

Urgent Field Safety Notice

Recall of Certain Lots of Medtronic MiniMed Model MMT-326A and MMT-332A Insulin Reservoirs

June xx, 2013

Medtronic Reference: FA586

Dear Healthcare Professional,

This letter is to notify you that Medtronic MiniMed is voluntarily recalling certain manufacturing lots of model MMT-326A and MMT-332A insulin reservoirs used with our Paradigm insulin pumps.

We are recalling these reservoirs due to the potential that reservoirs from these lots are at increased risk for leaking. A leak in the reservoir may result in delivery of less insulin than intended and, if there is an occlusion in the infusion set, the pump may not alarm.

Our investigation has indicated that this increased potential for reservoir leakage is related to abnormal wear of a manufacturing tool involved in the production of a component used in the affected lots of reservoirs. We have implemented additional testing and inspection steps to ensure that currently produced reservoirs will not be subject to this problem.

Attached please find a copy of the letter that Medtronic or our distributors will be sending to your patients. No action is required from your side. This notification is to inform you and to anticipate potential questions from your patients.

We apologize for any inconvenience this recall may cause you and we are here to assist you with any questions or concerns you may have. Please feel free to visit our website at <http://www.medtronic-diabetes.info> or contact us at XXXXXX if you would like more information. We appreciate your time and attention to this important notification.

Sincerely,

XXXXXXX

Medtronic Diabetes