

Urgent Field Safety Notice

Medtronic MiniMed Infusion Sets - Recall of specific Lot Numbers Potential over-delivery of insulin

September 2017

Medtronic reference: FA784

Dear Distributor, Service Provider,

The purpose of this letter is to notify you that we are voluntarily recalling specific lots of infusion sets used with Medtronic insulin pumps.

Medtronic has become aware of recent reports of potential over-delivery of insulin shortly after an infusion set change that have required medical intervention. Our investigation has shown this can be caused by fluid blocking the infusion set membrane during the priming/fill-tubing process. A membrane blocked by fluid most likely occurs if insulin, alcohol, or water is spilled on the top of the insulin reservoir which then could prevent the infusion set from working properly. Infusion sets currently being shipped by Medtronic contain an enhanced membrane material that significantly reduces this risk.

We request you to inform your patients of this recall, using the attached letter, to ask them to do the following:

- A. Patients are instructed to go to www.mmc.medtronic-diabetes.com/look and determine if they have recalled infusion sets. The website will prompt them to enter the REF and LOT numbers for all infusion sets in their possession. The website will then tell them which infusion sets are part of this recall and which are not.

The REF and LOT numbers are listed on the labels as shown in the below examples:



- B. Medtronic recommends that the recalled infusion sets are not used by patients.
 - a. If they have new and enhanced infusion sets that are not part of this recall, they should use only those sets starting with their next set change. As a reminder, we have enclosed Key Steps regarding the priming/fill-tubing process.
 - b. If they only have recalled infusion sets right now, it is very important that they carefully follow the Key Steps.
- C. Patients are instructed to discard their recalled infusion. Medtronic will replace the recalled infusion sets free of charge.

Medtronic

Instruct your patients to cut out the LOT numbers of the affected boxes and discard recalled infusion sets. Collect patients LOT numbers and contact Medtronic at <XXXX> for further instructions.

If there are any affected MiniMed Infusion Sets in your inventory, cut out the LOT number labels of the affected boxes, discard recalled infusion sets and contact Medtronic at <XXXX> for further instructions.

The Competent Authority of your country has been notified of this action.

Medtronic considers patient safety and customer satisfaction our primary priorities. We appreciate your time and attention in reading this important notification. In case of any questions contact your Medtronic representative at <XXXX>.

Sincerely,

Country/BU manager

Enclosures:

1. Pump user letter
2. HCP letter V2
3. Key Steps: Infusion Set Priming / Fill-tubing Process