ViCentra
not just promising

ViCentra B.V.
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Urgent Field Safety Notice

Date: 22/05/2017

Affected devices: Insulin cartridge of the Kaleido insulin infusion system .

Description of the problem: Through investigation we have found that the insulin cartridge component of the Kaleido system was under delivering.

Further investigation identified a manufacturing defect in a third party supplied item, this defect may be present and significant enough cause a clinically significant under delivery in a small proportionof cartridges in any manufacturing lot and which has not been reliably identified during internal testing.

If the user does not regularly monitor blood glucose levels this can, over the 3 days an individual cartridge is in use rise to the point where there is a risk of acidic ketoacidosis

Advise on action to be taken by the user:

- Please conclude the use of the Kaleido insulin infusion system as soon as is appropriate.
- Please return all Kaleido cartridges to ViCentra, you may retain your handset and pump for future use.
- We will notify users when we are again able to provide cartridges.
- Please re-engage with your former therapy and adhere to your medical professional's advice.

Transmission of this Field Safety Notice: This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of thecorrective action.

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