

## FDA Recall – Insulet Omnipod 5 Pods

**Purpose of this communication:**

We are writing to inform you that Insulet Corporation initiated a voluntary Medical Device Correction, classified by the FDA as a Class I recall, for specific lots of Omnipod<sup>®</sup> 5 Pods, including certain expired lots, after identifying a manufacturing issue through its ongoing product monitoring. The issue involves a possible small tear in the internal insulin-delivery tubing, which may result in under-delivery of insulin. This action applies only to identified lots distributed in the United States, and all other Omnipod<sup>®</sup> 5 Pods and Omnipod<sup>®</sup> products remain safe to use. Insulet has received 476 reports of serious injuries; no deaths have been reported. The 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 facilitate replacement in accordance with Insulet’s instructions outlined in the FDA Medical Device Correction notice. Impacted Pods are limited to specific identified lots, including certain expired lots, distributed in the United States; all other Omnipod<sup>®</sup> products remain safe to use.
  - Lot verification and replacement: Customers should visit [omnipod.com/check-pods](http://omnipod.com/check-pods) to confirm whether their Pod lot number is included in the voluntary Medical Device Correction and to request replacement Pods at no cost from Insulet.
  - Pods currently in use: If a Pod from an affected lot is currently in use, customers should discontinue use immediately and replace it with a Pod from an unaffected lot to avoid potential under-delivery of insulin and risk of hyperglycemia or DKA.
- 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.**