



URGENT: INSULIN PUMP 2.0 mL CARTRIDGE RECALL

February 24, 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.

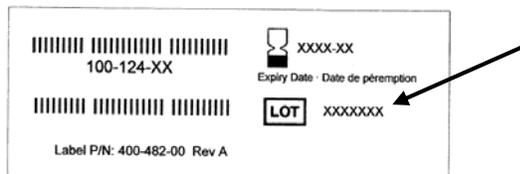
Please note that under-delivery of insulin can cause high blood sugar and/or diabetic ketoacidosis. These are serious conditions that can cause severe health impact, including death. Symptoms of diabetic ketoacidosis may include nausea, vomiting, shortness of breath and excess thirst/urination. Contact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

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:



A full list of questions and answers are provided to you below.

Animas has notified the FDA of this issue, and we have also sent a letter to healthcare providers to inform them 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

Frequently Asked Questions

What is the issue potentially affecting my pump's insulin cartridge?

We have learned of several cases where a leak has occurred at the plunger side of the cartridge resulting in under-delivery of insulin during basal or bolus of insulin.

What is Animas doing to address the issue?

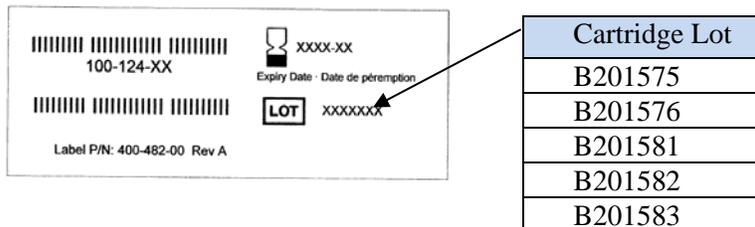
We are contacting EVERY Animas® pumper that potentially received affected cartridges to notify them of the issue and what they should do to avoid any problems. We are also replacing any product that is still in the patient's possession free of charge.

It is important to note that, this is a contained incident and this issue relates solely to the cartridges contained in the lots we identified. Once the cartridges are replaced, the pump will function as intended. There is not a problem with the pump.

How do I know if my cartridges are affected?

The following lot numbers have been identified as containing potentially affected cartridges. These lots were all shipped in the US:

The lot label appears as the following:



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.

What are the risks of using these affected cartridges?

If the affected cartridge is leaking insulin, your pump may not be delivering the proper amount of basal or bolus insulin. 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.

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

No. If you have an affected cartridge, you must stop using the cartridge immediately and replace it with a cartridge from a lot that has not been affected. If you do not have any additional cartridges on hand, please go to your backup insulin administration plan while you await a free replacement supply, or contact your healthcare professional for additional guidance with regards to insulin dosing.

Has my doctor been notified?

Yes, if you are a pumper who was affected by this issue, your health care provider has also been notified.

How do I get more insulin cartridges?

If you are a pumper who was affected by the recall, you should have received a new supply of new 2.0 mL insulin cartridges to replace your existing supply by March 2, 2011. All replacement cartridges should 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.

How long will it take for me to get my replacements?

Replacements were shipped by the Animas Cartridge Fulfillment Center to the address we have on file for each patient. The package was scheduled to be delivered the week of February 22nd, or by the beginning of the week of February 28th, at the latest.

If you have affected cartridges and do not receive a replacement supply by March 1, please contact Animas Cartridge Fulfillment Center at 1-877-280-2339.

What should I do if I did not receive a letter from Animas about the faulty cartridges?

We are contacting EVERY Animas® pumper that potentially received affected cartridges to notify them of the issue and what they should do to avoid any problems. If you did not receive notification from Animas, then you more than likely are not impacted by this recall. We suggest to still check your lot numbers.

I did not purchase my Animas cartridges directly from the company; I purchased them from a distributor. When will I be contacted about this issue?

All affected distribution partners have also been contacted and instructed to identify any patients who may have received the affected cartridges. If you have any affected supply, you will be contacted directly



by the distributor regarding replacement cartridges and with further instructions to collect your affected cartridges.

What do I do with the faulty cartridges?

We ask that you please return all of the unused affected cartridges using the box you received with your replacement supply. The box is affixed with a pre-paid US Postal Service label. The shipment must be returned using the United States Postal Service.

I received the box to return the faulty cartridges, but I lost my return label, what should I do?

Contact the Animas Cartridge Fulfillment Center at 1-877-280-2339.

What happens to the faulty cartridges once returned?

All returned faulty cartridges will be destroyed.

What if I have already used all my affected cartridges?

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 or calling the Call Center at 1-877-280-2339

What should I do if I don't have any unaffected cartridges left and my replacement supply has not arrived?

Contact us at the number above if it is past March 2, 2011 to report that you have not received your replacement supply. Until you receive your replacement and moving forward, continue to order cartridges as you normally do, as supplies are needed. If you do not have any additional cartridges on hand, please go to your backup insulin administration plan or contact your healthcare professional for additional guidance, with regards to insulin dosing.

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.

Could this cause any other problems with my pump if insulin leaks into the compartment?

The cartridge compartment is sealed so that insulin is unable to get into the pump's critical components. If you suspect that insulin is present in your cartridge compartment, invert your pump's cartridge compartment over a paper towel and allow any liquid to drain out. Do not clean the cartridge compartment or insert anything other than a cartridge into the cartridge compartment. Do not use household cleaners, chemicals, solvents, bleach, scouring pads or sharp instruments to clean your pump. Never put your pump in the dishwasher or use very hot water to clean it.

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.

Will the pump still recognize occlusions and alarm properly with this issue?

Cartridges which are affected by this issue may not allow the pump to recognize occlusions and therefore may not alarm properly. It is important that you check your cartridge supply and stop using the cartridges immediately if they match the LOT numbers identified.



My BG's have been running higher than normal, but I haven't seen any leaks. Do you think this is the cause?

Please contact our Customer Support team immediately at (877) YES-PUMP (877-937-7867) and choose Option 1 to determine if the issue is product related. Otherwise, contact your health care professional immediately.

How will Animas address this in the future to avoid a similar problem?

Animas has put controls in place to detect the leak condition for the cartridge. In addition, there is on-going inspection during the cartridge molding process to make sure the condition is eliminated.

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.