Medtronic

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.

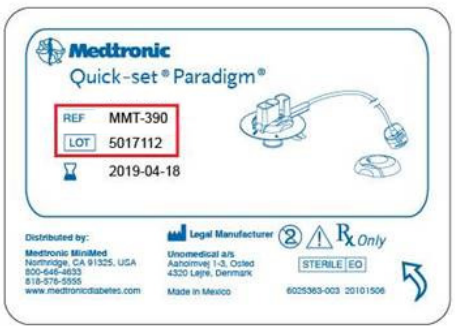
We request you to inform your patients of this recall, using the attached letter, to ask them to do the following:

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:

BOX LABEL

POUCH LABEL



Medtronic

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.

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,

Enclosures:

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

Medtronic

Urgent Field Safety Notice

Medtronic MiniMed Infusion Sets - Recall of specific Lot Numbers

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September 2017

Medtronic reference: FA784

Dear Physician, Healthcare Professional,

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 are informing your patients of this recall and have asked them to do the following:

A. Patients have been 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.

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    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 have been instructed to discard their affected infusion sets. Medtronic will replace the recalled infusion sets free of charge.

If there are any affected MiniMed Infusion Sets in your hospital 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,

Addendum:

Key Steps: Infusion Set Priming / Fill-tubing Process

Medtronic

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:

Medtronic

BOX LABEL

POUCH LABEL

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.
- 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,

Enclosure:

Key Steps: Infusion Set Priming / Fill-tubing Process

Medtronic

Medtronic MiniMed Infusion Sets
Potential over-delivery of insulin

September 2017

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Dear pump user,

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

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BOX LABEL

POUCH LABEL

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.
- 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.
- Our records indicate you may have only infusion sets that are affected by this recall, hence Medtronic will send proactively a box of the new and improved design, which will be delivered in the next days.

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,

Addendum:

Key Steps: Infusion Set Priming / Fill-tubing Process

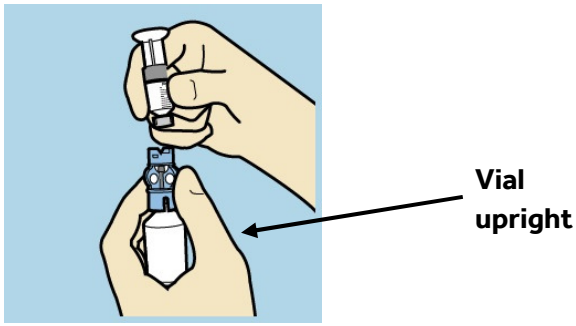
Medtronic

KEY STEPS
Infusion Set Priming / Fill-tubing Process

To avoid potential over-delivery of insulin shortly after an infusion set change

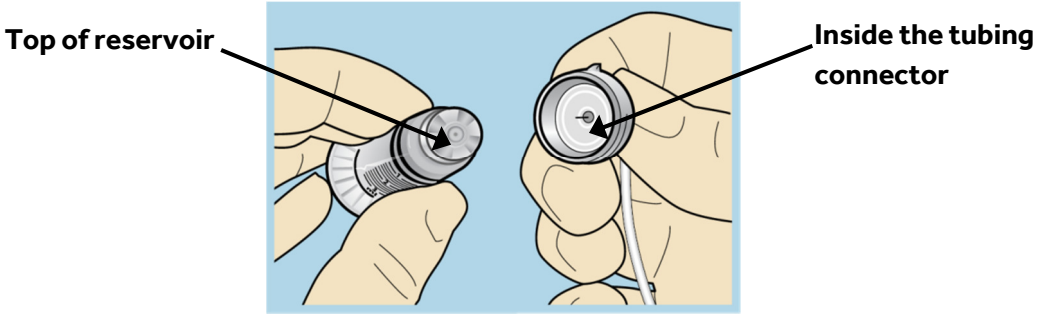
It is very important to follow the steps below to prevent fluid from getting on the infusion set membrane during the priming/fill-tubing process:

a) After filling the reservoir, make sure the vial of insulin is held upright when removing the reservoir from the blue transfer guard. This prevents insulin from accidentally getting on the top of the reservoir, which could be transferred onto the infusion set membrane.



Hold insulin vial upright when removing reservoir.

b) If any liquid (such as insulin, isopropyl alcohol, or water) gets on the top of the reservoir or inside the tubing connector, it can block the infusion set membrane. This may lead to increased pressure inside the pump's reservoir chamber during the priming/fill-tubing process. This may potentially lead to over-delivery of insulin shortly after the infusion set change. If liquid is visible on top of the reservoir or inside the tubing connector, start over with a new reservoir and infusion set.



Make sure these are dry when connecting.

Medtronic

If you notice anything unusual after the priming/fill-tubing process, such as insulin continuing to drip or squirt from the infusion set cannula, do not insert. Start over with a new reservoir and infusion set.

Best Practices for Changing Your Infusion Set Include:

- Do not change your infusion set before going to sleep so that you are able to monitor your glucose levels.
- As an extra precaution, check your blood glucose at 1 hour after your infusion set change in addition to your routine monitoring.

Following these best practices will allow you to identify potential hypoglycemia and hyperglycemia so you can take necessary action.