July 3, 2013

URGENT Medical Device Recall

Dear Healthcare Provider:

With safety as our top concern, we would like to make you aware that we are recalling certain manufacturing lots of Paradigm reservoirs that may have an increased potential for leaking. A leak in the reservoir may result in delivery of less insulin than intended, and if there is an insulin blockage in the infusion set, the pump may not alarm.

We will be contacting your patients and asking them to check the lot numbers on the reservoirs they have on hand, and to stop using reservoirs from the recalled lot numbers immediately.

The recall involves some of the manufacturing lots produced between October 2012 and February 2013, and in total, represents about 13% of the volume of reservoirs we make each year. Rest assured, we have corrected this problem and have placed additional testing and inspection steps into our manufacturing process. All Medtronic reservoirs other than those listed on the enclosed recall list are fine for your patients to use.

In order to make this as easy as possible, patients who received affected reservoirs from us in their last supply shipment will proactively receive a box of replacement reservoirs. In addition, we will provide replacement reservoirs to all patients who have affected lot numbers on hand at no additional cost. Please know that we have also shipped replacement reservoirs to diabetes camps across the country.

Because some patients get their pump supplies from direct mail pharmacies and other sources, we are sending this notice to all Paradigm users and asking them to reply back whether or not they have any reservoirs from the affected lots that need to be replaced. Once they reply to Medtronic, they may discard their affected reservoirs (there is no need to return them).

Enclosed are all of the materials your patients will receive.

We deeply apologize for any disruption this may cause. Please know that we are doing all that we can to make this process as easy as possible for your patients.

Sincerely,

Shirajul Karim
Vice President, Quality
Medtronic Diabetes