

NATIONAL RECALL ALERT CENTER - IMMEDIATE WARNING ALERT NOTIFICATION  
THE FOLLOWING HAVE BEEN RECALLED OR ARE SUBJECT TO FIELD CORRECTION  
THIS LISTING IS ISSUED BY - NATIONAL RECALL ALERT CENTER, WASHINGTON, D.C.

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**THE FOLLOWING PRODUCT IS A CLASS I RECALL. THERE IS A REASONABLE PROBABILITY THAT THE USE OF THE AFFECTED PRODUCT MAY CAUSE SERIOUS INJURY OR DEATH IF THE PROBLEM IS NOT CORRECTED.**

<b>PRODUCT</b>	a) INDURA 1P Intrathecal Catheter, model 8709SC b) Intrathecal Catheter, model 8731SC c) Sutureless Pump Connector Revision Kit, model 8578 d) Intrathecal catheter Pump Segment Revision Kit, model 8596SC <u>When paired with the IsoMed Pump Model 8472, which is no longer manufactured and marketed</u>
<b>RECALL NUMBER</b>	Not available at the time of publication
<b>CODE</b>	Products were distributed beginning on January 1, 2007 and are still in distribution
<b>NOTE</b>	The intrathecal catheter and intrathecal catheter revision kits use a sutureless connector for the final connection to the implanted Medtronic SynchroMed II and SynchroMed EL infusion pumps. The catheter is part of an infusion system that stores and delivers parenteral drugs to the intrathecal and vascular spaces. The catheters with sutureless connectors CANNOT be used with the IsoMed infusion pumps.
<b>NOTE</b>	Other types of intrathecal catheters and intravascular catheters for delivery of chemotherapy are not affected by this issue.
<b>MANUFACTURED &amp; RECALLED BY</b>	Medtronic Neuromodulation, Minneapolis, MN
<b>QUANTITY</b>	Not available at the time of this publication
<b>REASON</b>	The current labeling for Medtronic Sutureless Connector (SC) catheters and revision kits (known collectively as SC catheters) incorrectly states that SC catheters are intended to be used with Medtronic IsoMed constant-flow infusion pumps. SC catheters can only be used with Medtronic SynchroMed II and SynchroMed EL pumps. SC catheters cannot be used with Medtronic IsoMed pumps. A physical interference between the SC catheter connector and the IsoMed pump prevents the SC catheter from the completely connecting to the IsoMed pump even though it may appear to be connected and feels secure. Once an SC catheter is connected to an IsoMed pump, the sutureless connector is considered damaged. This incompatibility is a design issue and is not related to the implant technique. An incomplete connection may result in a catheter disconnection from the IsoMed pump or a blockage may occur at the connection site. Connecting an SC catheter to an IsoMed pump does not damage the IsoMed pump.
<b>CONTACT</b>	Professionals may contact 1-800-328-0810 – Monday – Friday, 8 AM to 5 PM Central Time

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