other risks, precautions, consequences, etc. pursuant to the laws of your country. Consult legal counsel.”)

I, _____, have been informed by

Dr. _____ of the following:

- The goals, benefits and risks of intrathecal morphine delivery via the SynchroMed® II Infusion System.
- Alternative methods of treatment for chronic pain.
- How intrathecal morphine delivery works to control pain and expectations for relief of pain.
- The surgical implant procedure for the SynchroMed II pump and catheter.
- My role and responsibilities during long-term intrathecal morphine therapy with the SynchroMed II Infusion System.
- Possible consequences and complications of morphine therapy via the SynchroMed II Infusion System.
- Short-term and long-term precautions I must take when implanted with the SynchroMed II Infusion System.

I agree to observe these short-term and long-term precautions.

- Avoid physical activities, which may damage the implant site or device, and restrict my activities to reduce catheter movement for six to eight weeks post-implant per my doctor’s orders.
- Schedule appointments for pump refills on a regular basis. This will be determined by the amount of medication used, but is generally at 1-6 month intervals.
- Carry my SynchroMed II Identification and Emergency cards with me at all times. These cards will identify me as a recipient of the SynchroMed II Infusion System in the event of an emergency.
- Inform my family or significant others of the emergency cards and procedures.

- Inform my doctor of the following:
 - Adverse side effects of the medication.
 - Pain, swelling, or drainage at the incision site. These symptoms may indicate infection.
 - Unusual changes in my pain patterns.
- Inform my physician of future travel plans. Referrals and arrangements *may* need to be made for out-of-town refills and troubleshooting.
- Inform other physicians I am seeing about this medication program and the SynchroMed II Infusion System.
- Avoid alcohol or mood altering drugs while receiving this type of medication as I may experience serious side effects.
- Consult a physician before operating a motor vehicle. It is my responsibility not to drive if I am experiencing any side effects.
- Avoid use of pain medications other than those prescribed by this physician.
- Avoid certain medical procedures/devices, unless approved by a physician that may effect the SynchroMed II Infusion System, such as diathermy, therapeutic hypothermia, high-output ultrasonic devices/lithotripsy, radiation therapy, or hyperbaric chamber treatment.
- Call my physician upon hearing any pump alarm. The alarm may mean that the pump is not delivering drug or will stop delivering drug in the near future (e.g., the pump needs to be refilled or the pump should be replaced).

I understand and agree that:

- Intrathecal morphine therapy may reduce, but not cure or eliminate, my pain. Successful therapy generally means reduction in pain, as well as improvements in my ability to function. I may need to be involved in additional therapies, such as physical therapy.
- Intrathecal morphine delivery via the SynchroMed II Infusion System will not eliminate the primary source of my pain or “cure” the disease that causes my pain.

- Intrathecal morphine delivery via the SynchroMed II Infusion System will not solve my personal and family problems. Because chronic pain may have adversely affected my life and my relationships with others, my physician may recommend counseling or support groups to help me cope with anxiety, depression, and other effects of chronic pain. The goal of this counseling is to provide the greatest opportunity to return to being as active and functional as possible.
- I have been selected as a candidate for intrathecal morphine delivery via the SynchroMed II Infusion System because alternative therapies, such as narcotic drugs and surgery, have not worked to control my pain.
- There will be a transition phase after the pump is implanted. I will have other medications gradually reduced so that the appropriate dose levels of the intrathecal drug can be determined. I may not have maximum pain relief during this transition. It is important to work with my physician during this time so that my body can get the maximum benefit of this type of pain medication.
- The implantation of the SynchroMed II Infusion System is associated with certain risks. Any complication that can occur with surgery and anesthesia is possible. In addition, there are risks unique to the implantation of the SynchroMed II Infusion System. They include but are not limited to: infection, accumulation of fluid or blood in the pump pocket site, spinal hygromas, cerebrospinal fluid leakage through the incision site, spinal headaches, pump pocket erosion, or wound re-opening. Patients usually experience pain and tenderness in the incision sites until healing occurs.
- System or procedural complications with the SynchroMed II Infusion System include, but are not limited to:
 - Dislodgement, kinking, or breaking of the intrathecal catheter
 - Pump inversion (pump “flips”)
 - Programming errors
 - Refill errors
 - Pump pocket problems
 - Problems with the pump itself
 - Inability to withdraw or inject into the catheter access port
 - Development of an inflammatory mass

- The following warning signs and/or symptoms may occur before the onset of more severe neurological impairment:
 - Change in character, quality, or intensity of pain
 - New radicular pain, especially at or near the dermatomal level of the catheter tip
 - Frequent or large escalations of the daily drug dose are required to maintain the analgesic effect
 - Dose escalations may alleviate the patient's increasing pain only temporarily
- All patients on intraspinal opioid therapy should be monitored carefully at each visit for any new neurological signs or symptoms, including:
 - New or different sensory symptoms (e.g., numbness, tingling, burning, hyperesthesia, or hyperalgesia)
 - New, occasional, or intermittent bowel and/or bladder sphincter dysfunction
 - New motor weakness, change in gait, and/or difficulty walking
 - Any neurological symptom or sign that differs from baseline (e.g., reflex changes)
- In patients with new neurological signs and/or symptoms, consider neurological consultation and the prompt performance of an imaging procedure (e.g., MRI) to confirm or rule-out the diagnosis of an inflammatory mass.
- Administration of intrathecal morphine has been associated with certain side effects and/or adverse effects, which include but are not limited to: itching, urinary retention, constipation, nausea, vomiting, dizziness, anxiety, depression, edema, and myoclonus. An overdose of medication is possible and can result in, but not limited to: respiratory depression, seizures and respiratory arrest. An underdose of medication is also possible. It may be recognized as malaise, anxiety, increased pain, headache, myalgias, backache, insomnia, dehydration and fever.
- Increased physical activity (made possible by the therapy) may cause tenderness and muscle weakness. A course of physical therapy may be prescribed to build muscle strength and reduce muscle and joint pain.

- The implantable pump is powered by a battery. Pump life is dependent on the flow rate of the pump. The pump is warranted for 2 years. The pump must be replaced at the End of Service, which is indicated by a critical End of Service alarm.

I hereby state that I have read and understand this document and terms of agreement. I have had the opportunity to ask my doctor questions about the SynchroMed II Infusion System and these questions have been answered to my satisfaction.

I believe that I have adequate knowledge of intrathecal morphine therapy via the SynchroMed II System and its potential risks, complications, and benefits to give my informed consent to the treatment.

Patient _____ Date _____

Witness _____ Date _____

SAMPLE

Patient Informed Consent Form for ITB TherapySM (Intrathecal Baclofen Therapy)

PATIENT INFORMED CONSENT FORM FOR ITB THERAPYSM (INTRATHECAL BACLOFEN THERAPY) VIA THE SYNCHROMED® II INFUSION SYSTEM (PUMP)

(“Insert other risks, precautions, consequences, etc. pursuant to the laws of your country. Consult legal counsel.”)

I, _____, have been informed by

Dr. _____ of the following:

- The goals, benefits and risks of ITB TherapySM via the SynchroMed® II Infusion System
- Alternative methods of treatment for severe spasticity.
- How intrathecal baclofen injection delivery works to treat spasticity and expectations for relief of severe spasticity.
- The surgical implant procedure for the SynchroMed II pump and catheter.
- My role and responsibilities during long-term ITB TherapySM with the SynchroMed II Infusion System.
- Possible consequences and complications of ITB TherapySM via the SynchroMed II System.
- Short-term and long-term precautions I must take when implanted with the SynchroMed II Infusion System.

I agree to observe these short-term and long-term precautions.

- Avoid physical activities, which may damage the implant site or device, and restrict my activities to reduce catheter movement per my doctor’s orders.
- Schedule appointments for pump refills on a regular basis. This will be determined by my doctor.
- Carry my SynchroMed II Identification and Emergency cards with me at all times. These cards will identify me as a recipient of the SynchroMed II pump in the event of an emergency.
- Inform my family or significant others of the emergency cards and procedures.

- Inform my doctor of the following:
 - Adverse side effects of the medication.
 - Pain, swelling, or drainage at the incision site. These symptoms may indicate infection.
 - Unusual changes in my spasticity.
- Inform my physician of future travel plans. Referrals and arrangements *may* need to be made for out-of-town refills and troubleshooting.
- Inform other physicians I am seeing about this medication program and the SynchroMed II Infusion System.
- Avoid alcohol or mood altering drugs while receiving this type of medication as I may have serious side effects.
- Use caution when operating a motor vehicle. It is my responsibility not to drive if I am experiencing any side effects.
- Inform my physician of other medications I am taking during ITB Therapy.
- Avoid certain medical procedures/devices unless approved by my physician that *may* affect the SynchroMed II Infusion System, such as diathermy, high-output ultrasonic devices/lithotripsy, radiation therapy, or hyperbaric chamber treatment.
- Call my physician upon hearing any pump alarm. The alarm may mean that the pump is not delivering drug or will stop delivering drug in the near future (e.g., the pump needs to be refilled or the pump should be replaced).

I understand and agree that:

- ITB Therapy via the SynchroMed II Infusion System will not eliminate the primary sources of my spasticity or “cure” the disease that causes my spasticity. A course of rehabilitation and physical therapy may be prescribed to build my muscle strength, prevent muscle wasting, increase my endurance and/or improve my ability to perform various activities of daily living.
- There will be a transition phase after the pump is implanted. I may have other medications gradually reduced so that the appropriate dose levels of the intrathecal drug can be determined. I may not have maximum spasticity relief during this transition. It is important to work with my physician during this time so that my body can get the maximum benefit of this type of medication.

- The implantation of the SynchroMed II Infusion System is associated with certain risks. Any complication that can occur with surgery and anesthesia is possible. In addition, there are risks unique to the implantation of the SynchroMed II Infusion System. They include but are not limited to: infection, accumulation of fluid or blood in the pump pocket site, spinal hygromas, cerebrospinal leakage through the incision site, spinal headaches, pump pocket erosion, or wound re-opening. Patients usually experience pain and tenderness in the incision sites until healing occurs.
- System or therapy complications with the SynchroMed II Infusion System include, but are not limited to:
 - Dislodgement, kinking, or breaking of the intrathecal catheter
 - Pump inversion (pump “flips”)
 - Programming errors
 - Refill errors
 - Pump pocket problems
 - Problems with the pump itself
 - Inability to withdraw or inject into the catheter access port
- ITB TherapySM drug side effects are usually temporary and manageable by adjusting the dose. The most common side effects include loose muscles, drowsiness, nausea/vomiting, headache, and dizziness. Close attention to your doctor’s instructions is required since abrupt cessation of intrathecal baclofen can result in high fever, altered mental status, returned spasticity, and muscle rigidity, and in rare cases has been fatal.

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- In clinical trials, Lioresal® Intrathecal (baclofen injection) (10 mg/5 mL, 10 mg/20 mL, 0.05 mg/1 mL) was shown to reduce severe spasticity. Results vary; not every individual will receive the same benefits.
- Administration of Lioresal® Intrathecal (baclofen injection) has been associated with certain side effects and/or adverse effects. During administration of Lioresal® Intrathecal (baclofen injection) reports of adverse effects and/or side effects have included but are not limited to: very loose muscles, sleepiness, nausea, vomiting, headache, and dizziness. An overdose of medication is possible and can result in, but is not limited to: breathing difficulties, seizures, very loose muscles, sleepiness, and loss of consciousness proceeding to coma. An underdose of medication is also possible. It may be recognized as a return of spasticity, rigid muscles, itchiness (without a rash), a fever, numbness and tingling, or a lower than normal blood pressure. Attending all scheduled refill and dose adjustment appointments will minimize the potential risk of such an event.
- For more information, please read the Lioresal® Intrathecal (baclofen injection) labeling.
- The implantable pump is powered by a battery. Pump life is dependent on the flow rate of the pump. The pump is warranted for 2 years. The pump must be replaced at the End of Service, which is indicated by a critical End of Service alarm.

I hereby state that I have read and understand this document and terms of agreement. I have had the opportunity to ask my doctor questions about ITB Therapy and these questions have been answered to my satisfaction.

I believe that I have adequate knowledge of ITB Therapy via the SynchroMed II pump and its potential risks, complications, and benefits to give my informed consent to the treatment.

Patient _____ **Date** _____

Witness _____ **Date** _____

Lioresal® is a registered trademark of Novartis Pharmaceuticals Corporation.

Brief Disclosures

SYNCHROMED® II DRUG INFUSION SYSTEM BRIEF SUMMARY:

PRODUCT TECHNICAL MANUALS AND THE APPROPRIATE DRUG LABELING MUST BE REVIEWED PRIOR TO USE FOR DETAILED DISCLOSURE.

INDICATIONS: US: Chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for the management of severe spasticity; chronic intravascular infusion of floxuridine (FUDR) or methotrexate for the treatment of primary or metastatic cancer. Outside of US: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling.

CONTRAINDICATIONS: When infection is present; when the pump cannot be implanted 2.5 cm or less from the surface of the skin; when body size is not sufficient to accept pump bulk and weight; when contraindications exist relating to the drug. Do not use the Personal Therapy Manager accessory to administer opioid to opioid-naïve patients or to administer ziconotide.

WARNINGS: Comply with all product instructions for initial preparation and filling, implantation, programming, refilling, and injecting into the catheter access port (CAP) 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, or a clinically significant or fatal drug under- or overdose. Refer to the appropriate drug labeling for specific under- or overdose symptoms and methods of management. Avoid using short wave (RF) diathermy within 30 cm of the pump or catheter. Diathermy may produce significant temperature rises in the area of the pump and continue to heat the tissue in a localized area. If overheated, the pump may over infuse the drug, potentially causing a drug overdose. Effects of other types of diathermy (microwave, ultrasonic, etc.) on the pump are unknown. An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients on intraspinal opioid therapy carefully for any new neurological signs or symptoms. For intraspinal therapy, use only preservative-free sterile solution indicated for intraspinal use. Use only Medtronic components indicated for use with this system. Failure to firmly secure connections can allow drug or cerebrospinal fluid (CSF) leakage into tissue and result in tissue damage or inadequate therapy. A postoperative priming bolus should not be programmed if the pump is a replacement and the catheter has not been aspirated. Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures. Physicians must be familiar with the drug stability information in the technical manual and must understand the dose relationship to drug concentration and pump flow rate before prescribing pump infusion. Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the infusion system.

Inform patients of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention. Instruct patients to notify their clinician of travel plans, to return for refills at prescribed times, avoid activities such as strenuous exercise or contact sports that jar, impact, twist, or stretch the body, to always carry their Medtronic device identification card, to avoid manipulating the pump through the skin, and to notify healthcare professionals of the implanted pump before medical tests/procedures. Patients must consult their physician before engaging in activities involving pressure or temperature changes (e.g., scuba diving, saunas, hot tubs, hyperbaric chambers, flights, skydiving, etc.) Inform patients that pump has an Elective Replacement Indicator (ERI) that sounds when the pump is nearing its end of service. When the alarm sounds, patients must contact their doctor to schedule pump replacement.

PRECAUTIONS: The pump is ethylene oxide sterilized. Do not use if the product or package is damaged, the sterile seal is broken, or the "Use By" date has expired. Do not reuse or resterilize the pump; it is intended for "single use only." Do not expose the pump to temperatures above 43°C or below 5°C. Consider use of peri- and post-operative antibiotics for pump implantation, for any subsequent surgical procedure, or if infection is present. For patients prone to CSF leaks, clinicians should consider special procedures, such as a blood patch. Follow instructions for emptying and filling the pump during a replacement or revisions that require removal of the pump from the pocket. Explant the pump postmortem if incineration is planned (to avoid explosion), or if local environmental regulations mandate removal. Return explanted devices to Medtronic for analysis and safe disposal. Do not implant a pump dropped onto a hard surface or showing signs of damage. Implant the pump less than 2.5 cm from the surface of the skin. Ensure pump ports will be easy to access after implant, that the catheter is not kinked and secured well away from pump ports before suturing. Keep the implant site clean, dry, and protected from pressure or irritation. If therapy is discontinued for an extended period of time, fill the reservoir with preservative-free saline in intraspinal applications or appropriate heparinized solution (if not contraindicated) in vascular applications.

The magnetic field or telemetry signals produced by the programmer may cause sensing problems and inappropriate device responses with an implantable pacemaker and/or defibrillator. Electromagnetic interference (EMI) is an energy field generated by equipment found in the home, work, medical, or public environments. Most EMI normally encountered will not affect the operation of the pump. Exceptions include: injury resulting from heating of the pump which can damage surrounding tissue (diathermy, MRI), system damage which can require surgical replacement or result in loss/change in symptom control (defibrillation, electrocautery, high-output ultrasonics, radiation therapy), and operational changes to the pump causing the motor to stop, loss of therapy, return of underlying symptoms, and require confirmation of pump function (diathermy, high magnetic field devices, hyperbaric/hypobaric conditions, magnetic resonance imaging (MRI)). MRI will temporarily stop the pump motor's rotor due to the magnetic field of the MRI scanner and suspend drug infusion during MRI exposure which will cause the pump alarm to sound. The pump should resume normal operation upon termination of MRI exposure. Prior to MRI, the physician should determine if the patient can safely be deprived of drug delivery. If not, alternative delivery methods for the drug can be utilized during the MRI scan. Prior to scheduling an MRI scan and upon its completion, pump status should be confirmed.

ADVERSE EVENTS: Include, but are not limited to, cessation of therapy due to end of device service life or component failure, change in flow performance due to component failure, inability to program the device due to programmer failure, CAP component failure; inaccessible refill port due to inverted pump, pocket seroma, hematoma, erosion, infection, post-lumbar puncture (spinal headache), CSF leak, radiculitis, arachnoiditis, bleeding, spinal cord damage, meningitis (intrathecal applications), anesthesia complications, damage to the pump, catheter and catheter access system due to improper handling and filling before, during, or after implantation; change in catheter performance due to catheter kinking, disconnection, leakage, breakage, occlusion, dislodgement, migration, or catheter fibrosis; body rejection phenomena, surgical replacement of pump or catheter due to complications; local and systemic drug toxicity and related side effects, complications due to use of unapproved drugs and/or not using drugs in accordance with drug labeling, or inflammatory mass at the tip of the catheter in patients receiving intraspinal morphine or other opioid drugs.

N'Vision Handheld Programmer

Brief Summary: Product Technical Manuals and Programming Guides must be reviewed prior to use for detailed disclosure.

Indications For Use: The N'Vision™ Programmer is indicated for use with Medtronic Neurological therapies and devices provided on Medtronic removable application cards. Refer to specific programming guides to determine compatibility.

Warnings:

- Refer to the appropriate implant/device manual for instructions on specific therapy applications and a complete listing of the warnings, precautions, contraindications and instructions for use for all applications. The N'Vision Programmer can only be used to program Medtronic Neurological devices that have software provided on the application card.
- The separate magnet is for use with Medtronic SynchroMed® and SynchroMed EL implantable infusion pumps only. Remove the magnet before using the N'Vision Programmer with other Medtronic devices, including neurostimulators. The magnet may turn on, turn off, or change the stimulation amplitude of a neurostimulator if not removed from the programming head.
- When using the N'Vision programmer in the sterile field, place the programmer and programming head in a sterile bag. The programmer is not sterile and cannot be sterilized.
- If the display is not working, insert four fresh "AA" alkaline batteries into the programmer. If the batteries are fresh AND the display is not working, do not use the N'Vision Programmer because inadvertent programming may occur. Return the device to Medtronic for repair.
- Use only fresh batteries. Replace batteries when indicated or power loss could result. Power loss during use could prematurely end programming session and will reinitialize the programmer and which may result in the loss of current session data depending on the application.
- Do not immerse the N'Vision programmer in water or other fluids. Exposure to excessive amounts of water or other fluids may damage the programmer.
- Do not connect the N'Vision programmer to any equipment not specifically listed in the N'Vision programmer technical manual. All peripheral equipment connected to the N'Vision programmer must be certified according to the respective International Electrotechnical Commission (IEC) standards.
- Do not use the N'Vision programmer if it is damaged.

Precautions:

- Power interruptions during programming will revitalize the programmer and patient session data will be lost.
- Do not remove the application card while the N'Vision programmer is on.
- Do not insert generic non-Medtronic, Compact Flash cards into the programmer.
- Telemetry failures will result in loss of communication between the programmer and the implanted device. To ensure that telemetry is established and maintained, keep the telemetry head as close as practical to the implanted device. The green light indicates that telemetry has been established. Do not move the telemetry head once telemetry has been established.
- Do not use the N'Vision Programmer in close proximity to equipment that generates electromagnetic interference (EMI). EMI may cause a disruption in communication between the programmer and the implanted device. Medtronic neurostimulators programmed by the N'Vision programmer may affect the operation of other implanted medical devices, such as cardiac pacemakers and implantable cardioverter defibrillators (ICDs). For patients with concurrent implantable pacemaker and/or defibrillation therapy, evaluation of any potential interference problems and careful programming of each system may be necessary to optimize the patient's benefit from each implanted device.
- The red THERAPY-STOP button will not function unless an application card is in place in the programmer and a therapy has been selected.

Rx Only

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