

Medtronic MiniMed Infusion Sets Potential over-delivery of insulin

September 2017

Medtronic reference: FA784

Dear pump user,

Because the safety of our customers is our top priority, we are voluntarily recalling specific lots of infusion sets used with Medtronic insulin pumps.

Explanation of the Issue

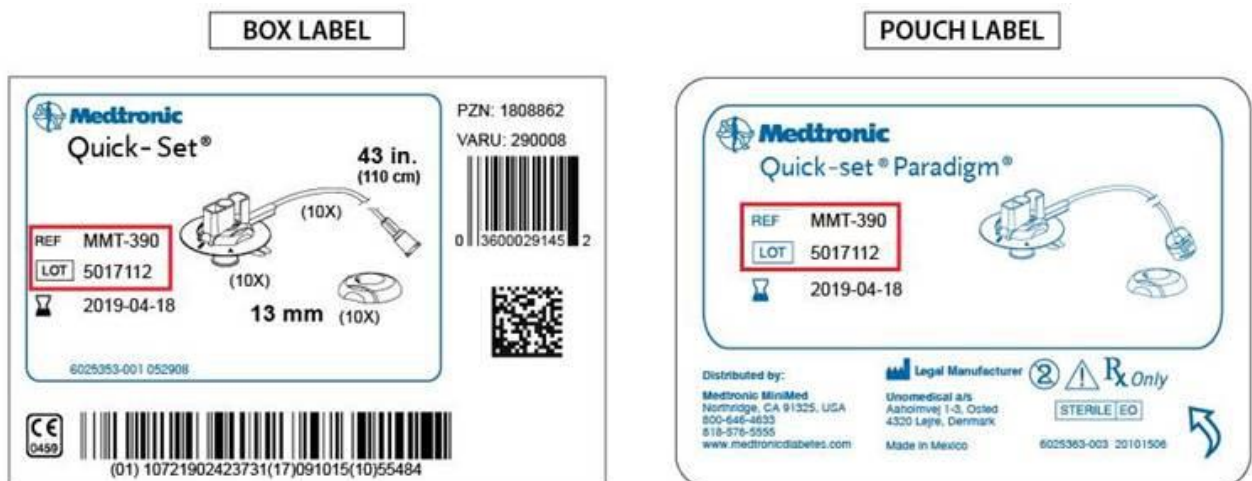
Medtronic has become aware of recent reports of potential over-delivery of insulin shortly after an infusion set change. Over-delivery of insulin can cause hypoglycemia and in extreme cases, death. Medtronic has received reports of hypoglycemia requiring medical intervention potentially related to this issue.

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 top of the insulin reservoir which then could prevent the infusion set from working properly. Infusion sets currently being shipped by Medtronic contain a new and enhanced membrane material that significantly reduces this risk.

Actions Required by You

- A. Go to www.mmc.medtronic-diabetes.com/look determine if you have recalled infusion sets. You will be prompted to enter the Ref and Lot number for all infusion set boxes in your possession. The website will then tell you which infusion sets are part of this recall and which are not.

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



- B. Medtronic recommends you not use recalled infusion sets.
 - If you have new and enhanced infusion sets that are not part of this recall, use only those new and improved sets starting with your next set change.

Medtronic

- If you only have recalled infusion sets, **it is very important to carefully follow the instructions for use** regarding the priming/fill-tubing process. You will find key steps enclosed.
- C. Discard recalled infusion sets when you have new and improved infusion sets and follow instructions on the website www.mmc.medtronic-diabetes.com/look. Medtronic will replace the recalled infusion sets free of charge.

What if I have more questions?

Follow the process on the website at www.mmc.medtronic-diabetes.com/look. If you have additional questions call Medtronic at <XXXX>.

Medtronic considers patient safety and customer satisfaction our top priorities. We appreciate your time and attention in reading this important notification.

Sincerely,

Country/BU manager

Enclosure:

Key Steps: Infusion Set Priming / Fill-tubing Process