

## URGENT MEDICAL DEVICE RECALL

### Notification Letter

### Medtronic MiniMed Infusion Sets

Potential over-delivery of insulin

September 7, 2017

Dear Valued Customer:

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 <https://checklots.medtronicdiabetes.com> to determine if you have recalled infusion sets. You will be prompted to enter the REF and LOT numbers for all infusion sets 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 examples below:



- 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 sets starting with your next set change. As a reminder, we have enclosed Key Steps regarding the priming/fill-tubing process.
  - If you only have recalled infusion sets right now, **it is very important that you carefully follow the Key Steps.**
- C. Return your recalled infusion sets within the next four weeks using the enclosed prepaid label. Medtronic will replace the recalled infusion sets free of charge. For detailed information on returns, see the Return Instructions enclosed.

### What if I have more questions?

Follow the process on the website at <https://checklots.medtronicdiabetes.com>. If you have additional questions, please refer to the enclosed Frequently Asked Questions or call Medtronic at 1.888.204.7616.

You can also report an adverse event to the FDA's MedWatch Adverse Event Reporting program:

- A. Online at: <http://www.fda.gov/safety/medwatch/howtoreport/default.htm>
- B. Report by telephone: 1.800.FDA.1088
- C. Fax report: 1.800.FDA.0178

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

Sincerely,



**James Dabbs**  
Vice President, Quality Assurance  
Medtronic Diabetes