

REPUBLIC OF LEEANON

MINISTRY OF PUBLIC HEALTH

The Director General



الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٥٧/٢٥

رقم الصادر: ١٢/٧٢٠٦

بيروت، في:

٥ - آب - ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Medtronic Intrathecal Catheter Pump Segment Revision Kit Model (8596SC, 8709SC, 8578, 8731SC)

الجهاز المعني بالمتابعة:

- Medtronic Intrathecal Catheter Pump Segment Revision Kit Model (8596SC, 8709SC, 8578, 8731SC)
- Trade Mark: Medtronic Neuromodulation
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

والذي يشير الى وجود خلل في عمل الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

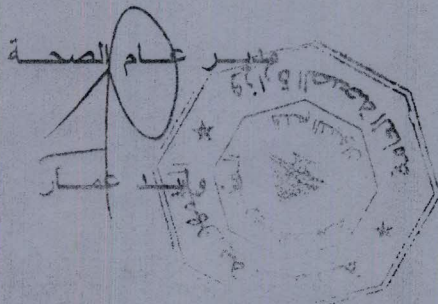
- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع

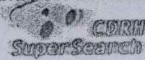
- المستشفيات الحكومية

- المحفوظات



FDA Home³ Medical Devices⁴ Databases⁵

Medical & Radiation Emitting Device Recalls

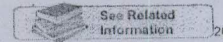


510(k)⁷ Registration & Listing⁸ Adverse Events⁹ Recalls¹⁰ PMA¹¹ Classification¹² Standards¹³
 CFR Title 21¹⁴ Radiation-Emitting Products¹⁵ X-Ray Assembler¹⁶ Medsun Reports¹⁷ CLIA¹⁸ TPLC¹⁹

New Search

[Back to Search Results](#)

Class 1 Recall
Medtronic Sutureless Pump Connector Revision Kit



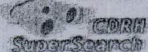
Date Posted	June 24, 2013
Recall Number	Z-1573-2013
Product	Medtronic Sutureless Pump Connector Revision Kit, model 8578. Contents: catheter interface with attached sutureless pump connector, catheter, connector pin, and strain-relief sleeve to be used with Medtronic SynchroMed implantable drug infusion pumps. Contents of inner package are STERILE. The Medtronic Model 8578 Sutureless Pump Connector Revision Kit is used when a pump connector for an Indura 1P Model 8709 or Model 8709SC catheter is required. The catheter is part of an infusion system that stores and delivers parenteral drugs to the intrathecal space. The implanted infusion system components consist of a Medtronic pump and an Indura 1P Model 8709 or Model 8709SC catheter. The catheter connects to the pump with the Model 8578 sutureless pump connector at the catheter port.
Code Information	Product having a Use By Date prior to 25 Aug 2014
Recalling Firm/Manufacturer	Medtronic Neuromodulation 7000 Central Ave NE Minneapolis, Minnesota 55432-3568
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Technical Services 800-707-0933
Reason for Recall	The Sutureless Connector (SC) Intrathecal Catheter connector has been redesigned to reduce the potential for occlusion at the catheter to pump interface. Medtronic is removing the unused products from the market that were manufactured with the previous design, and recommend the previous design no longer be used due to greater potential for misalignment and subsequent occlusion.
Action	The firm, Medtronic, sent an "Urgent: Medical Device Removal" letter dated May 2013 to its customers. The letter described the product, problem and actions to be taken. Representatives (Rep) are visiting all locations, beginning June 3, 2013, to retrieve devices with a Use By date of 2014 08 14 (August 14, 2014) or sooner. The Rep is leaving a letter with the hospitals to tell them that the Sutureless Connector Intrathecal Catheter connector has been redesigned and that they are removing unused devices. They also do not recommend using any of the old design. An Account Specific Customer Confirmation Form will be completed by the Rep. A copy of the completed form will be left with the Hospital along with the Urgent Medical Device Removal letter. If you have questions, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am - 6pm CST.
Quantity in Commerce	115,722 total
Distribution	Worldwide distribution, US (nationwide) and countries of: Aruba, Australia, Austria, Belgium, Canada, Chile, China, Colombia, Costa Rica, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Finland, France, Georgia, Germany, Greece, Guadeloupe, Hong Kong, Hungary, Iceland, India, Ireland, Israel, Italy, Jordan, Korea, Kuwait, Lebanon, Lithuania, Luxembourg, Malta, Martinique, Morocco, Netherlands, Netherlands Antilles, New Zealand, Norway, Panama, Poland, Portugal, Puerto Rico, Qatar, Romania, Russian Federation, San Marino, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, Trinidad and Tobago, Turkey, United Arab Emirates, United Kingdom, Uruguay, and Venezuela.

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. [../cfPMN/pmnm.cfm](..cfPMN/pmnm.cfm)
8. [../cfRL/rl.cfm](..cfRL/rl.cfm)
9. [../cfMAUDE/TextSearch.cfm](..cfMAUDE/TextSearch.cfm)

[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

Medical & Radiation Emitting Device Recalls

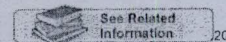


510(k)⁷ | [Registration & Listing](#)⁸ | [Adverse Events](#)⁹ | [Recalls](#)¹⁰ | [PMA](#)¹¹ | [Classification](#)¹² | [Standards](#)¹³ | [CFR Title 21](#)¹⁴ | [Radiation-Emitting Products](#)¹⁵ | [X-Ray Assembler](#)¹⁶ | [Medsun Reports](#)¹⁷ | [CLIA](#)¹⁸ | [TPLC](#)¹⁹

[New Search](#)

[Back to Search Results](#)

**Class 1 Recall
Medtronic Intrathecal Catheter Pump
Segment Revision Kit**



Date Posted	June 24, 2013
Recall Number	Z-1574-2013
Product	Medtronic Intrathecal Catheter Pump Segment Revision Kit, model 8596SC. Contents: 60-cm pump segment with attached sutureless pump connector, Spinal Segment Strain-relief sleeves, Pump segment strain-relief sleeves, Connector pin. Contents of inner package are STERILE. The Medtronic Model 8596SC Pump Segment Revision Kit is used when a revision to the pump segment of the Model 8731 or Model 8731SC catheter is required. The catheter is part of an infusion system that stores and delivers parenteral drugs to the intrathecal space. The implanted infusion system components consist of a Medtronic pump and a Model 8731 or Model 8731SC catheter. The catheter connects to the pump at the catheter port.
Code Information	Product having a Use By Date prior to 25 Aug 2014
Recalling Firm/ Manufacturer	Medtronic Neuromodulation 7000 Central Ave NE Minneapolis, Minnesota:55432-3568
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Technical Services 800-707-0933
Reason for Recall	The Sutureless Connector (SC) Intrathecal Catheter connector has been redesigned to reduce the potential for occlusion at the catheter to pump interface. Medtronic is removing the unused products from the market that were manufactured with the previous design, and recommend the previous design no longer be used due to greater potential for misalignment and subsequent occlusion.
Action	The firm, Medtronic, sent an "Urgent: Medical Device Removal" letter dated May 2013 to its customers. The letter described the product, problem and actions to be taken. Representatives (Rep) are visiting all locations, beginning June 3, 2013, to retrieve devices with a Use By date of 2014 08 14 (August 14, 2014) or sooner. The Rep is leaving a letter with the hospitals to tell them that the Sutureless Connector Intrathecal Catheter connector has been redesigned and that they are removing unused devices. They also do not recommend using any of the old design. An Account Specific Customer Confirmation Form will be completed by the Rep. A copy of the completed form will be left with the Hospital along with the Urgent Medical Device Removal letter. If you have questions, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am - 6pm CST.
Quantity in Commerce	115,722 total
Distribution	Worldwide distribution: US (nationwide) and countries of: Aruba, Australia, Austria, Belgium, Canada, Chile, China, Colombia, Costa Rica, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Finland, France, Georgia, Germany, Greece, Guadeloupe, Hong Kong, Hungary, Iceland, India, Ireland, Israel, Italy, Jordan, Korea, Kuwait, Lebanon, Lithuania, Luxembourg, Malta, Martinique, Morocco, Netherlands, Netherlands Antilles, New Zealand, Norway, Panama, Poland, Portugal, Puerto Rico, Qatar, Romania, Russian Federation, San Marino, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, Trinidad and Tobago, Turkey, United Arab Emirates, United Kingdom, Uruguay, and Venezuela.

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. [../cfPMN/pmn.cfm](..../cfPMN/pmn.cfm)
8. [../cfRL/rl.cfm](..../cfRL/rl.cfm)
9. [../cfMAUDE/TextSearch.cfm](..../cfMAUDE/TextSearch.cfm)
10. [../cfRES/res.cfm](..../cfRES/res.cfm)