

NATIONAL PBM COMMUNICATION • July 13, 2009

Medtronic Quick-Set Infusion Sets and Urgent Medical Device Recall

- Medtronic Diabetes is voluntarily recalling Quick-set® infusion sets used with MiniMed Paradigm® Insulin Pumps.
- Only lot numbers starting with the number "8" (for example, 8XXXXXX marked on both the product box label and on each individual infusion set package), are being recalled.
- Approximately 2% of the infusion sets in the affected lots may not allow the insulin pump to vent properly, which could potentially result in **too much or too little insulin being delivered and may lead to serious injury or death.**
- The following VA PRODUCTS and reference numbers are associated with the affected lot number being recalled:

VA PRODUCT DESCRIPTION	REFERENCE NUMBERS	LOT NUMBER
SET, INFUSION MINIMED	#MMT - 396	ALL LOT NUMBERS STARTING WITH THE NUMBER "8"
SET, INFUSION MINIMED	#MMT - 397	
SET, INFUSION MINIMED	#MMT - 398	
SET, INFUSION MINIMED	#MMT - 399	

- Return all remaining product at the facility/CMOP level with the affected lot numbers as instructed on the Medtronic website: <http://www.medtronicdiabetes.com/lot8>. Affected lots of in-house stock are to be sequestered within 24 hours of this notice. Please inform your Facility Recall Coordinator when the sequestering actions have been completed.
- Determine whether the affected lot numbers (refer to lot numbers provided above) were dispensed to any patient(s). It is recommended to use a 12-month time frame for this determination. CMOP data will be provided by a CMOP representative to Pharmacy Chiefs.
- If the affected lots were dispensed to a patient(s), then:
 - Identify the patient(s).
 - Contact patient(s) who may have received the affected product for home administration by any appropriate method.
 - A sample letter can be found at: <http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc>.
 - This template can be altered according to site-specific needs.
- Provide affected patient(s) with instructions on the following:
 - How to obtain a new device.
 - How to return the device being recalled to the pharmacy.
 - To continue using the device with the affected lot number until they receive a new device. When correct device is received, patient should begin using the new device and return the recalled device as instructed.
- Report any adverse reactions experienced with the use of this device to the VA ADERS program.

ACTIONS:

- **Facility Director (or physician designee):** Report completion of actions to the VISN Director.
- **Facility COS and Chief Nurse Executives:** Forward this document to all appropriate providers who utilize this device (e.g., primary care providers, and diabetes specialists, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate. Report completion of actions to the Facility Director.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).
- **VISN Directors:** Within 10 business days of receipt (due 07/27/2009), communicate to PBM/VAMedSAFE that all actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx