



URGENT: INSULIN PUMP 2.0 mL CARTRIDGE RECALL

February 22, 2011

Important Information about the 2.0 mL Animas Insulin Pump Cartridges

Dear Valued Healthcare Professional:

Animas Corporation has learned that some of the 2.0 mL insulin cartridges shipped between Nov. 30, 2010 and Jan. 4, 2011, can leak insulin, resulting in the delivery of less insulin than intended. In addition, if the cartridge has a leak, the pump may not alarm if there is an occlusion in the infusion set.

As you know, under-delivery of insulin can cause high blood glucose and/or diabetic ketoacidosis. These are serious conditions that can cause severe health impact, including death.

Affected patients were also notified of this recall by email and letter (see enclosed). Animas is providing these patients with a replacement supply of insulin cartridges as well as instructions for returning their affected cartridge supply.

The lot numbers affected by this recall are:

B201575

B201576

B201581

B201582

B201583

You can find the lot number on the side panel of the cartridge box and on the packaging of each individual cartridge adjacent to the symbol

LOT

Please be assured that the issue identified relates solely to the cartridges contained in the lots identified above. **There is not a problem with the pump or the infusion set.** Leaking of insulin from the cartridge will not damage the pump. Animas has notified the FDA of this issue.

If you have any questions regarding this communication, please contact Animas at (855) 254-5668. A healthcare professional will be available 24/7, to answer questions you may have about this letter.

What if I need to report a potential product issue?

Please contact Customer Technical Support at (855) 254-5668.

Animas is dedicated to ensuring the highest level of customer support and continues to work to deliver the highest level of quality to our customers. Thank you for the quality care and support you provide to our patients.

Sincerely,

Animas Corporation

Note: In an attempt to make sure that we reach you, you may get more than one notice from Animas about this issue.