



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,

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.

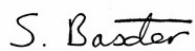
Medtronic

In order to check MiniMed Infusion Sets in your inventory, please visit www.mmc.medtronic-diabetes.com/look to check if you have any affected lot inventory. If you do, please cut out the LOT number labels of the affected boxes and discard recalled infusion sets and contact your Medtronic Representative who will discuss replacement stock and collate your LOT numbers labels.

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.

Sincerely,



Samantha Baxter
Regulatory Affairs Manager UK and Ireland

Enclosures:

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

Note: Medtronic Ireland will also contact affected patients that we hold contact details for directly.



Urgent Field Safety Notice

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

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.

Because Medtronic does not have your patients' records on file*, we ask 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/link 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

In order to check MiniMed Infusion Sets in your hospital inventory, please visit www.mmc.medtronic-diabetes.com/look to check if you have any affected lot inventory, if you do please discard recalled infusion sets and contact your Medtronic Representative who will order you replacement stock free of charge.

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.

Sincerely,



Samantha Baxter
Regulatory Affairs Manager UK and Ireland

***Note: Medtronic Ireland will also contact affected patients that we hold contact details for directly.**

Enclosures:

1. Pump User Letter
2. Key Steps: Infusion Set Priming / Fill-tubing Process



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

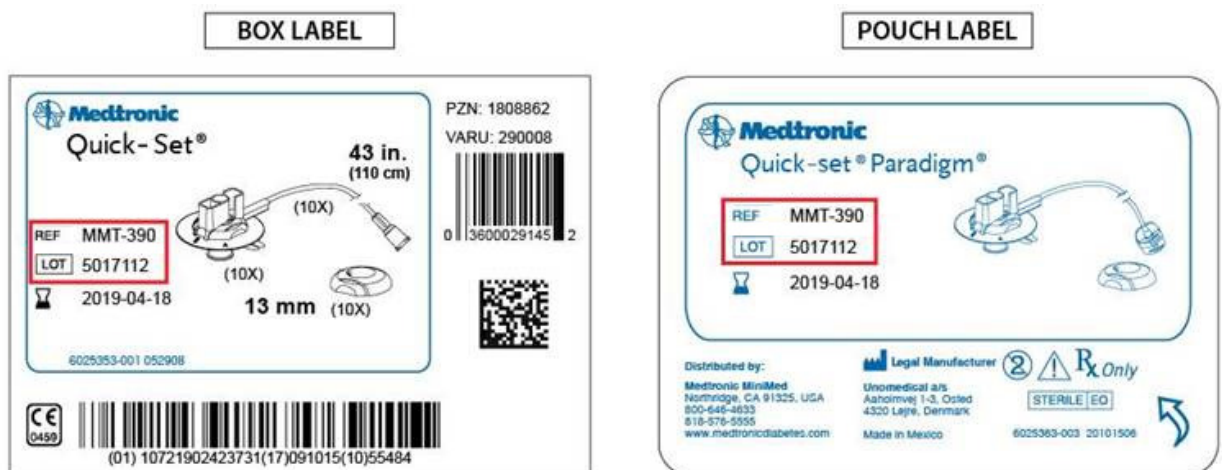
Medtronic has become aware of recent reports of potential over-delivery of insulin shortly after an infusion set change. Over-delivery of insulin can cause hypoglycemia and in extreme cases, death. Medtronic has received reports of hypoglycemia requiring medical intervention potentially related to this 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 01511 1444.

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

Sincerely,



Samantha Baxter
Regulatory Affairs Manager UK and Ireland

Enclosure:

Key Steps: Infusion Set Priming / Fill-tubing Process

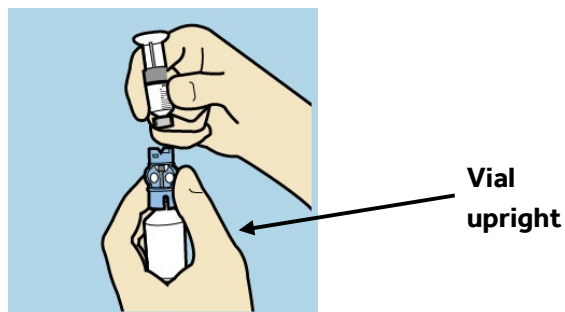
KEY STEPS

Infusion Set Priming / Fill-tubing Process

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

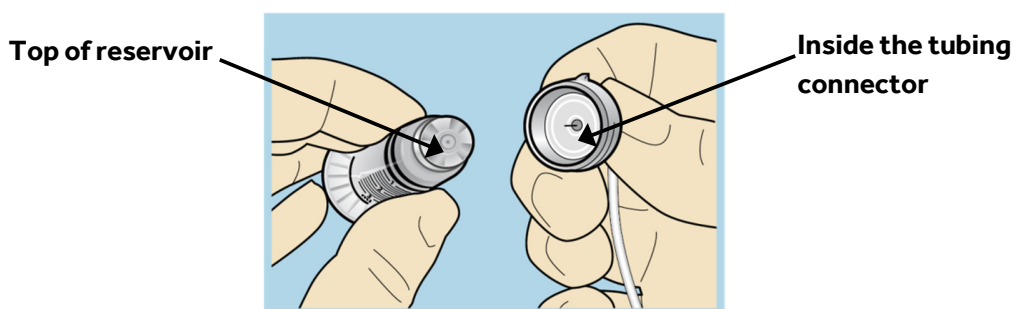
It is very important to follow the steps below to prevent fluid from getting on the infusion set membrane during the priming/fill-tubing process:

- 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.

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.

FA784 Affected Lots Distributed in Ireland

Product Number	Lot Serial Number	Expiry Date
MMT-368	5018235	15/01/18
MMT-368	5046554	15/11/18
MMT-368	5135966	15/01/21
MMT-368	5119768	15/08/20
MMT-368	5131873	15/11/20
MMT-368	5156825	15/07/21
MMT-368	5161553	01/09/21
MMT-399	5154358	01/09/19
MMT-368	5004175	15/08/17
MMT-368	5009099	15/10/17
MMT-368	5011831	15/10/17
MMT-368	5012330	15/10/17
MMT-368	5002988	15/10/17
MMT-368	5019152	15/01/18
MMT-368	5022898	15/02/18
MMT-368	5028303	15/03/18
MMT-368	5030861	15/04/18
MMT-368	5031734	15/04/18
MMT-368	5029838	15/04/18
MMT-368	5037923	15/07/18
MMT-368	5051351	15/10/18
MMT-368	5056651	15/12/18
MMT-368	5059299	15/01/19
MMT-368	5064182	15/03/19
MMT-368	5064849	15/03/19
MMT-368	5064848	15/03/19
MMT-368	5066434	15/06/19
MMT-368	5078887	15/08/19
MMT-368	5075369	15/08/19
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MMT-368	5129182	15/11/20
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MMT-368	5147467	15/04/21
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MMT-368	5152671	15/07/21
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