

Field Awareness Notice

15th July 2016

Cellnovo Insulin Infusion System – Insulin Cartridge

Cellnovo are voluntarily informing you of a potential issue with your Cellnovo System Insulin Cartridges.

Affected Product:

Part No.: 2000041
 Description: Insulin Cartridge
 Batch Nos.: 60002341, 60002472, 60002528, 60002538 and 60002577

Part No.: 7000102
 Description: 1M 150 5.5mm (Supply Kit)
 Batch Nos.: 60002638

Part No.: 7000105
 Description: 1M 150 6mm (Supply Kit)
 Batch Nos.: 60002486, 60002564, 60002611, 60002612, 60002615, 60002683, 60002684, 60002722,

Part No.: 7000111
 Description: 1M 150 9mm (Supply Kit)
 Batch Nos.: 60002198R

Part No.: 2000044
 Description: 150 IC Box of 10
 Batch Nos.: 6002577

The issue:

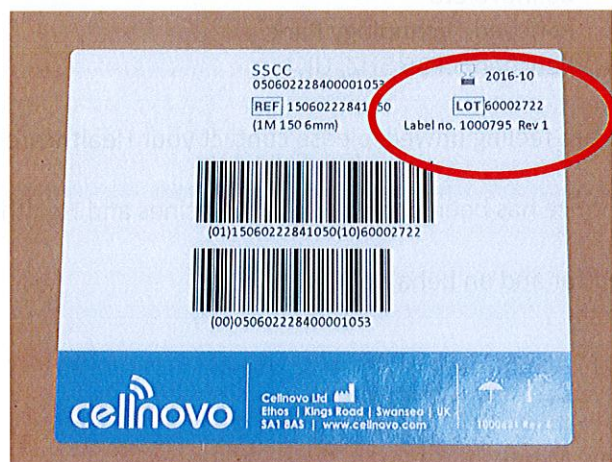
There is a small possibility that you may notice an increase in Bolus Abort and Low Flow alarms when using this batch of insulin cartridges. Whilst the protective systems are in place to make you aware of these occurrences, we understand that interruptions to your therapy can be frustrating.

How to find your Batch Number:

The Batch Number [LOT] is printed onto the label of your Insulin Cartridge pouch or Supply Kit Carton as shown:



Insulin Cartridge Pouch



Supply Kit Carton

What you must do:

If you receive a **Bolus Abort Alarm**, you should:

- Try once again to deliver your bolus. Your system will know how much insulin you have received and will recommend the correct amount of remaining bolus to deliver.
- If your bolus fails to deliver for a second time, you should change the Insulin Cartridge as per standard procedure.

In the absence of Bolus Abort alarms, you should continue to use your Cellnovo System as normal.

If you receive a Low Flow Alarm, you should:

- Change your Insulin Cartridge at the earliest opportunity.

What we are doing:

Cellnovo are already implementing measures to address this issue. In the mean time we will be supplying extra Insulin Cartridges on a free of charge basis for users who experience this issue.

Safety Reminder:

Your safety and wellbeing are very important to Cellnovo. We would like to remind all users that maintaining compliance to your therapy will minimize any risk of symptoms associated with diabetic ketoacidosis (DKA).

As always, compliance to therapy means you must:

- Take a minimum of four blood glucose readings per day
- Always carry your Emergency Kit with you
- Always carry your other (fully charged) Pump, a spare Insulin Cartridge, infusion set, filling kit and insulin
- React appropriately to system alarms

In the meantime, if you have any questions, comments or if any part of this notice is unclear, please contact Cellnovo Customer Care on 0800-025-8009. Alternatively, you can contact Cellnovo by any of the following methods:

Post: Customer Support

Cellnovo Ltd

Pencoed Technology Park

Pencoed, CF35 5HZ, UK

Email: support@cellnovo.com

If you are feeling unwell, please contact your Healthcare Professional.

This notice has been copied to the Medicines and Healthcare Products Regulatory Agency (MHRA)

Signed for and on behalf of Cellnovo



Andrew Mann

Director, Regulatory Affairs

Field Awareness Notice Acknowledgement Form

Please read thoroughly the enclosed Field Awareness Notice FSCA-0015.

Please ensure you understand all of the information provided, if you do not, please call Cellnovo Customer Care on 0800-025-8009.

Once you are satisfied you understand the information, please print, sign, date and provide your postal code, before returning this acknowledgement form in the pre-paid envelope provided.

I, the undersigned do hereby declare that I have received, read and understood Field Safety Notice FSCA-0015.

Name (print): _____

Name (sign): _____

Date: _____

Post Code: _____

