

NATIONAL PBM COMMUNICATION · July 23, 2013

Medtronic Recall of Certain Lots of Reservoirs Used With Paradigm® Insulin Pumps

- On July 3, 2013, Medtronic, Inc., voluntarily recalled certain lots of model MMT-326A (1.8 mL) and MMT-332A (3.0 mL) reservoirs used with Paradigm insulin pumps.
- Reservoirs from these lots may be at increased risk for leaking because of abnormal wear on a manufacturing tool involved in the production of reservoir stoppers.
- A leak in the reservoir may result in delivery of less insulin than intended, and may lead to possible diabetic ketoacidosis (DKA).

PRODUCT SEQUESTERING ACTIONS

- Affected lot(s) include:

H8416432	H8461538	H8489386	H8512826
H8420977	H8463297	H8491921	H8515317
H8422490	H8464121	H8492449	H8517079
H8424676	H8467888	H8494645	H8521052
H8437486	H8469703	H8496561	H8539013
H8441420	H8471745	H8500423	H8541843
H8442973	H8473106	H8500472	H8584244
H8451531	H8473271	H8503372	H8603292
H8452933	H8476270	H8503728	H8604958
H8455959	H8478398	H8509305	H8627745
H8457716	H8485398	H8510440	H8635301
H8459557	H8486688	H8512566	

- For your convenience, you may also enter reservoir lot numbers at the following website (www.medtronicdiabetes.com/checklots) to confirm which reservoirs are included in this recall.
- Following the action due dates in **Product Recall Office Log # 7108** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>), sequester and then return all remaining affected product at the CMOP/facility per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs. Affected product(s) was manufactured between October 2012 and February 2013. Any affected lot(s) that was sold to distributor partners was shipped from October 2012 through May 2013.
- If an affected lot(s) was dispensed to a patient(s) for home administration, then:
 - Identify the patient(s).
 - Contact patient(s) who may have received the affected product(s) 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 patient(s) in possession of the recalled product with instructions on the following:
 - How to return the product being recalled to the pharmacy.
 - How to obtain a new supply of product.
 - Patients should continue to use the current reservoir until a replacement reservoir is obtained. A replacement reservoir should be provided as soon as possible.
 - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
- Providers should continue to report any adverse reactions with the use of any insulin delivery product(s) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

FEEDBACK NOTIFICATION 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 prescribe this agent (e.g., **primary care providers, endocrinology, and pharmacy staff, 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 issue (due 08/06/2013), communicate to PBM/VAMedSAFE that all product sequestration actions have been completed via the Feedback tool:
https://vaww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx.