August 2009

Medical Device Correction

Sutureless Connector (SC) Intrathecal Catheters Are Not Compatible with IsoMed® Constant–Flow Infusion Pumps

SC Catheter and Revision Kit Models: 8709SC, 8731SC, 8596SC, 8578
IsoMed Pump Model: 8472

Dear Healthcare Professional,

This letter provides important safety information regarding Medtronic Sutureless Connector (SC) catheters and revision kits (hereafter referred to as "SC catheters"). The current SC catheter labeling incorrectly states that SC catheters are compatible with Medtronic IsoMed® constant-flow infusion pumps.
SC catheters are not compatible with IsoMed pumps.

SC catheters are compatible with Medtronic SynchroMed® II and SynchroMed EL pumps.

Nature of the Issue:
Medtronic has determined that SC catheters are not compatible with IsoMed pumps. A physical interference between the SC catheter connector and the IsoMed pump prevents the SC catheter from completely connecting to the IsoMed pump (reference Attachment A), even though it may appear to be connected and feel secure. This incompatibility is a design issue and is not related to implant technique.

Incomplete connection may result in catheter disconnection from the IsoMed pump or an occlusion at the connection site. Connection of an SC catheter to an IsoMed pump may also result in permanent damage to the SC catheter connector, which may subsequently prevent complete connection of the damaged SC catheter connector to a Medtronic SynchroMed II or SynchroMed EL pump. Connection of an SC catheter to an IsoMed pump does not damage the IsoMed pump.

Scope:
This issue affects all SC catheters that are, or have been, connected to an IsoMed pump[1]. Through June 2009, Medtronic has received ten (10) reports worldwide related to improper connection of an SC catheter to an IsoMed pump (an occurrence rate of approximately 2%). Nine (9) of these reports were for catheter disconnection from the IsoMed pump and one (1) was for occlusion. Although these 10 events reportedly occurred sometime between 1 and 415 days post-implant, disconnections or occlusions due to this issue are not dependent upon implant duration.

Potential Severity of the Issue:
In all ten (10) reports referenced above, medical intervention was required to correct the condition. The 10 reported events included reports of return of underlying symptoms, withdrawal symptoms, and seroma. In one case, it was reported that a patient death occurred two (2) days following device revision. It can not be substantiated whether the cause of death is or is not related to the device.

The clinical manifestations of an incomplete connection of an SC catheter to an IsoMed pump may include, but are not limited to:

- Drug or cerebrospinal fluid (CSF) leakage into surrounding tissue, resulting in tissue damage
- Loss of or change in therapy
- A return of underlying symptoms
- Drug withdrawal symptoms, and/or
- A clinically significant or fatal drug underdose

[1] Medtronic stopped producing IsoMed pumps in September 2008 as part of a planned product phase-out.

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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 baclofen injection) are at higher risk for adverse events as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively[2].

Recommendations:

- For future revisions and implants, SC catheters must not be used with IsoMed pumps. In addition, an SC catheter previously connected to an IsoMed pump must not be connected to a SynchroMed pump because the SC connector may have been permanently damaged.
- If an SC catheter is, or has been, connected to an IsoMed pump, clinical judgment should be used to determine if prophylactic revision is warranted. Appropriate consideration should be given to individual patient medical needs. The following risks should be considered:
    - The medical risk of recurrent or worsening symptoms, particularly for patients at risk for complications due to withdrawal.
    - The surgical risk of prophylactic revision (e.g. risk of infection and consequent delay of reinitiating drug infusion).
- If a disconnection or occlusion is identified, revision is necessary. Refer to Attachment B for appropriate revision options.

  Important Consideration: Consider patient dosing parameters if a disconnection or occlusion is corrected. Patients who have had their intrathecal therapy interrupted for any reason may be effectively drug naive at the time of system revision. For this reason, there is the potential for drug overdose subsequent to correction of any catheter disconnection or occlusion. Always follow applicable drug labeling for appropriate therapy initial dosing parameters and patient monitoring recommendations.

- 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.

Additional Information:

The US Food and Drug Administration (FDA) has been made aware of this SC catheter / IsoMed pump incompatibility issue. Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation Technical Services at 1-800-707-0933 and FDA's MedWatch Program (www.fda.gov/medwatch).

As always, Medtronic requests you return any explanted products to Medtronic Returned Products Analysis. If you have questions please contact your Medtronic field representative, or contact Medtronic Neuromodulation Technical Services at 1-800-707-0933. This important patient management information is also available at http://www.professional.medtronic.com under the heading *Advisories*.

Sincerely,

George Aram
Vice President Quality
Medtronic Neuromodulation

[2] Intrathecal baclofen therapy is not indicated for use in IsoMed pumps in the US. 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 Lioresal is a registered trademark of Novartis Corporation.

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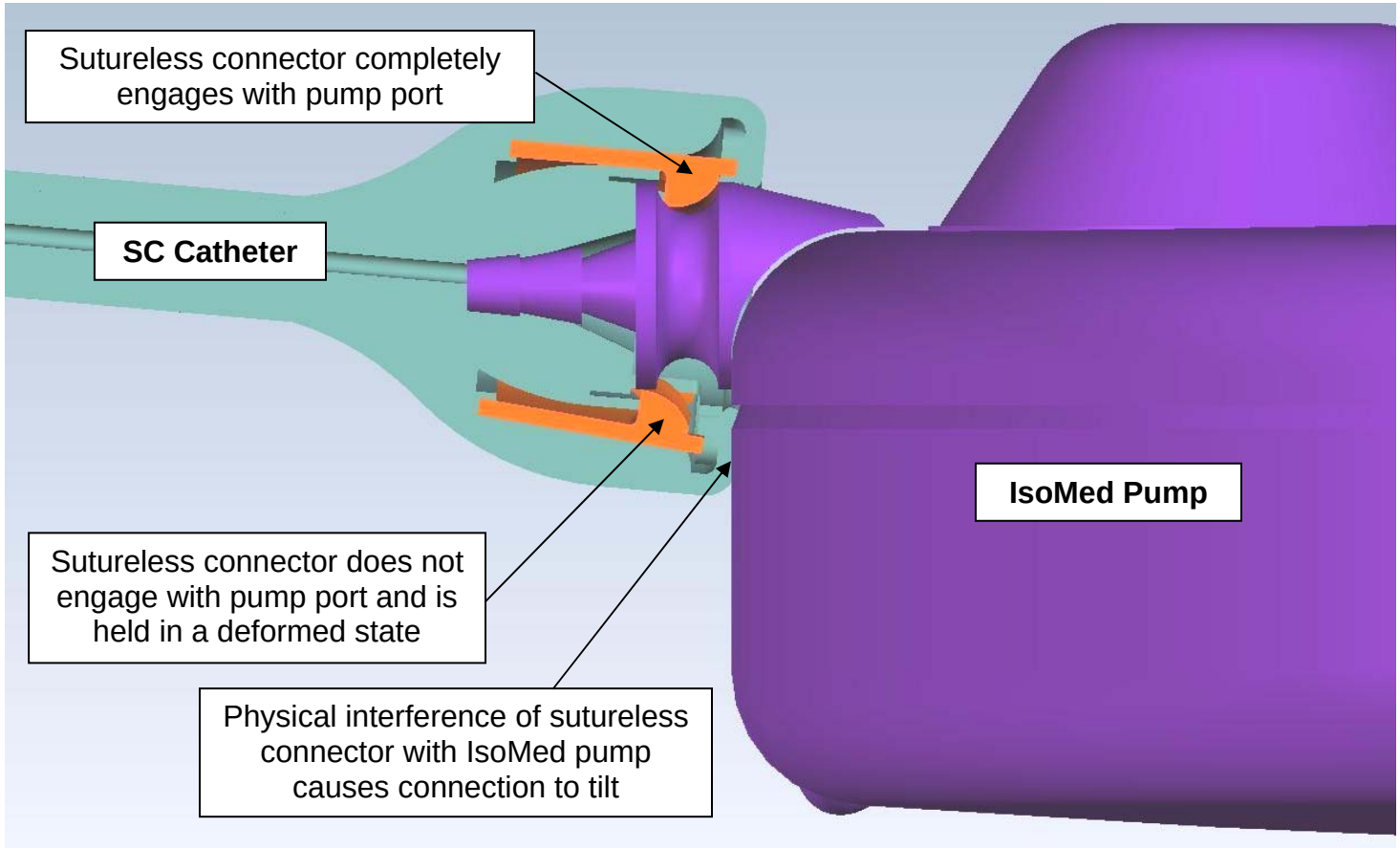
Attachment A

SC Catheter / IsoMed Pump Incompatibility (Physical Interference)



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Attachment B

Replacement Options for SC Catheter / IsoMed Pump Configurations

CURRENT CONFIGURATION			REPLACEMENT OPTIONS[1]			
Configuration	**Pump**	**Catheter / Pump Segment**	**Pump Segment Only**	**Catheter Only**	**Pump Segment and Pump**	**Catheter and Pump**
1	8472	8709SC	8577[2]	8709 or 8711	8578 and 8637	Any catheter and 8637
2	8472	8731SC	8596	8709 or 8711	8596SC and 8637	Any catheter and 8637
3	8472	8578	8577[2]	8709 or 8711	8578 and 8637	Any catheter and 8637
4	8472	8596SC	8596	8709 or 8711	8596SC and 8637	Any catheter and 8637

[1]Replacing only the pump to address this issue is not an option. An SC catheter previously connected to an IsoMed pump should not be connected to any pump because the SC connector may have been permanently damaged.
[2]The 8577 pump connector is 7.6 cm shorter than the 8709SC and 8578 pump connectors. Ensure adequate catheter length at the pump end of the catheter is available for making the pump connection before performing a revision. Ensure the reduced total catheter length is recorded and used for calculating catheter volume.

Model Descriptions

Model	Description
8472	IsoMed implantable constant-flow infusion pump
8577	90 degree pump connector (sutured connector for IsoMed pumps and 8709/8709SC catheters)
8578	Pump connector revision kit (sutureless pump connector for 8709/8709SC catheters)
8596	Pump segment revision kit (sutured connector for 8731/8731SC catheters)
8596SC	Pump segment revision kit (sutureless pump connector for 8731/8731SC catheters)
8637	SynchroMed II infusion pump
8703	Intraspinal catheter, two-piece (with sutured pump connector)
8703W	Intraspinal catheter, two-piece (with sutured pump connector)
8709	InDura® intrathecal catheter, one-piece (with sutured pump connector)
8709AA	InDura intrathecal catheter, one-piece (with sutured pump connector)
8709SC	InDura intrathecal catheter, one-piece (with sutureless pump connector)
8711	InDura intrathecal catheter, two-piece (with sutured pump connector)
8731	Intrathecal catheter, two-piece (with sutured pump connector)
8731SC	Intrathecal catheter, two-piece (with sutureless pump connector)