



NEWS RELEASE

Insulet Initiates Voluntary Medical Device Correction for Certain Omnipod® Pods in the U.S. and Affected International Markets

2026-05-26

ACTON, Mass.--(BUSINESS WIRE)-- Insulet Corporation, Inc. (NASDAQ: PODD) ("Insulet" or the "Company") today announced a voluntary Medical Device Correction for specific lots of Omnipod® 5, Omnipod DASH®, and Omnipod® Insulin Management System (Omnipod Eros) Pods due to a manufacturing issue, identified through ongoing product monitoring, that could result in insulin under-delivery.

This action is separate from the voluntary Medical Device Correction issued on March 12, 2026 affecting certain Omnipod 5 Pods in the U.S. and includes certain Pod lots distributed in the U.S. and affected international markets. Pods not included in the affected lots remain safe to use.

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.

Individuals using an affected Pod 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 is not delivered properly, users 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.



Approximately 7 million Pods are included within the scope of this action, approximately 60% of which have been consumed or are expired. The Pods affected by this correction represent approximately 8.5% of 2025 global Omnipod Pod production. 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.

This issue does **not** affect continuous glucose monitoring (CGM) systems or CGM readings.

The issue was identified through the Company's ongoing product monitoring.

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.

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. The Company has sufficient supply available to replace affected Pods and does not anticipate any disruption to product availability.

The U.S. Food and Drug Administration (FDA) and all other relevant regulatory authorities have been notified of this action.

Important Information for Omnipod Pod Users

Customers should visit **Check Pod Lot** to confirm whether their Pod lot number is included in this voluntary Medical Device Correction and request replacement Pods at no cost. A full list of affected lots is available on this site.

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.

Customers in the U.S. who have questions or need assistance may contact Insulet Product Support at 1-800-641-2049 (available 24/7) or use the live agent chat at www.omnipod.com/current-podders.

Customers outside the U.S. should visit www.omnipod.com and click the banner at the top of the page for more information.

Forward-Looking Statement:

This press release includes certain forward-looking statements within the meaning of the Private Litigation Securities Reform Act of 1995, as amended. Forward-looking statements relate to future events, including statements concerning the Company's plans or expectations regarding any voluntary medical device correction and

effects of any voluntary medical device correction on the Company's business, operations, and financial performance or guidance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond the Company's control, that may cause the actual results, performance or achievements of the Company to be materially different from its current expectations, assumptions, plans, guidance, estimates and projections, including (but not limited to) the financial, operational, and reputational impact and costs of any voluntary medical device correction, future actions by the FDA and other regulatory bodies, the possibility that any voluntary medical device correction could subject the Company to disputes, claims or proceedings that may adversely affect its business and financial operation and other factors detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including those discussed under "Risk Factors" in the Company's Form 10-K for the year ended December 31, 2025. The Company encourages you to consider all of these risks, uncertainties and other factors carefully in evaluating the forward-looking statements contained in this press release. The forward-looking statements made in this press release are made only as of the date of this press release, and the Company undertakes no obligation to update them to reflect subsequent events or circumstances except as required by applicable law.

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