Medtronic

Medtronic International Ltd.
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URGENT MEDICAL DEVICE RECALL

Model 53912 External Pulse Generator (EPG) Extension Cable, Reusable
Model 53912A EPG Extension Cable, packaged with Model 5391 EPG
Model 53912D EPG Extension Cable, Disposable

July 2017

Dear Risk Manager or Health Care Professional,

Medtronic was recently notified by Oscor, Inc. of a revised customer communication titled "Voluntary Product Removal of Certain Lots of ATAR™ Extension Cables" (see enclosed). You may have also received the enclosed communication directly from Oscor. This communication by Oscor was issued due to the possibility that both Reusable and Disposable Oscor ATAR extension cables could separate from the connector at the proximal end. In response to this communication, Medtronic is initiating this **Urgent Medical Device Recall. This communication replaces an earlier Medical Device Correction communication, dated May 2017, that you may have received from Medtronic for 53912 and 53912A Reusable EPG Cables.**

Medtronic sells these Oscor ATAR extension cables individually as the following:

- Model 53912 Reusable External Pulse Generator (EPG) Extension Cable
- Model 53912A Reusable EPG Extension Cable (packaged with Medtronic 5391 EPGs)
- Model 53912D Disposable EPG Extension Cable

This issue affects all lots and serials of the above product distributed by Medtronic, but does not affect any other EPG cables or any EPG devices distributed by Medtronic. Our records indicate that your facility has received one or more of the above cables.

Through 27 June 2017, Medtronic has identified 34 confirmed complaints with **four (4) reports of malfunctions during use requiring intervention to restore patient health, and zero (0) reports of permanent injury or death related to this issue**. This results in an estimated complaint rate from 0.011% to 0.032% (1.1 to 3.2 per 10,000 uses) for Medtronic distributed cables. These complaints were confirmed by Oscor to be related to this issue. Medtronic does not have visibility to other complaints that Oscor could have received regarding this product.

Oscor has advised that for pacing dependent patients, continuous monitoring, such as monitoring with an EKG, is required.

Medtronic is requesting that you carry out the actions below; in addition to requested actions indicated in the enclosed communication sent by Oscor:

- Please review your inventory for product affected by this issue.
- Immediately identify and quarantine all affected product in your inventory.
- Return all affected product in your inventory to Medtronic by contacting Medtronic CRHF number +65 94775075 and referencing this communication to initiate a return of product.
- Your Medtronic sales representative can assist you in the return of affected product as necessary.
- Complete the enclosed Customer Confirmation Certificate and return it to Medtronic sales representative.

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Share this notice with those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Sales Representative.

Sincerely,

Joo Ee Yap
Business Director CRHF SEA

Enclosures:

- Oscor's "Voluntary Product Removal of Certain Lots of ATAR™ Extension Cables" customer communication
- Medtronic Customer Confirmation Certificate

cc: Chairman Medical Board and relevant Head of Departments