



Medtronic

Medtronic, Inc.
18000 Devonshire Street
Northridge, CA 91325-1219

July 7, 2009

URGENT MEDICAL DEVICE RECALL

RECALL OF QUICK-SET® INFUSION SETS

Models MMT-396, MMT-397, MMT-398 and MMT-399 (Lots Starting with 8)

Dear Quick-set® Infusion Set User:

Medtronic's diabetes business unit is voluntarily recalling Quick-set infusion sets that have lot numbers starting with the number "8" ("Lot 8" Quick-set infusion sets). These infusion sets are used with MiniMed Paradigm® insulin pumps. We are taking this action because we identified a small percent of infusion sets that may not work properly.

The situation is related to the tubing connector. Approximately 2% of the affected infusion sets (which represents approximately 60,000 infusion sets out of an estimated 3 million infusion sets with customers) may not allow the insulin pump to vent properly. Venting is necessary to equalize the pressure in the reservoir compartment with the surrounding atmosphere. If the vent does not work properly, this **could potentially result in too much or too little insulin being delivered and may lead to serious injury or death.**

The venting issue has been corrected and we are providing replacement boxes to people who need them. Our records indicate that you have not ordered any Quick-set infusion sets from Medtronic within the last six months. Therefore, we do not know if you are still using this product or if you have any unused boxes that need to be returned. Our first priority is to provide you replacement infusion sets if you need them. If you have switched to another type of infusion set, please be assured no other Medtronic infusion sets are affected by this recall.

Actions to Take

- Step 1. **Stop using "Lot 8" Quick-set infusion sets right away**
- Step 2. Switch to an unaffected infusion set or implement the back-up injection plan established with your doctor
- Step 3. Contact us using one of these methods:
 - Fill out the enclosed reply card and drop it in the mail
 - Visit our website at www.medtronicdiabetes.com/lot8
 - Call our automated system at 800.345.8139
- Step 4. Return any unused "Lot 8" Quick-set infusion sets using the enclosed pre-paid return label. Simply drop your package off at any UPS location or call UPS at 800.742.5877 to schedule a pick up.

The notification actions in Step 3 above will allow us to know if you need to be sent replacement infusion sets. If you do, we will ship your replacement infusion sets via UPS overnight delivery within 48-Hours of receiving your notification. Even if you do not need replacement sets, please follow the notification process as regulatory guidelines require us to collect this information. So that we can serve all our customers, we will be sending replacements and new orders of Quick-set infusion sets at the rate of one box every three weeks until we are able to ship more.

If you do not have an adequate supply of infusion sets, please see the attached document.

You may have questions or concerns that are not fully addressed in this letter. For this reason, we have set up a website at www.medtronicdiabetes.com/lot8 with answers to frequently asked questions. **The website is also the quickest and most efficient way to exchange "Lot 8" Quick-set infusion sets and/or place new supply orders.**

In the event you cannot access the above website, or have additional questions, you may also call 800.345.8139 at Medtronic Diabetes 24-hours a day. Doctors who would like to speak with a Medtronic Diabetes medical officer may contact Medtronic Diabetes by calling 818.576.4211.

As is always the case, you should report a product problem by calling 800.345.8139 at any time. Adverse reactions or quality problems may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: Use the postage-paid FDA form 3500 available at:
www.fda.gov/MedWatch/getforms.htm
Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1.800.FDA.0178

We deeply apologize for the inconvenience of this process. We are taking this action to ensure your safety and we are doing all that we can to make this as easy as possible for you.

At your service,

Medtronic Diabetes



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“LOT 8” QUICK-SET® INFUSION SET RECALL IMPORTANT THERAPY CONSIDERATIONS

Please review this information regarding therapy considerations associated with the “Lot 8” Quick-set infusion set recall:

“Lot 8” Quick-set® infusion sets are the only infusion sets affected by this recall. If you do not have replacement Quick-set infusion sets, **you can use any other Medtronic infusion sets you have been trained on and have available.** These include Quick-sets other than “Lot 8,” Silhouette® infusion sets, Sof-set QR® / Sof-set Ultimate QR® infusion sets, Sure-T® infusion sets and Polyfin® infusion sets for use with MiniMed Paradigm® insulin pumps. Any therapy adjustments, including the use of a different infusion set, should be made in consultation with your healthcare provider.

If circumstances occur where you do not have an alternative infusion set available, one option is to revert to the back-up injection plan established with your doctor. Please be aware of the following risks associated with continued use of “Lot 8” Quick-set infusion sets:

Risks Associated with Using “Lot 8” Quick-set Infusion Sets

Too Much Insulin Can be Delivered

- Changes in air pressure could cause too much insulin to be delivered when using an infusion set that does not vent properly.
- A rapid change in air pressure may cause a significant over delivery of insulin that may not be detected until after it has occurred.
- Examples where an increase in altitude can change air pressure include when an airplane is taking off, and when traveling from sea level to a higher elevation, such as driving up a mountain.

Any sign or symptom of hypoglycemia requires immediate attention and treatment.

Too Little Insulin Can be Delivered

- Even at stable altitude or stable air pressure, insulin delivery can be interrupted when using an infusion set that does not vent properly.
- The priming process builds up air pressure in the reservoir compartment and makes the insulin pump appear to be working properly when it is not.
- As always with insulin pump therapy, any interruption in insulin delivery would be detected through frequent blood glucose monitoring.

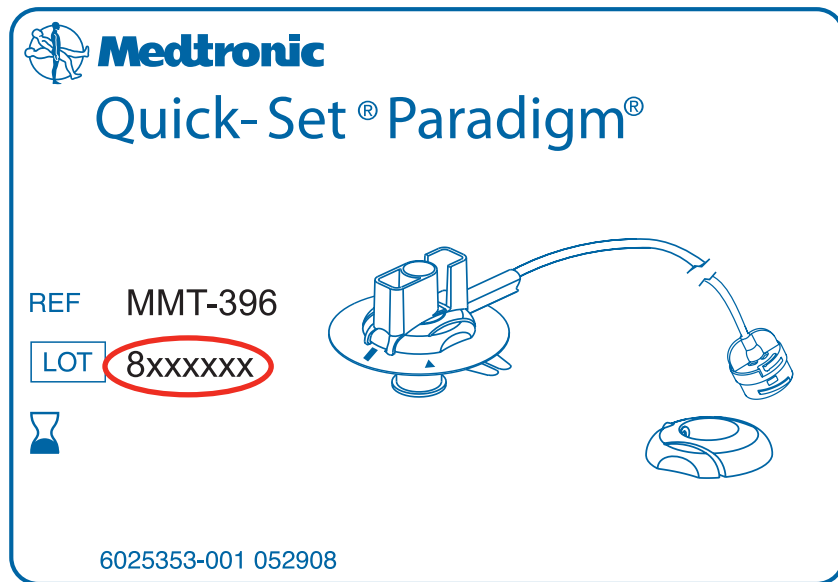
When blood glucose does not respond to a correction dose, you must always suspect that the infusion set is not working properly. Therefore, be prepared to give an injection and change your infusion set.

FOR EASY REFERENCE

HOW TO LOCATE THE LOT NUMBER ON YOUR INFUSION SET PACKAGING

The lot number is clearly marked on both the box label and on each individual infusion set package. The pictures below will help you identify where to find the lot number. Please note, that this product recall affects only "Lot 8" Quick-set infusion sets with the following reference numbers: MMT-396, MMT-397, MMT-398 and MMT-399.

Box Label



Individual Package Label

