Medtronic

URGENT FIELD SAFETY NOTICE

Minimed™ Implantable Pump Endotoxin Level MMT-2007D Recall

April 2020

Medtronic reference: FA911

Dear Valued Customer,

At 10 April 2020, Medtronic initiated a verbal communication about an Urgent Field Safety Notice for specific MiniMed™ Implantable Pumps (MIP) in your inventory which may be impacted by a potential safety risk. This notice is a follow-up to that verbal notification provided to your facility, where Medtronic requested that you put unused affected pumps in quarantine.
Because your patient's safety is our top priority, we are making you aware of the actions required by you.

Issue Description:
Routine testing is performed on samples of the MiniMed™ Implantable Pump (MIP) as part of the manufacturing process to ensure the level of endotoxins present inside the insulin chamber of the device meets an approved limit. Endotoxins are remnants of gram-negative bacteria that may remain after the device is sterilized and are non-toxic when present below a pre-specified level. Recently, we received an endotoxin-related test result in our manufacturing process that did not meet our quality specifications.

If pumps have higher than allowed endotoxin levels, patients may have an effect of fever, hypotension, anaphylactic shock, hyperglycemia, or diabetic ketoacidosis (DKA), potentially followed by secondary multi-organ failure (primarily renal and hepatic) and/or death. Considering the immediate nature of a pyrogenic response, no incremental risk is expected for patients with implanted devices.

This issue affects MiniMed™ Implantable Pumps produced since May 21, 2019. As of April 15, 2020, there have been no reported complaints from customers for affected pumps as a result of this issue. There are no recommended actions required for implanted pumps.

Actions required from you:

1. Immediately identify and quarantine all unused affected pumps in your inventory with the following serial number(s): 31359 and 31360.
2. Return all unused affected pumps in your inventory to Medtronic. Your Medtronic Representative can assist you in the return and replacement of this pump as necessary.
3. Forward this notice to all those who need to be aware within your organization and to any organization where the affected pumps may have been transferred. Please maintain a copy of this notice in your records.

The Competent Authority of your country has been notified of this action.
Please contact our Customer Support team at 0800-3422338 if you have any questions.

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies. We appreciate your time and attention to this important update and apologize for any inconvenience this may cause you.

Sincerely,

.....

LET'S TAKE HEALTHCARE
FURTHER, TOGETHER