



## URGENT: INSULIN PUMP 2.0 mL CARTRIDGE RECALL

February 22, 2011

### Important Information about your 2.0 mL Animas Insulin Pump Cartridges

Dear Animas Pumper:

Animas Corporation is dedicated to supporting pumpers with quality customer service and products. As part of that commitment, we contact our pumpers whenever we have urgent information about our products.

We are sending you this letter because we have 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.

**Please note that under-delivery of insulin can cause high blood sugar and/or diabetic ketoacidosis. These are serious conditions that can cause severe health impact, including death. Symptoms of diabetic ketoacidosis may include nausea, vomiting, shortness of breath and excess thirst/urination. Contact your healthcare professional immediately if you are experiencing any of these symptoms.**

**Our records show that you have received a shipment with cartridges that have the potential to leak. It is important that you check your cartridge supply and stop using these cartridges immediately.**

Cartridge lot numbers affected by this recall are:

**B201575**

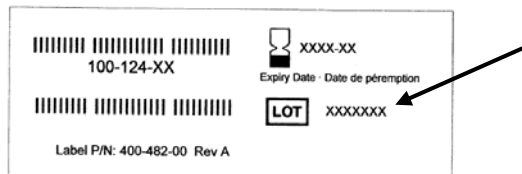
**B201576**

**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 as illustrated below:





**What if I am currently using a cartridge with one of these lot numbers in my pump?** Change your cartridge immediately using the following instructions. See your Owners Booklet or User Guide for more detailed instructions.

1. **Disconnect** the infusion set from your body (*failure to follow these important safety instructions can lead to unintended delivery of insulin*).
2. Unscrew the cartridge cap, leaving the tubing connected to the cartridge.
3. With the tubing connected to the cartridge, pull the cartridge straight out of your pump.
4. Disconnect tubing from cartridge, set the cartridge aside to return to Animas.
5. Fill a new cartridge from an unaffected lot not listed above, and attach infusion set tubing
6. **While still disconnected**, rewind, load the cartridge and prime.
7. Connect tubing to site once prime is complete.
8. Fill cannula only if you have inserted a new infusion set.

**How do I get more insulin cartridges?**

Enclosed, please find new 2.0 mL insulin cartridges to replace your existing supply. All replacement cartridges have been sent to you free of charge. The replacements are clearly affixed with a green dot for ease of identification and to ensure they are not confused with the affected cartridges that must be returned.

**What do I do with the faulty cartridges?**

We ask that you please return all of the unused affected cartridges using the enclosed box affixed with a US Postal Service label. The shipment must be returned using the United States Postal Service.

**Is there anything wrong with my pump? No, there is *not* a problem with the pump.** Any leaking of the insulin from the cartridge will not damage your pump.

**Should I adjust my basal or bolus rates to correct the under-delivery of insulin?**

No. If you have an affected cartridge, stop using it immediately and replace it with another cartridge that is not affected, or go to your back up plan. Also, if you have any questions about adjusting your insulin dosing, contact your health care professional.

**I haven't had any problems with this affected lot yet, can I continue to use them?**

No, if your cartridges belong to one of the lots affected, you should immediately discontinue use of this cartridge and use a cartridge from an unaffected lot. If you do not have any additional unaffected cartridges, please go to your backup insulin administration plan, or contact your healthcare professional for additional guidance with regards to insulin dosing.

**What if I have other questions?**

If you have technical questions or concerns, please call Animas Customer Support at 1-855-254-5668 or you can call the toll-free number on the back of your pump at 1-877-937-7867.

Should you have any questions about returning the product, please contact the Animas Cartridge Fulfillment Center, which is handling the return and shipment process at 1-877-280-2339. The call center is available 24 hrs/7 days a week.



If you do not have any product to return, please notify us that you have used all of the affected lot by logging on to the following website: [www.animasnotification.com](http://www.animasnotification.com) or calling the Call Center at 1-877-280-2339

Animas has notified the FDA of this issue, and we have also sent a letter to your healthcare provider to inform him or her of this issue.

Again, Animas is dedicated to providing our pumpers with quality customer service and products. We know that you had a choice when choosing the pump that would work best for your lifestyle and we appreciate that you trust us. We assure you that we are doing everything we can to address this issue quickly to avoid any further concerns.

Sincerely,

Animas Corporation

**Note:** In an attempt to make sure that we reach you, you may have received a similar email if we had an email address on file.