Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC26-006-CG
March 30, 2026

FDA announced that, **CDRH is issuing an *Early Alert* to notify the public of a potentially high-risk device issue**. The FDA will keep the public informed and updated as significant new information becomes available.

Insulet stated that Omnipod 5 Pods from certain lots may have a small tear in the internal tubing that delivers insulin. If this occurs, insulin may leak inside the Pod instead of being fully infused in the body as intended.

The FDA is aware that Insulet has issued a letter to affected customers recommending certain Omnipod 5 Pods be removed from where they are used or sold.

RECOMMENDATIONS

1. Customers in the U.S. with adverse reactions, quality problems, or questions about this recall should contact Insulet at 1-800-641-2049 or visit https://www.omnipod.com/current-poddersExternal Link Disclaimer to reach a live chat agent.

2. Review your inventory to identify existence of recalled products.

3. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

Cordially,

MC-Rx Pharmacy Services Department

T. (800) 377-1037
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Early Alert: Insulin Pump Issue from Insulet

CDRH is issuing this Early Alert to notify the public of a potentially high-risk device issue. *The FDA will keep the public informed and updated as significant new information becomes available.*

Affected Product

The FDA is aware that Insulet has issued a letter to affected customers recommending certain Omnipod 5 Pods be removed from where they are used or sold.

Affected devices:
Device Name: Omnipod 5 Pods
Unique Device Identifier: 10385083000527
Full List of Affected Product [XLSX 17 KB]

Omnipod 5 Pods	
Lot Number	**UDI**
PH1U02252541	10385083000527
PH1U03282511	10385083000527
PH1U03282522	10385083000527
PH1U03312511	10385083000527
PH1U03312521	10385083000527
PH1U04012511	10385083000527
PH1U04012521	10385083000527
PH1U05052511	10385083000527
PH1U08162531	10385083000527
PH1U08182531	10385083000527
PH1U08182541	10385083000527
PH1U09242511	10385083000527
PH1U09242521	10385083000527
PH1U09242531	10385083000527
PH1U09252521	10385083000527
PH1U09252531	10385083000527
PH1U10152541	10385083000527
PH1U10162531	10385083000527

Omnipod 5 Pods	
Lot Number	**UDI**
PH1U10162541	10385083000527
PH1U10172531	10385083000527
PH1U10172541	10385083000527
PH1U10182531	10385083000527
PH1U10182541	10385083000527
PH1U10202511	10385083000527
PH1U10202521	10385083000527
PH1U10202531	10385083000527
PH1U10202541	10385083000527
PH1U10212531	10385083000527
PH1U10212541	10385083000527
PH1U10222531	10385083000527
PH1U10222541	10385083000527
PH1U10232531	10385083000527
PH1U10232541	10385083000527
PH1U10242521	10385083000527
PH1U10242531	10385083000527
PH1U10242541	10385083000527

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What to Do

Do not use affected Pods. If you do not have enough Pods due to this issue, talk to your health care provider about other methods of insulin delivery.

On March 12, Insulet sent all affected customers a letter recommending the following actions:

- Check the lot number on the Pod packaging or device to determine if it is from an affected lot.
- Do not use pods from affected lots. Discontinue use of any impacted Pods immediately.
- If you do not have enough Pods due to this issue, talk with your health care provider to find other methods of insulin delivery while waiting for Pods to be replaced. Always follow your health care provider's guidance on appropriate glucose monitoring.
- Always confirm Pod expiration dates prior to use and do not use Pods that are past expiration.
- Visit omnipod.com/check-pods to acknowledge receipt and check to see if your lot is affected.
- Contact Insulet to request replacement Pods and return unused Pods from affected lots or to receive additional support by:
  - Utilizing Insulet's live agent chat by clicking the Podder Support button in the lower right of this page: https://www.omnipod.com/current-poddersExternal Link Disclaimer
  - Calling Insulet's Product Support phone line at **1-800-641-2049**, available 24/7

Check this web page for updates. The FDA is currently reviewing information about this potentially high-risk device issue and will keep the public informed as significant new information becomes available.

Reason for Alert

Insulet stated that Pods from certain lots may have a small tear in the internal tubing that delivers insulin. If this occurs, insulin may leak inside the Pod instead of being fully infused

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in the body as intended. 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.

If there is a fluid leak inside the Pod, the device may trigger a hazard alarm. If a hazard alarm occurs, users should remove their Pod and replace it immediately to restore insulin delivery. The risk of under-delivery increases if a user applies more than one Pod from an affected lot consecutively.

This issue does not affect continuous glucose monitoring systems (CGM) or CGM readings. As of March 12, Insulet has reported 18 serious injuries and no deaths associated with this issue.

Device Use

Omnipod is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Contact Information

Customers in the U.S. with adverse reactions, quality problems, or questions about this recall should contact Insulet at **1-800-641-2049** or visit https://www.omnipod.com/current-poddersExternal Link Disclaimer to reach a live chat agent.

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