REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٧٥
رقم الصادر: ١٢/٧٥٦٠
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

مدير عام الصحة
وليد عمار

Museum Street - Hussein Mansour Bldg. - Beirut, Lebanon - Tel: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: directorgeneral@moph.gov.lb

## 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<br>7000 Central Ave NE<br>Minneapolis, Minnesota 55432-3568 |
| **Consumer Instructions** | Contact the recalling firm for information |
| **For Additional Information Contact** | Technical Services<br>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. |

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## Medical & Radiation Emitting Device Recalls



Class 1 Recall
Medtronic Intrathecal Catheter Pump Segment Revision Kit

See Related Information[20]

| | |
|---|---|
| **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<br>7000 Central Ave NE<br>Minneapolis, Minnesota 55432-3568 |
| **Consumer Instructions** | Contact the recalling firm for information |
| **For Additional Information Contact** | Technical Services<br>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. |

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