



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 Diabetes 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 infusion sets (which represents approximately 60,000 infusion sets out of an estimated 3 million infusion sets currently 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. Please note that no other Medtronic infusion sets are affected by this recall, so you may use any other Paradigm infusion set you have available.

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. Fill out and mail the enclosed postage paid Reply Card to let us know if you have any unused "Lot 8" Quick-set infusion sets. Even if you do not have any, regulatory guidelines require us to collect this information.
- Step 4. Use the UPS Return Label that came with your notification to return your unused "Lot 8" Quick-set infusion sets.

If you do not have an adequate supply of new infusion sets, please see the attached document entitled *Important Therapy Considerations*.

Because you have purchased "Lot 8" Quick-set infusion sets from a supplier, Medtronic does not have your prescriptions or patient records on file. As a result, your supplier will continue to provide you with Quick-set infusion sets. Expect to receive your supplies at the rate of 1 box every 3 weeks until all your supplies have been replaced.

We realize that some people will be concerned and have questions that are not fully addressed in this letter. For this reason, we have attached a frequently asked questions document for your reference. 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