

Patient Safety Alert

Veterans Health Administration Warning System
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October 24, 2008

Item:

Medtronic Neuromodulation Sutureless Connector Catheters used with SynchroMed and IsoMed implantable infusion pumps:

- **INDURA One-Piece (1P) Intrathecal Catheters, Model 8709SC**
- **Intrathecal Catheters, Model 8731SC**
- **Sutureless Pump Connector Revision Kit, Model 8578**
- **Intrathecal Catheter Pump Segment Revision Kit, Model 8596SC**

Specific Incident:

There is a potential for misconnections of the Medtronic sutureless connector catheters from the catheter port on the pump. These misconnections have resulted in a blockage (occlusion) between the sutureless pump connector and the catheter port on the pump and disconnections from the pump connector. Misconnections can result in lack of therapeutic effect, clinically significant or fatal drug underdose, or return of underlying symptoms and/or withdrawal symptoms. Drug withdrawal from Intrathecal Baclofen (ITB) therapy (in the patient's spine) can cause death if not treated immediately and effectively. Medical intervention has been required to fix the misconnections.

Medtronic issued a field communication to physicians, and this issue was classified as a Class I recall by the FDA on June 26, 2008. The information was updated on FDA's website on October 7, 2008.

General Information:

The intrathecal catheters and intrathecal catheter revision kits use a sutureless connector for attachment of the catheter to the implanted Medtronic SynchroMed II, SynchroMed EL, and IsoMed infusion pumps. The catheter is part of an infusion system that stores and delivers parenteral drugs to the intrathecal space.

Medtronic's investigation indicates that reported events have been caused by misalignment or incomplete connection of the sutureless pump connector to the catheter port. Proper alignment and full engagement of the sutureless pump connector to the catheter port during attachment is critical to ensure the catheter is properly and completely connected to the pump.

Actions:

1. By close of business October 31, 2008, physicians responsible for implanting and managing patients must do the following:

- a. Read Attachments 1, 2, and 3.
- b. Begin to perform the following procedures during implantation. Detailed instructions are provided in Attachments 2 and 3.
 - **verify cerebrospinal fluid (csf) backflow through the catheter**
 - **ensure alignment of the sutureless connector to the pump**
 - **snap the sutureless connector into place**
 - **tug and rotate to test the connection**
- c. Follow recommendations for managing patients with implanted sutureless "SC" catheters, as outlined in Attachment 1.

2. By close of business October 31, 2008, contact your patients who have these devices to educate them about the signs and symptoms of drug underdose and withdrawal.

3. Effective immediately, all patients that present with an intrathecal pump should be provided with education about the signs and symptoms of drug underdose and withdrawal.

Additional Information: Clinicians should be aware that VHA patients may have had these catheters implanted at non-VHA facilities and if they present at your facility, they need to be informed of the signs and symptoms of drug underdose and withdrawal.

Sources: A VA Medical Center, FDA, Medtronic

Attachments:

1. Medtronic Safety Alert, June 2008
2. Medtronic Recommendations for Implant Techniques
3. Medtronic Recommendations for Patency Verification

Contact: Tom Bauld, National Center for Patient Safety, (734) 930-5890
Andrew Rennie, Medtronic Neuromodulation, (763) 526-9738

ATTACHMENT 1

Medtronic Safety Alert



June 2008

SAFETY ALERT

Proper Connection of Sutureless Connector Intrathecal Catheters

Catheter Models: 8709SC, 8731SC, 8596SC, 8578

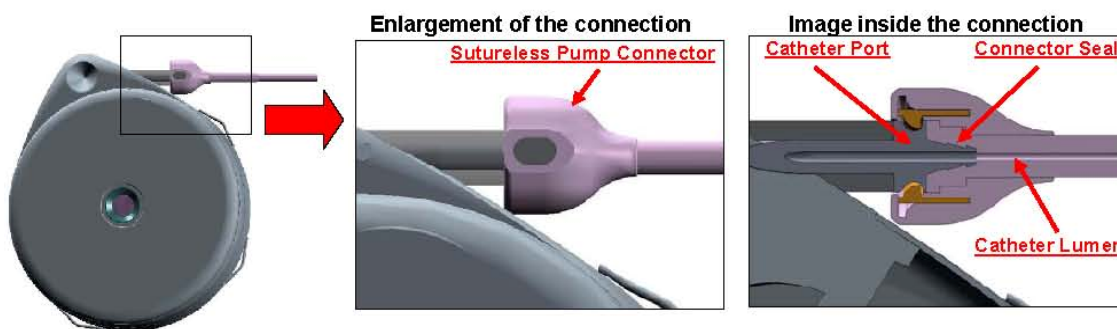
Dear Healthcare Professional,

This letter provides important safety information concerning potential disconnection of the Medtronic sutureless connector ("SC") catheters from the catheter port on the pump, or occlusion between the sutureless pump connector and the catheter port on the pump. These catheters (Model Numbers 8709SC, 8731SC, 8596SC, 8578) are used with Medtronic SynchroMed® and IsoMed® implantable infusion pumps. Please note that this issue **does not** involve Medtronic MiniMed insulin pumps.

Description of the Problem:

Medtronic has received reports of infusion system difficulties that have been attributed to occlusion between the sutureless pump connector and the catheter port, and disconnections of the sutureless pump connector from the catheter port. Medtronic investigation indicates these events are caused by misalignment or incomplete connection of the sutureless pump connector to the catheter port. Proper alignment and full engagement of the sutureless pump connector to the catheter port during attachment is critical in ensuring the catheter is properly and completely connected to the pump.

Images of Correct SC Catheter Connection to the SynchroMed II Infusion Pump



Occlusion of Connection between Catheter and Pump: To date, Medtronic has received 23 reports of infusion system difficulties worldwide that have been attributed to occlusion between the sutureless pump connector and the catheter port. This represents approximately 0.15% of the total SC catheter implants worldwide. Return product analysis suggests that this occlusion is related to misalignment during connection, resulting in the catheter port embedding into the inner wall of the connector seal, rather than aligning with the catheter lumen within the connector.

Catheter Disconnection: To date, Medtronic has received 34 reports worldwide related to disconnection of the sutureless pump connector from the catheter port. This represents



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approximately 0.22% of the total SC catheter implants worldwide. Medtronic investigation suggests that the disconnections are related to misalignment during connection, resulting in an improper attachment of the catheter to the pump. Improper attachment can result in catheter connector damage, leaks at the connection site, or catheter disconnection some time after implant.

Severity of the Problem:

Occlusion: In all twenty-three (23) reports associated with occlusion between the sutureless pump connector and the catheter port, medical intervention was required to correct the condition. In one (1) case, baclofen withdrawal symptoms prompted replacement of an occluded catheter. Six days after catheter replacement, and following extensive medical intervention, the patient expired. The preliminary cause of death was stated as DIC (disseminated intravascular coagulation), a known sequela of baclofen withdrawal. In one (1) case, lack of therapy prompted device replacement. Patient death was reported after device replacement, however it was reported that the death was not considered to be device related. In the remaining twenty-one (21) cases either no symptoms, a return of underlying symptoms, or withdrawal symptoms were reported, with no death or permanent patient injury.

Disconnection: In all thirty-four (34) reports associated with disconnection of the sutureless pump connector from the catheter port, medical intervention was required to correct the condition. No death or permanent patient injury has been reported due to this issue. The reports that were received indicated either no patient symptoms, a return of underlying symptoms, or withdrawal symptoms.

The clinical manifestations of a sutureless pump connector occlusion and sutureless pump connector disconnection from the catheter port may include:

- Lack of therapeutic effect
- A clinically significant or fatal drug underdose
- A return of underlying symptoms and/or withdrawal symptoms

For signs and symptoms of drug underdose, please refer to the labeling for the drug being administered. Patients receiving intrathecal baclofen therapy (e.g. Lioresal[®] Intrathecal) are at higher risk for adverse events as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively¹.

Important Implant Information:

Proper alignment of the central axis of the sutureless pump connector to the central axis of the catheter port, in addition to full engagement of the sutureless pump connector to the catheter port are imperative in ensuring proper connection.

Please refer to the enclosed *Recommendations for Implant Techniques* for detailed information on connecting the catheter to the pump and verifying proper attachment.

¹ For complete product information refer to the Lioresal[®] Intrathecal (baclofen injection) Package Insert, Copyright Medtronic Inc. 2002 <http://www.medtronic.com/physician/itb/disclosure-package-insert.html>



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Recommendations for Managing Patients with implanted SC Catheters:

- Continue to educate patients and caregivers about the signs and symptoms of drug underdose and withdrawal. Instruct patients to seek immediate medical assistance in the event that signs or symptoms of drug underdose or withdrawal appear.
- If an occlusion between the sutureless pump connector and the catheter port on the pump is suspected, contrast medium indicated for intrathecal use may be used to confirm patency. Please refer to the attached *Recommendations for Patency Verification* for detailed information on performing a catheter contrast study.
- If an occlusion or disconnection is identified, replacement of the SC catheter is necessary because improper connection may damage the sutureless pump connector over time. Please refer to the attached *Recommendations for Implant Techniques* for details on properly connecting the catheter to the pump.
- Consider patient dosing parameters if an occlusion or disconnection is corrected. Patients who have had their intrathecal therapy interrupted for any reason may be effectively drug naive at the time of system revision.

This safety alert is being made with the knowledge of the Food and Drug Administration. Please report any malfunction or adverse event related to a device to:

Medtronic Neuromodulation Technical Services: 1-800-707-0933

And

FDA's MedWatch Program:

- Phone: 1-800-FDA-1088,
- Fax: 1-800-FDA-0178,
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Internet: www.fda.gov/medwatch.

Medtronic is committed to providing you with the highest quality products, services and ongoing support as you care for your patients. If you have any questions or comments, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933.

Sincerely,

George Aram
Vice President and President
Medtronic Neurological

Enclosures: Recommendations for Implant Techniques
Recommendations for Patency Verification

ATTACHMENT 2

Medtronic Recommendations for Implant Techniques



Sutureless Connector ('SC') Intrathecal Catheters (Models 8709SC, 8731SC, 8596SC, 8578)

Recommendations for Implant Techniques

The following 4 steps reinforce recommended implant techniques identified in the product labeling that are important in mitigating the potential for catheter occlusions and disconnections.

1. Verify **CSF backflow** through the catheter
2. Ensure **Alignment** of sutureless connector to the Pump
3. **Snap** the sutureless connector into place
4. **Tug** and **Rotate** to test the connection

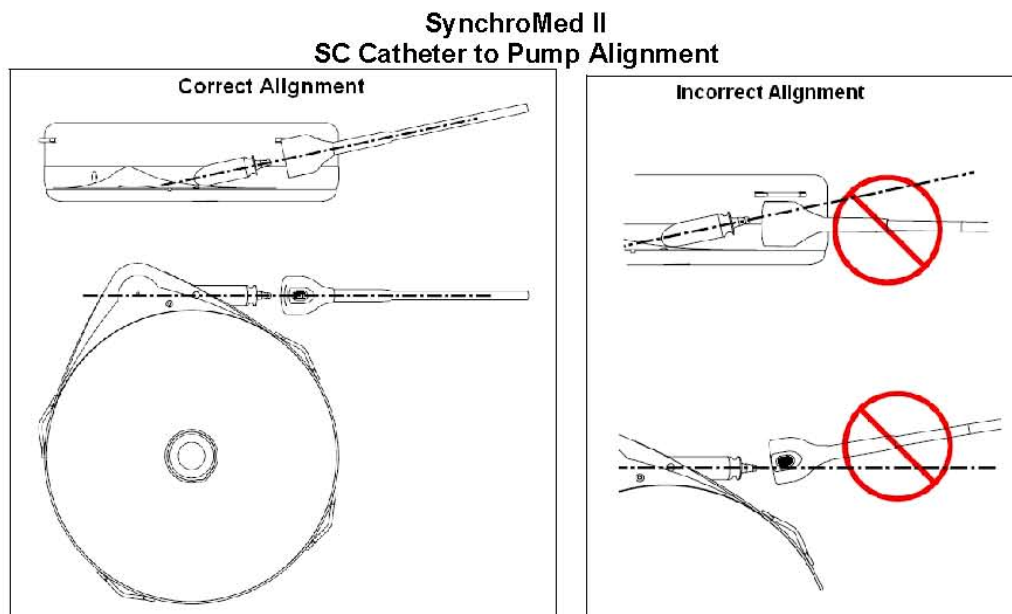
1. Verify CSF backflow through the catheter

Prior to connection of the catheter to the pump, cerebrospinal fluid (CSF) backflow should be confirmed through observation.

2. Ensure Alignment of sutureless connector to the Pump

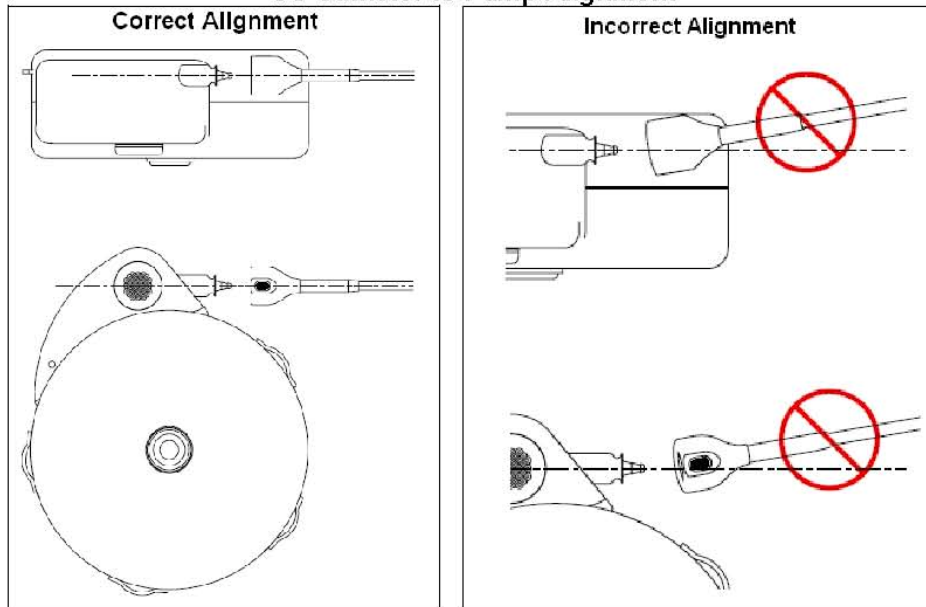
Proper alignment and full engagement of the sutureless pump connector to the catheter port on the pump during attachment is critical in ensuring the catheter is properly and completely connected to the pump.

- At the pump pocket site, position the catheter port of the pump *in line* with the opening of the sutureless pump connector. The following figures show correct and incorrect catheter alignment with reference to lateral and top views of Medtronic infusion pumps.

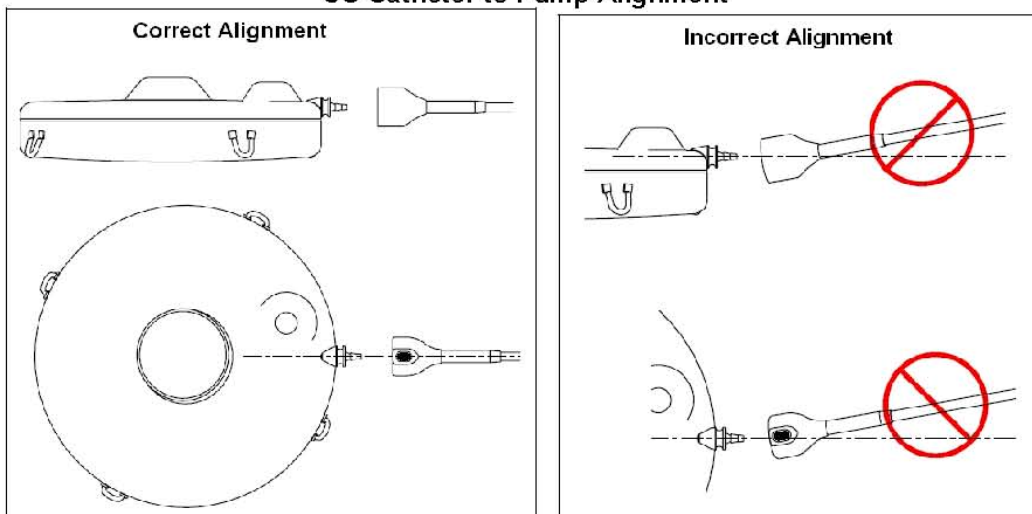




**SynchroMed EL
SC Catheter to Pump Alignment**



**IsoMed
SC Catheter to Pump Alignment**



- Exercise care when connecting the catheter or pump connector to metal connectors or fittings. These can cut or puncture the catheter or pump connector.

ATTACHMENT 2 (CONT)

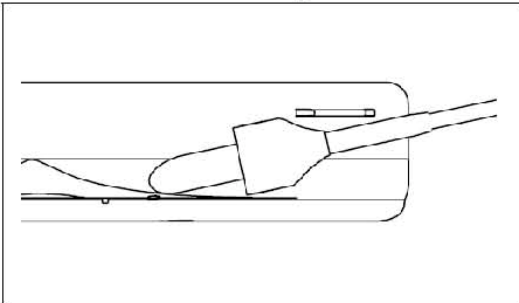


3. Attaching the sutureless connector to the pump – snap the SC into place

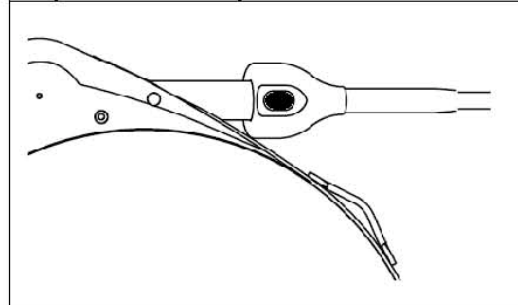
The sutureless pump connector snaps into place providing tactile and audible indication of full connection.

- There are two recommended methods for attaching the sutureless pump connector to the pump.
 - 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:
 - Firmly squeeze precisely on the oval marks of the sutureless pump connector.
 - While squeezing, **carefully** press the sutureless pump connector onto the catheter port until the connector fully covers the catheter port.
 - The connector **snaps** into place.
- The sutureless pump connector fully covers the catheter port as depicted below. The following images show a fully connected catheter with reference to lateral and top views of a Medtronic SynchroMed II pump.

Lateral View of Complete Connection

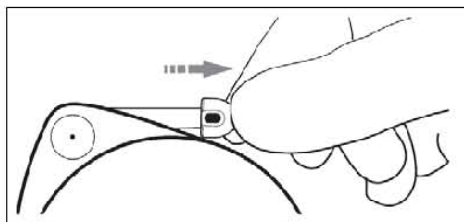


Top View of Complete Connection



4. Tug and Rotate the sutureless connector to verify the sutureless connector is properly attached to the pump

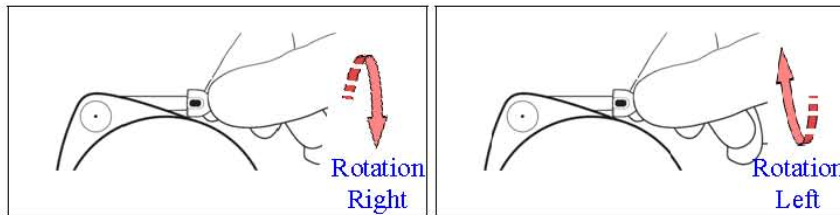
- Check that the sutureless pump connector is properly attached by using the following method:
 - Grasp the **tapered portion** of the sutureless pump connector.
 - **Tug** as if to remove the connector from the pump. The connector should feel firmly attached.



ATTACHMENT 2 (CONT)



- **Rotate** the sutureless pump connector at least 90° to the right and to the left.
Note: the catheter **should not** appear to 'wobble' when rotated. The catheter port should not be visible from any position.



- If the sutureless pump connector does not feel firmly attached, **do not** use additional methods to secure the connector. **Remove** the connector and reattach it to the pump beginning with alignment of the sutureless pump connector with the pump catheter port.

ATTACHMENT 3

Medtronic Recommendations for Patency Verification



Sutureless Connector ('SC') Intrathecal Catheters (Models 8709SC, 8731SC, 8596SC, 8578)

Recommendations for Patency Verification

If there are any questions related to the patency of the catheter-pump connection, a contrast medium may be used with fluoroscopy to verify flow from the pump to the catheter.

Warnings Associated with Performing a Catheter Contrast Study

**(For complete warnings and precautions, refer to the
Medtronic Catheter Access Port Kit Technical Manual)**

Contrast Medium

- When injecting contrast medium into the intraspinal space: Use only contrast medium indicated for intraspinal use. Using non-indicated medium can result in adverse events including, but not limited to, extreme pain, cramps, seizures, and death.
- Before injecting contrast medium or any fluids through the catheter access port, aspirate approximately 1 - 2 mL from the catheter (unless contraindicated). A significant amount of drug may be present in the catheter access port and catheter. Failure to remove the drug during catheter access port injections can result in a clinically significant or fatal drug overdose.

Injection Error

- Be certain you are accessing the correct port when injecting fluids into the reservoir fill port or accessing the catheter access port of an implanted pump.
- ALWAYS:
 - Identify the pump model and reservoir volume;
 - Identify the location of the reservoir fill port and catheter access port.
 - Use the instructions, needles, and other accessories provided in the appropriate kit
 - Verify the location of the correct port during needle insertion, using other medical procedures as appropriate
 - Refer to the appropriate drug labeling for indications, contraindications, warnings, precautions, adverse events, and dosage and administration information. Improper injection into the pump pocket or catheter access port can result in significant tissue damage or a clinically significant or fatal drug underdose or overdose.

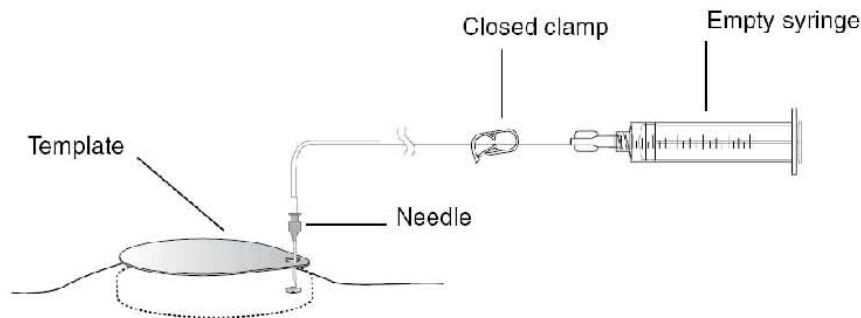
Catheter Contrast Study

- Only use a Medtronic catheter access port (CAP) kit to access the catheter access port septum. NOTE: For complete instructions, warnings, and precautions, refer to the Catheter Access Port Procedure in the appropriate catheter access port kit technical manual.
 - Part Number 8540: SynchroMed Catheter Access Port Kit
 - Part Number 8543: IsoMed Catheter Access Port Kit

ATTACHMENT 3 (CONT)



- Prepare a 10 mL syringe with 5 mL of water-soluble, preservative-free, radiopaque contrast solution labeled for intraspinal use. Omnipaque^{®1} (for intrathecal use) is an example of a commonly used contrast solution.
- Using sterile procedures, assemble the needle, extension tubing, and empty syringe (Figure 1).



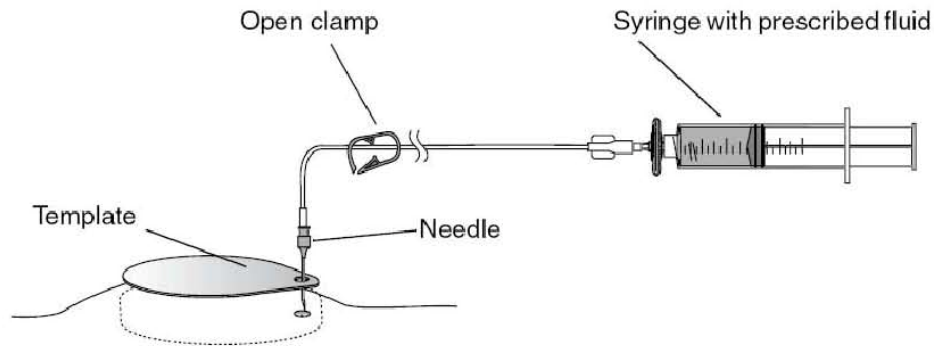
- Close the clamp and gently insert the needle into the catheter access port septum until the needle touches the needle stop.
- Open the clamp and aspirate approximately 1-2 mL of fluid from the catheter access port to ensure removal of drug from the catheter access port and catheter. If a complete occlusion has occurred, aspiration from the catheter access port may be impossible. If partial occlusion has occurred, aspiration may be difficult. If drug cannot be aspirated from the catheter, carefully consider the possibility of overdose before proceeding with this study.
- Close the clamp and remove the syringe.
Note: Keep the needle in the catheter access port septum and the clamp closed for the procedure that follows.
- Attach the filter to the syringe containing the prescribed fluid and purge the air from the fluid pathway.

¹ Omnipaque manufactured by Amersham Health, Princeton, NJ.

ATTACHMENT 3 (CONT)



- Attach the syringe with the prescribed fluid and filter to the extension tubing set (Figure 2).



- Open the clamp and inject 2-5 mL of imaging solution into the catheter access port using the prepared 10 mL syringe.
- Observe the full length of the catheter and all connections.
 - Radiopaque solution may be detected at the catheter tip or the site of catheter disconnection or leak.
 - The solution will darken the appearance of the catheter on X-ray.
 - For intrathecal catheters, the contrast medium will diffuse rapidly throughout the cerebrospinal fluid.
 - Elevating the head of the X-ray table will enhance the caudal diffusion of the solution.
 - For epidural catheters, the contrast medium will diffuse more slowly and remain localized.
 - If a complete occlusion has occurred, injection of the contrast medium through the access port will be impossible. If a partial occlusion has occurred, injection will be difficult. Be aware that contrast medium injected into a partially occluded catheter may push through the occlusion giving the patient a drug bolus if the catheter was not aspirated.
- Complete the procedure by flushing contrast medium through the catheter access port with 5 mL of sterile, preservative-free 0.9% normal saline.
- Subsequent to a contrast study, if the catheter is found patent, the appropriate priming bolus must be performed per the implant manual to advance the drug to the catheter tip.