

## SAFETY ALERT

### **Proper Connection of Sutureless Connector Intrathecal Catheters**

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

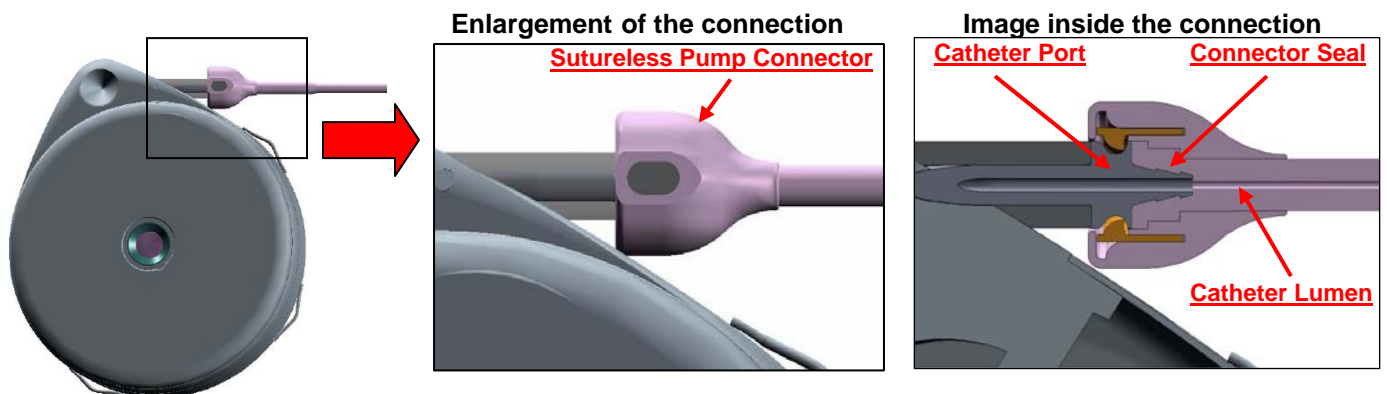
Dear Healthcare Professional,

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

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<sup>®</sup> Intrathecal) are at higher risk for adverse events as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively<sup>1</sup>.

**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.**

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

**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](http://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