Medtronic

Urgent Field Safety Notice

LINQ II™ Insertable Cardiac Monitoring Systems

Brady, Pause & PVC Detections Disabled Following Partial Electric Reset

Customer Notification

Affected Model Number	Model Description
LNQ22	LINQ II™

August 2021

Medtronic Reference: FA979 phase II

Dear Healthcare Professional,

This letter is to inform you of the availability of LINQ II™ Insertable Cardiac Monitors (ICMs) with an TÜV approved update addressing the issue disclosed in June Communication (our reference FA979). Updated LINQ II ICMs will not be susceptible to the potential for disabled Brady, Pause, and PVC detection after a partial electrical reset.

Updated LINQ II ICMs can be distinguished as described in the attached Tip Card.

Please work with your local Medtronic Representative to learn more about availability of updated LINQ II ICMs for your patients.

Note that:

- LINQ II ICMs manufactured prior to the approval of this update cannot be corrected in the field.
  - LINQ II ICMs implanted prior to the release of this update will continue to be susceptible to this issue.
- Please continue to return all unused, affected LINQ II ICMs in your inventory to Medtronic. Please contact your local Medtronic Representative at <XXXX> to assist you with a product return.
- Initial supply of the updated LINQ II ICMs may be limited, therefore it may be necessary to use an alternative ICM if Medtronic is unable to fulfil any current request you may have. Please be reassured that Medtronic is working diligently to increase production to meet demand.

We regret any difficulties this issue may have caused you or your patients. We remain dedicated to ensuring the highest level of quality and will continue to monitor device performance to ensure we meet your needs and those of your patients.

Sincerely,

Local / BU Manager

Enclosure: Tip Card – Identification of updated LINQ II ICMs