

### Medical Device Correction – Insulet Omnipod 5 Pods

#### **Purpose of this communication:**

We are writing to inform you that the Insulet Corporation initiated a voluntary Medical Device Correction for specific lots of Omnipod® 5 Pods after identifying a manufacturing issue through its ongoing product monitoring. This action applies to specific identified lots distributed in the United States, and all other Omnipod® 5 Pods and Omnipod® products remain safe to use. Insulet has received 18 reports of serious adverse events associated with high blood glucose levels, including hospitalization and DKA. No deaths have been reported. This issue does not affect continuous glucose monitoring (CGM) systems or CGM readings.

#### **What do I need to do?**

- Please review the following Medical Device Correction from the FDA [here](#).
- Notify impacted patients and to facilitate replacement, according to the guidelines issued by the manufacturer in the FDA notification in the above link.
  - Customers should visit [omnipod.com/check-pods](http://omnipod.com/check-pods) to confirm whether their Pod lot number is included in this voluntary Medical Device Correction and request replacement Pods at no cost.
  - If a Pod from an affected lot is currently in use, customers should discontinue use and replace it with a Pod from an unaffected lot.
- Confirm if you have any CareCentrix patients affected by this FDA Early Alert and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

**Thank you in advance for your cooperation and continued partnership.**