الموضوع: إشعار بمتابعة جهاز طبي:
Medtronic Intrathecal Catheter Pump Segment Revision Kit Model (8596SC, 8709SC, 8578, 8731SC)

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

FDA بناء على التقرير الصادر عن وكالة ال
والذي يشير الى وجود خلل في عمل الصفن المذكور أعلاه، نرجو منكم تعميم هذه النشرة على
جميع المستشفى المعنية.

مرفق ربط:
- التقرير الصادر عن وكالة ال
- يبلغ:
  - دائرة الضرم والمشاريع
  - المستشفى الحكومية
  - المحفوظات
Medical & Radiation Emitting Device Recalls

Class 1 Recall
Medtronic Sutureless Pump Connector Revision Kit

Date Posted
June 24, 2012

Recall Number
Z-1575-2013

Product
Medtronic Sutureless Pump Connector Revision Kit, model 8578. Contents: catheter interface with attached sutureless pump connector, catheter, connector pin, and sterile 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 peripherally 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, MN 55429-3668

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 (nationally) and countries of: Arabia, Australia, Austria, Belgium, Canada, China, Chile, 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, 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:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesat/a/index.cfm
7. /cPMSN/ppms.cfm
8. /cDRU/s.cfm
9. /cPMADE/TextSearch.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=118593
7/23/2013
Medical & Radiation Emitting Device Recalls

Class 1 Recall
Medtronic Intrathecal Catheter Pump Segment Revision Kit

Date Posted: June 24, 2013
Recall Number: 2-1574-2013

Product: Medtronic Intrathecal Catheter Pump Segment Revision Kit, model 65666C.
Content: 60-cm pump segment with attached Sureplast pump connector, Spinal Segment Strain-relief sleeves, Pump segment strain-relief sleeves, Connector pin.
Contents of inner package are STERILE. The Medtronic Model 65666C Pump Segment Revision Kit is used when a revision to the pump segment of the Model 8731 or Model 87310C catheter is required. The catheter is part of an infusion system that stores and delivers peripherally drugs to the intrathecal space. The implanted, infusion system components consist of a Medtronic pump and a Model 8731 or Model 87310C 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 Neurotechnology
7020 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 Sureplast 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 recommends 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. In the letter, the product, problem, and actions to be taken were described. Representatives (Rep) are visiting, in 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 Sureplast 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 Neurotechnology Technical Services at 800-707-0933 weekdays 7am - 6pm CST.

Quantity in Commerce: 115,722 total

Distribution: Worldwide distribution: US (nationwide) and countries of: Arabia, 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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