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URGENT MEDICAL DEVICE CORRECTION

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

May, 2017

Dear Risk Manager or Health Care Professional,

Medtronic was recently notified by Oscor of a customer communication titled "Important Information Regarding Reusable ATAR Extension Cables" (see enclosed). This communication by Oscor was issued due to the possibility that Reusable OSCOR ATAR extension cables could separate from the connector during use when the instructions for reuse are not being followed.

Medtronic sells the Oscor ATAR extension cables individually as the model 53912 Reusable External Pulse Generator (EPG) Extension Cable, and with 5391 EPGs as the model 53912A Reusable EPG Extension Cable. This issue affects reusable cables of these models and does not affect any other EPG cables including model 53912D single use disposable cables. Our records indicate that your facility has received one or more of the cable models impacted by this notification.

Through 20 April 2017, Medtronic has identified 34 confirmed complaints with **4 reports of malfunctions during use requiring intervention to restore patient health, and no reports of death related to this issue**. This results in an estimated complaint rate from 0.012% to 0.042% (1.2 to 4.2 per 10,000 uses) for Medtronic distributed cables. These complaints were confirmed by Oscor to be related to this issue.

During continued use of these cables, to minimize the potential for a connector to cable separation, and other potential issues with the cables, Medtronic is requesting that you carry out the actions below; in addition to requested actions indicated in the enclosed communication sent by Oscor:

- Limit use of these extension cables to first use + 2 re-uses
- After each use of the 53912 or 53912A extension cables, the cables should be sent to Oscor for inspection and sterilization per the instruction for use.
- Complete, sign, and return the enclosed customer confirmation certificate.

Contact Medtronic Representative to arrange for return to Oscor per the Instructions For Use (IFU).

Please share this notification with others in your organization as appropriate. If product within scope of this notification has been forwarded to another facility, please notify the facility of the issue.

If you have any questions, please do not hesitate to contact your Medtronic representative.

We appreciate your cooperation and apologize for the inconvenience that this issue may cause.

Sincerely,

Joo Ee Yap
Business Director CRHF SEA

Enclosures:

- Oscor's "Important Information Regarding Reusable ATAR Extension Cables" customer communication
- Medtronic Customer Confirmation Certificate

cc: Chairman Medical Board and relevant Head of Departments