

## Field Awareness Notice

2<sup>nd</sup> April 2015**Cellnovo Insulin Infusion System**

We have become aware of an issue with one of our protective systems.

**Affected Products:**

Part No. 7000081  
Description: Cellnovo Insulin Infusion System  
Batch No: All batches

**The Issue:**

We recently informed you of an issue regarding the very rare chance of an over delivery of insulin from your Cellnovo System. We have taken the decision to ask you to stop the use of the system immediately.

**What you must do:**

As a company, safety is our first priority. We have considered this potential risk to be high and have therefore taken the decision to recall all systems. **We ask you to no longer use your Cellnovo System.** Until such time as this issue is resolved, you should revert to alternate means of managing your therapy.

We will arrange collection from you of all Handsets, Pumps and Insulin Cartridges that you have in your possession. We need to record that the units have been returned to Cellnovo.

We have notified your Healthcare Professional about this potential safety issue.

If you have any concerns, questions or doubts about how to proceed with alternative therapy, you must contact your Healthcare Professional for advice.

**What we are doing:**

Cellnovo are already implementing measures to ensure that you will be able to return to using your Cellnovo system as soon as possible. We will inform you when solutions are in place and you are able to start using your Cellnovo system once again.

We will contact you to ensure you have received this message.

We are here to assist you with any questions or concerns you may have. Please feel free to contact Cellnovo Customer Care on 0800-025-8009 should you require further information.

We appreciate your time and attention to this important notification. We regret the inconvenience caused and look forward to your continued trust in Cellnovo.

This notice has been copied to the National Competent Authority, the Medicines and Healthcare Products Regulatory Agency (MHRA).

Signed for and on behalf of Cellnovo



John Gethin  
V.P. Operations