Urgent Field Safety Notice

Medtronic Perfusion Tubing Packs
Manufactured with devices missing Bacterial Endotoxin Testing (BET) results
Recall

October 2021

Medtronic reference: FA1200

Dear Risk Manager, Health Care Professional, or Perfusionist:

Medtronic is writing to inform you about specific lots of Medtronic Perfusion Tubing Packs that were manufactured without device-level testing for bacterial endotoxin which is necessary to support the non-pyrogenic label claim. Globally, 165 lots of Medtronic Perfusion Tubing Packs are affected by this issue. Our records indicate that your facility has received one or more of the affected Medtronic Perfusion Tubing Pack lots as listed in the enclosed product list report.

Issue Description:
Some individual devices contained within the affected Medtronic Perfusion Tubing Packs were manufactured and distributed without device-level bacterial endotoxin testing. These results are necessary to support the non-pyrogenic label claim. Evaluation of the existing manufacturing controls and historical data suggest that the affected devices likely meet the requirement to be non-pyrogenic; however, due to the lack of data required to support the non-pyrogenic label claim, Medtronic is recalling the 165 lots of Medtronic Perfusion Tubing Packs.

Through October 6, 2021, Medtronic has received zero (0) complaints or reports of adverse events related to this issue. For affected product that has been used, no action is necessary, and patients should continue to be managed in accordance with your standard patient management protocol.

The potential patient harms resulting from endotoxin-mediated pyrogenicity include fever, infection, toxic reaction (acute systemic), and death resulting from complete organ failure.

Customer Actions:
To mitigate risks associated with this issue, Medtronic is requesting that you carry out the actions below:

- Please review your inventory for Medtronic Perfusion Tubing Packs affected by this issue as listed in the enclosed product list report
- Immediately identify and quarantine all unused, affected product in your inventory.
- Return unused, affected Medtronic Perfusion Tubing Packs in your inventory to Medtronic. Your local Medtronic Field Representative can assist you as necessary in initiating the return and replacement of this product.

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

Please maintain a copy of this communication in your records. Medtronic has notified the Competent Authority of your country of this action.

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 Representative

Sincerely,
Medtronic

Enclosure A: Product list report
Enclosure A:

Table 1: List of affected Lots, Germany

<table>
<thead>
<tr>
<th>Product Names, Unique Device Identifier (if applicable)</th>
<th>Global Trade Item Number (GTIN)</th>
<th>Customer Facing Number (CFN)</th>
<th>Lot/Serial Number</th>
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