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URGENT FIELD SAFETY NOTICE

Sutureless Connector Intrathecal Catheter Products
Models 8709SC, 8731SC, 8596SC, 8578 with Use By Date prior to August 25, 2014
RECALL

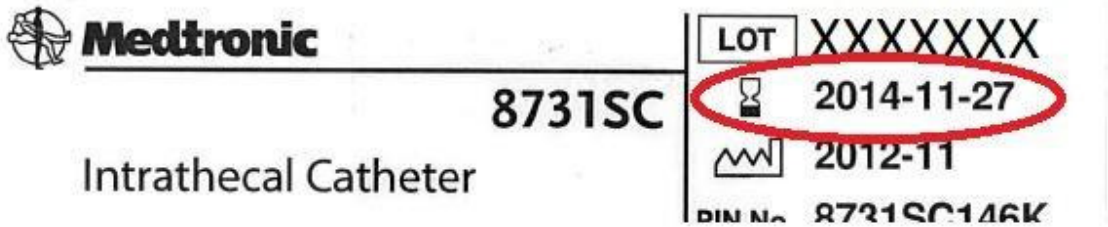
Medtronic Reference: FA579 5 June 2013

Dear Healthcare Professional,

The Sutureless Connector (SC) Intrathecal Catheter connector has been redesigned to reduce the potential for occlusion at the catheter to pump interface. SC catheters are used with Medtronic SynchroMed implantable drug infusion pumps. Medtronic is removing 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.

Your account will be credited for the returned products upon receipt by Medtronic. Current design products are available for order, and your Medtronic Representative can facilitate immediate replacement as needed to support scheduled procedures. We are leaving this letter for your records to document the product removal that is being facilitated by your Medtronic representative.

All SC Catheter products with a Use By date prior to August 25, 2014 are affected by this action. The image below is an example showing where the Use By date is located at the bottom of the label.



The Irish Medicines Board has been notified of this action.

Please share this notification with others in your organization as appropriate.

If you have any questions related to the removal of this inventory please contact your Medtronic representative at 01 511 1400. Medtronic thanks you for your continued business and is committed to providing you with the highest quality products, services, and ongoing support as you care for your patients.

Yours sincerely,

LJ Bridge

Lezlie Bridge BSc. DMS
Regulatory Affairs Manager – UK & Ireland