



# Compliance Alert

July 20, 2009

## **Express Scripts – Urgent –Emerging Therapeutic Issue**

Medtronic and the U.S. Food and Drug Administration (FDA) have issued a recall of Quick-set® infusion sets that are used with MiniMed Paradigm insulin pumps because a small number (approximately 2%) of the infusion sets may not allow the insulin pump to vent air pressure properly. This could potentially result in the device delivering too much or too little insulin and may lead to serious injury or death.

Affected infusion sets are reference numbers MMT-396, MMT-397, MMT-398, and MMT-399 with lot numbers starting with the number “8”. Patients should discontinue using “Lot 8” Quick-set infusion sets. Lot numbers beginning with any number other than 8 are not affected by this recall and may continue to be used by patients and dispensed by pharmacies. However, according to the manufacturer, other lot numbers are only in limited supplies.

If you have additional questions, you can call Medtronic Diabetes at 800.345.8139.

### **Express Scripts’ response:**

- In an effort to inform members of this recall, we have identified members who have received a prescription for Quick-Set infusion sets since January 1, 2009. A communication summarizing the information provided by the manufacturer will be sent to these members.
- The above communication will be distributed for those clients enrolled in the member portion of the Emerging Therapeutic Issues Patient Safety Program.
- Express Scripts Home Delivery will also send letters to members identified as receiving a prescription for Quick-Set infusion sets in 2009, informing them of the recall.

If you have any questions regarding this information, please contact your Group Benefit Services Account Manager at 1.800.638.6085.

*This communication is not intended to be legal advice and should not be construed as legal advice. If you have any legal questions or concerns about your plan, GBS recommends seeking counsel from an ERISA attorney.*

---

***Keeping you informed. Just one more reason to choose GBS.***