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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

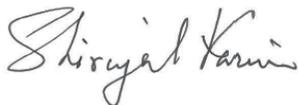
At Medtronic, making quality products that you can trust is our top priority. We are committed to improving our products and to communicating about potential issues when they arise. We will continue to communicate as often as needed because we know that is what you expect from Medtronic as your partner 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

QUESTIONS AND ANSWERS REGARDING THE RESERVOIR RECALL

Q1. Why is Medtronic recalling certain manufacturing lots of model MMT-326A and MMT-332A insulin reservoirs?

A. 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.

Q2. Which lot numbers are being recalled?

A. We have provided an online tool at www.medtronicdiabetes.com/checklots where you can enter the lot numbers from the reservoirs you have on hand to see if they are part of this recall. In addition, below is the complete list of lot numbers for MMT-326A and MMT-332A that are being recalled:

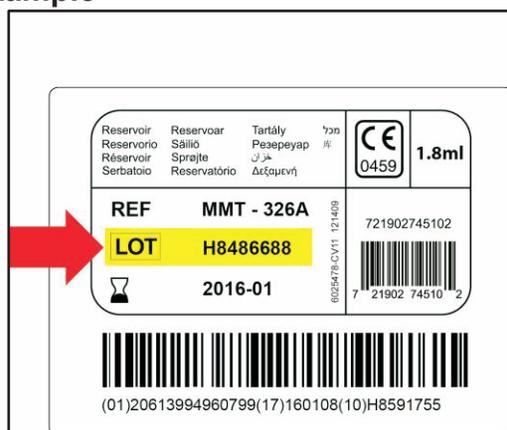
H8416432	H8461538	H8489386	H8512826
H8420977	H8463297	H8491921	H8515317
H8422490	H8464121	H8492449	H8517079
H8424676	H8467888	H8494645	H8521052
H8437486	H8469703	H8496561	H8539013
H8441420	H8471745	H8500423	H8541843
H8442973	H8473106	H8500472	H8584244
H8451531	H8473271	H8503372	H8603292
H8452933	H8476270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

We recommend you check all reservoirs you have on hand against this list (or use the online verification tool on our website).

Q3. How do I locate the lot number?

A. The lot numbers are located on the side panel of the reservoir box, as well as on the side of the individual reservoir packaging. The lot number starts with an “H” and is followed by a 7-digit number. For example, H8486688 (see visual reference below).

Reservoir Box Example



Individual Reservoir Package Example



Q4. Has Medtronic stopped shipping affected lots of reservoirs?

A. Yes, Medtronic has stopped shipping reservoirs from the affected lots.

Q5. Does this recall affect all Medtronic reservoirs?

A. No. Only the reservoirs with the lot numbers listed above are affected by the recall. All Medtronic reservoirs other than those listed above are fine to use.

This recall affects approximately 13% of the volume of reservoirs Medtronic manufactures in a year. We are being cautious and recalling certain reservoir lots that were manufactured between October 2012 and February 2013 that may have an increased potential for leaking. Rest assured, we've corrected this problem and have placed additional testing and inspection steps into our manufacturing process.

Q6. What solution is Medtronic providing to its customers?

A. Medtronic will replace all affected reservoirs that customers have on hand at no cost, and will make this process as easy as possible.

Q7. Is Medtronic committed to product quality?

A. Absolutely! 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.

Q8. Has Medtronic notified my healthcare professional?

A. Yes. Medtronic has notified healthcare professionals who prescribe Medtronic insulin pumps, as well as clinicians who train patients on our product.

Q9. May I wait a few days to change my reservoir? I just started using a reservoir from the affected lot and have a full insulin reservoir. I would prefer to use my insulin so I don't waste it.

A. You should stop using your reservoir from an affected lot right away, even if you need to discard some insulin. Please know we are making this recommendation for your safety. We recognize there will be some insulin waste and deeply apologize for this situation.

Q10. Should I return my affected reservoirs to Medtronic?

A. No, you do not need to return the affected reservoirs. Any reservoirs included in this recall should be disposed of immediately. Please remember to follow your local governmental regulations for disposal of sharps.

Q11. I have reservoirs from the affected lots. How do I get replacements for these reservoirs?

A. Use one of the following methods to notify us:

- Online form at www.medtronicdiabetes.com/support/product-updates (fastest method)
- Mail the enclosed reply card

Q12. I've notified Medtronic that I need replacement reservoirs, when will I receive them?

A. Replacement reservoirs will be shipped as soon as possible via UPS. If you have an immediate need, enter your information into the online form on our website, www.medtronicdiabetes.com/support/product-updates.

Q13. Medtronic indicates that it fixed a manufacturing process related to the production of reservoir stoppers. What is a stopper?

A. The reservoir stopper is pushed by the piston to deliver insulin once it is inside the pump. It is the part with two O-rings that is left in the reservoir barrel after you have removed the plunger during the reservoir fill process.