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July 3, 2013

URGENT Medical Device Recall Notice
Recall of Certain Lots of MMT-326A and MMT-332A Reservoirs
Used With Paradigm® Insulin Pumps

Dear Valued Medtronic Customer:

Because the safety of our customers is our top priority, we are voluntarily recalling certain manufacturing lots of model MMT-326A (1.8 mL) and MMT-332A (3.0 mL) reservoirs used with our Paradigm insulin pumps. We are recalling these reservoirs due to the potential that reservoirs from these lots may be at increased risk for leaking. A leak in the reservoir may result in delivery of less insulin than intended. In addition, if you have a leaky reservoir and an insulin blockage occurs in the infusion set, the pump may not alarm to notify you.

Our investigation has indicated that this increased potential for reservoir leakage was caused by abnormal wear on a manufacturing tool involved in the production of reservoir stoppers. We are recalling all lots of reservoirs that contain any stoppers from that tool. We have corrected this problem and have placed additional testing and inspection steps into our manufacturing process.

Affected Reservoir Lot Numbers

Our records indicate that Medtronic has NOT shipped you any reservoirs from the affected lot numbers. However, if you obtain your reservoirs from a mail order supplier, distributor, pharmacy, your doctor's office, or anywhere else, you will need to follow the actions below to determine if you have affected lots.

Required Actions

1. Check your reservoir lot numbers to see if they are on the recall list:
 - Use our online tool at www.medtronicdiabetes.com/checklots; or
 - Refer to the recall list in the attached Q&A
2. Don't use reservoirs from the recalled lots.
- 3A. If you only have reservoirs from affected lot numbers:
 - Switch to your back-up insulin injection plan according to the direction of your healthcare professional.
 - Call us to expedite a replacement box at 1.866.450.0890.
- 3B. If you have a combination of supply from both affected and unaffected lot numbers, let us know your replacement needs using one of the following methods:
 - Online form at www.medtronicdiabetes.com/support/product-updates (fastest method)
 - Mail the enclosed reply card
- 3C. If you do not require replacement reservoirs, check the appropriate box on the reply card and drop it in the mail.
4. Dispose of your affected reservoirs (they do not need to be returned). Please remember to follow your local governmental regulations for disposal of sharps.

Please know that we will replace all reservoirs that you have from the affected lots at no cost to you, and will make this process as easy as possible. A list of frequently asked questions is included with this letter and posted on our website at www.medtronicdiabetes.com/support/product-updates.

Risk to Health

Under-delivery of insulin can cause high blood sugar, which if untreated can lead to diabetic ketoacidosis (DKA). DKA is a serious condition that can cause a severe impact to health, including death. Symptoms of diabetic ketoacidosis may include nausea, vomiting, shortness of breath and excess thirst/urination. Seek medical attention immediately if you are experiencing any of these symptoms.

In most cases, the impact of a leaking reservoir is limited to a temporary increase in glucose levels. We have received a small number of reports of patients being hospitalized for diabetic ketoacidosis which may be a result of insulin under-delivery due to the reservoir leaking. Adverse reactions or quality problems experienced with the use of Medtronic Diabetes insulin pumps, infusion sets or reservoirs may be reported to the FDA's MedWatch Adverse Event Reporting program:

Online at: <http://www.fda.gov/safety/medwatch/howtoreport/default.htm>
Report by telephone: 1.800.FDA.1088
Fax report: 1.800.FDA.0178

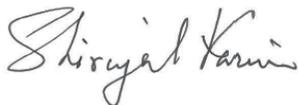
At Medtronic, making quality products that you can trust is our top priority. We are committed to improving our products and to communicating about potential issues when they arise. We will continue to communicate as often as needed because we know that is what you expect from Medtronic as your partner in diabetes care. We believe doing so makes our customers the safest, most educated and informed patients.

For more information:

Visit our website at www.medtronicdiabetes.com/support/product-updates or
Call for replacements at 1.866.450.0890 Monday through Friday, 8 AM – 6 PM Central Time. If you have an urgent issue, our 24-Hour HelpLine is always available.

We appreciate your time and attention to this important notification.

Sincerely,



Shirajul Karim
Vice President, Quality
Medtronic Diabetes