

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Insulet is conducting a Medical Device Correction for specific lots of Omnipod 5, Omnipod DASH, and Omnipod Insulin Management System (Omnipod Eros) Pods due to a manufacturing issue we identified through ongoing product monitoring, that could result in insulin under-delivery. This action is separate from the voluntary Medical Device Correction issued March 12, 2026 affecting certain Omnipod® 5 Pods in the US.

Insulet identified that some Pods from specific lots may have a small tear in the tubing (cannula) just above the skin, between the Pod and the point where the cannula enters the body. If this occurs, insulin may leak outside of the Pod instead of being fully delivered into the body as intended, potentially leading to under-delivery of insulin. If a patient is using an affected Pod, they may notice wetness on their skin or Pod adhesive or detect the smell of insulin. However, in some cases, this issue may be difficult to detect and go unnoticed.

If insulin leakage occurs, the patient's blood glucose levels may rise and may not respond as expected to insulin delivery. If using Omnipod 5 in Automated Mode, this could trigger an Automated Delivery Restriction alert, advising them to troubleshoot. However, this issue may happen without triggering any alert, meaning patients could receive less insulin than needed without realizing it. Patients should **not** rely only on Pod alerts to know if something is wrong.

Note that this issue does **not** affect continuous glucose monitoring (CGM) systems or CGM readings.

This action affects certain Omnipod 5, Omnipod DASH, and Omnipod (Eros) Pod lots distributed in the US and affected international markets. Pods not included in the affected lots remain safe to use.

Customers should visit [here](#) to acknowledge receipt and check whether their Pod lot number is included in this voluntary Medical Device Correction. Customers should check the lot number on their Pod tray lid, Pod box, or Pod itself. All Pods within a single box will be from a single lot. Customers should not use Pods from affected lots.

If insulin is not delivered properly, customers may experience high blood glucose levels due to under-delivery of insulin. In the most severe cases, prolonged and persistent high blood glucose levels can lead to diabetic ketoacidosis (DKA), a serious medical condition that requires prompt medical treatment and can be life-threatening if not treated.

Globally, there have been 24 reports of serious adverse events associated with high blood glucose levels, including hospitalization and DKA. There have been no deaths reported.

Insulet is communicating proactively with affected customers and providing clear instructions to help them identify affected lots, discontinue use of impacted Pods, and obtain replacement Pods at no cost. Customers will not require a new prescription from their healthcare provider. Because affected customers will receive communications directly from Insulet, no proactive outreach from retail pharmacies to patients is required.

Insulet has identified the cause of this manufacturing issue and implemented corrective actions designed to prevent recurrence. In addition, the Company has further strengthened its in-process monitoring and quality controls designed to detect cannula tears of this nature.

**Products Affected** Omnipod® 5 Automated Insulin Delivery System  
Omnipod DASH® Insulin Management System  
Omnipod® Insulin Management System (Omnipod Eros)

**UDI** 20385081120033, 10385081120036, 20385082000051  
10385082000023, 10385083000114, 20385083000425  
10385083000411, 20385083000579, 10385083000527

**Omnipod 5 Starter Kit part # PT-001659**

Affected Lot Numbers

PK00315	PK00389
PK00316	PK00390
PK00319	PK00394
PK00324	PK00396
PK00327	PK00401
PK00331	PK00407
PK00350	PK00415
PK00354	PK00417
PK00359	PK00420
PK00365	PK00425
PK00370	PK00432
PK00371	PK00509
PK00381	PK00513
PK00383	PK00518
PK00389	

**Omnipod 5 Starter Kit part # PT-001998**

Affected lot Numbers

PK00522	PK00523
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**Omnipod® 5 Pod**

Affected Pod lots

PH1U01032521	PH1U09212421	PH1U12102421	PR1U02132611	PR1U11262521	PH1U02042521
PH1U01102521	PH1U09262411	PH1U12122421	PR1U02132641	PR1U11262541	PH1U04092521
PH1U01132521	PH1U09262421	PH1U12132422	PR1U11182531	PR1U12012521	PH1U04112521
PH1U01172521	PH1U10042421	PH1U12172421	PR1U11182541	PR1U12022521	PH1U10142421
PH1U01222521	PH1U10102421	PH1U12182421	PR1U11192531	PR1U12032521	PH1U10152421
PH1U01232522	PH1U10112422	PR1U01132621	PR1U11192532	PR1U12102522	PH1U10162421
PH1U02132511	PH1U10122421	PR1U01152621	PR1U11192541	PR1U12112521	PH1U11212421
PH1U02212521	PH1U10172522	PR1U01162621	PR1U11192542	PR1U12122521	PH1U11222421
PH1U02222521	PH1U10182521	PR1U01172621	PR1U11202521	PR1U12132511	PH1U11252421
PH1U03202521	PH1U10202521	PR1U01202621	PR1U11202532	PR1U12132521	PH1U11262421
PH1U03262521	PH1U10212521	PR1U01212621	PR1U11202533	PR1U12152521	PH1U01302522
PH1U03282521	PH1U10222521	PR1U01222621	PR1U11202541	PR1U12162521	PH1U01312511
PH1U03312521	PH1U10232521	PR1U01232621	PR1U11202542	PH1U09172421	PH1U02032521
PH1U04032521	PH1U10242521	PR1U01272621	PR1U11212521	PR1U12172521	PH1U04102521
PH1U04042521	PH1U10252521	PR1U01302641	PR1U11222521	PH1U01092621	PH1U09182421
PH1U04302524	PH1U11152521	PR1U01312631	PR1U11222531	PH1U02202521	PH1U09192421
PH1U05012521	PH1U11172511	PR1U02022641	PR1U11222541	PH1U04222521	PH1U09202421
PH1U05022521	PH1U11172521	PR1U02032631	PR1U11232541	PH1U04232511	PH1U10172421
PH1U05052521	PH1U11182521	PR1U02032641	PR1U11242521	PH1U04232521	
PH1U06282422	PH1U11192511	PR1U02042641	PR1U11242531	PH1U10182422	
PH1U09112421	PH1U11192521	PR1U02052631	PR1U11252512	PH1U11142521	
PH1U09122421	PH1U12022421	PR1U02052641	PR1U11252521	PH1U12042521	
PH1U09122422	PH1U12092421	PR1U02062631	PR1U11252531	PH1U12052521	
PH1U09162421	PH1U12102412	PR1U02112641	PR1U11252541	PH1U01312521	

**Omnipod DASH® Pod**

Affected Pods Lots

PD1U09062421	PD1U10282421	PD1U01082621	PD1U10292521	PD1U11032521
PD1U09092421	PD1U10292421	PD1U02152521	PD1U10302521	PD1U11042521
PD1U09102421	PD1U10312421	PD1U02192521	PD1U10312521	PD1U11052421
PD1U10242421	PD1U11042421	PD1U04242522	PD1U11012421	

PD1U10252421

PD1U11192421

PD1U10282522

PD1U11022421

**Omnipod (Eros) Pod**

Affected Pod Lot

L72514