March 25, 2013

RE: Potential loose drive support cap and water damage

Dear Healthcare Professional:

At Medtronic we are committed to continually evaluating and improving the quality and reliability of our products and services. This letter is to notify you of two potential safety issues relating to our Paradigm® insulin infusion pumps.¹ We are also sending letters to your patients. As always, please feel free to contact your local representative or our support team at 1.888.204.7616, option 1, if you have any questions regarding this letter.

1. LOOSE DRIVE SUPPORT CAP

The insulin pump's drive support cap holds the pump motor in place and allows the motor's piston to press against the reservoir to deliver insulin.

Some customers have experienced a loose drive support cap, and in rare cases the cap may stick out from the bottom of the reservoir compartment. This condition can occur when the insulin pump is damaged due to impact with a hard surface (for example if it is dropped). As of February 2013, we have one report of a customer who attempted to push the drive support cap back into place while attached to the insulin pump. This resulted in unintended delivery of insulin and associated severe hypoglycemia.

A normal insulin pump and an insulin pump with a loose drive support cap are shown in the pictures below.

¹ The model numbers of the pumps that may be affected by these issues are MMT-511, MMT-512, MMT-712, MMT-712E, MMT-515, MMT-715, MMT-522, MMT-722, MMT-522K, MMT-722K, MMT-523, MMT-723, MMT-523K, MMT-723K, MMT-554, and MMT-754.
Below are the recommendations that we are providing to your patients:
Examine your insulin pump. If the drive support cap is sticking out, as shown in the photo, **DO NOT PRESS ON THIS PORTION OF THE PUMP**. Please discontinue use of the insulin pump and contact Medtronic at 1.888.204.7616, option 1, to arrange for the insulin pump to be replaced. During this time you will need to manage your diabetes with insulin injections, per the back-up plan provided to you by your healthcare professional.

2. WATER DAMAGE

As explained in the insulin pump user guide, exposure to water can damage the pump’s internal electronics. Water damage may result in an insulin pump alarm or cause the buttons to stop working. Although it is unlikely that water damage will occur if an insulin pump is splashed or briefly dunked, it should not be immersed in water.

Below are the recommendations that we are providing to your patients:
To swim or participate in other water activities, always disconnect from your insulin pump, keep it in a safe place and reconnect after you are out of the water.

If you accidentally submerge your insulin pump in water, dry the insulin pump quickly using a soft, clean towel and verify that it is working properly by selecting Self-test from the insulin pump's Utilities Menu. If you believe that water has entered your insulin pump or you observe any other possible insulin pump malfunction, please contact us at 1.888.204.7616, option 2, for assistance with troubleshooting.

We are notifying your patients about these potential safety issues. You and your patients can also find information online at www.medtronicdiabetes.com/support/product-updates. Please know, patient safety is our top priority. Feel free to call us 1.888.204.7616 (option 1 for loose drive support cap related questions and option 2 for water damage related questions) if you have any questions or concerns. We appreciate your time and attention to this important notification, and thank you for continuing to put your trust in Medtronic.

Sincerely,

Shirajul Karim
Vice President, Quality
Medtronic Diabetes