Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC26-012-CG
May 1st, 2026

FDA announced that *this recall involves correcting devices, and does not involve removing them from FDA announced that, Insulin Pump Recall: Insulet Removes Certain Omnipod 5 Pods.*

This recall involves removing certain devices from where they are used or sold. The FDA has identified this recall as the most serious type. This device may cause serious injury or death if you continue to use it.

RECOMMENDATIONS

1. 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.

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

   a. Do not use pods from affected lots.
   b. Check the lot number on the Pod tray lid, the Pod box or the Pod itself to determine if your Pods are affected. For more information on how to find the lot number, go to Appendix A on this page: https://www.omnipod.com/mdc-3-26External Link Disclaimer
   c. Discontinue use of any impacted Pod immediately. If the Pod you are currently using is from an affected lot, it is important that you immediately change your Pod to resume insulin delivery. When changing your Pod, confirm that the new Pod is not from an affected lot.
   d. 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.
   e. Always check the expiration date before using a Pod. Do not use any Pod that is past its expiration date, as expired Pods may not function as intended.
   f. Visit omnipod.com/check-podsExternal Link Disclaimer to acknowledge receipt and check to see if your lot is affected.

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g. 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 page: https://www.omnipod.com/current-poddersExternal Link Disclaimer
h. Calling Insulet's Product Support phone line at 1-800-641-2049, available 24/7

3. On April 10, 2026, Insulet sent all affected customers an updated letter expanding the list of affected Pod lots and providing additional details on this issue to clarify that the Pod defect may not be detectable by users. Insulet is also sending targeted communications to users who activate a Pod from an impacted lot with information on Pod discontinuation.

4. Contact Information: Customers in the U.S. with adverse reactions, quality problems, or questions about this issue should contact Insulet at 1-800-641-2049 or visit https://www.omnipod.com/current-podders.

5. Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

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

7. 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

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FDA U.S. FOOD & DRUG ADMINISTRATION

Insulin Pump Recall: Insulet Removes Certain Omnipod 5 Pods

The affected product lots and information about the issue below have changed. *This recall involves removing certain devices from where they are used or sold. The FDA has identified this recall as the most serious type. This device may cause serious injury or death if you continue to use it.*

Affected Product

- **Device Name:** Omnipod 5 Pods
- **Unique Device Identifier:** 10385083000527
- **Full List of Affected Product** attached

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:

- Do not use pods from affected lots.
- Check the lot number on the Pod tray lid, the Pod box or the Pod itself to determine if your Pods are affected. For more information on how to find the lot number, go to Appendix A on this page: https://www.omnipod.com/mdc-3-26External Link Disclaimer

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- Discontinue use of any impacted Pod immediately. If the Pod you are currently using is from an affected lot, it is important that you immediately change your Pod to resume insulin delivery. When changing your Pod, confirm that the new Pod is not from an affected lot.
- 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 check the expiration date before using a Pod. Do not use any Pod that is past its expiration date, as expired Pods may not function as intended.
- Visit omnipod.com/check-podsExternal Link Disclaimer 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

On April 10, 2026, Insulet sent all affected customers an updated letter expanding the list of affected Pod lots and providing additional details on this issue to clarify that the Pod defect may not be detectable by users. Insulet is also sending targeted communications to users who activate a Pod from an impacted lot with information on Pod discontinuation.

Reason for Recall

Insulet stated that Pods from certain lots may have a small tear in the internal tubing that delivers insulin. If this happens, insulin may leak inside the Pod instead of being fully infused in the body as intended, potentially leading to under-delivery of insulin.
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. The risk of under-delivery increases if users apply more than one affected Pod in a row.
If there is a fluid leak inside the Pod, users may receive a hazard alarm notifying them to remove the Pod. In some cases, there may be no alarm or alert, and the issue may go

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unnoticed, potentially leading to under-delivery of insulin with the potential for prolonged high blood glucose levels. If this occurs, the user's blood glucose levels may increase and may not respond as expected to additional insulin delivery. This could result in an Automated Delivery Restriction alert advising users to troubleshoot.

Because this problem may happen without triggering an alarm or alert, users could receive less insulin than needed without realizing it. For this reason, affected users should not rely only on alarms to know if something is wrong. If users have Pods from an affected lot, they should switch to a Pod from a nonaffected lot as soon as possible or talk with their healthcare provider about other options for insulin delivery.

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

As of April 17, Insulet has reported 476 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 issue should contact Insulet at 1-800-641-2049 or visit https://www.omnipod.com/current-poddersExternal Link Disclaimer to reach a live agent chat.

Additional FDA Resources

- CDRH Medical Device Recall Database
- FDA Enforcement Report
- Insulet Initiates Voluntary Medical Device Correction for Certain Omnipod® 5 Pods in the U.S. [03/13/2026]

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Additional Company Resources

Company-provided information is posted here by the FDA as a public service.

1. Urgent Medical Device Correction | OmnipodExternal Link Disclaimer [03/12/2026]
2. Insulet Corporation - Insulet Initiates Voluntary Medical Device Correction for Certain Omnipod® 5 Pods in the U.S.External Link Disclaimer [03/12/2026]

Unique Device Identifier (UDI)

The unique device identifier (UDI) helps identify individual medical devices sold in the United States from manufacturing through distribution to patient use. The UDI allows for more accurate reporting, reviewing, and analyzing of adverse event reports so that devices can be identified, and problems potentially corrected more quickly.

- How do I recognize a UDI on a label?
- AccessGUDID database - Identify Your Medical Device
- Benefits of a UDI System

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

Device Name	Lot Number	UDI	Lot Number	UDI
Omnipod 5 Pods	PH1U02252541	10385083000527	PH1U10202521	10385083000527
Omnipod 5 Pods	PH1U03282511	10385083000527	PH1U10202531	10385083000527
Omnipod 5 Pods	PH1U03282522	10385083000527	PH1U10202541	10385083000527
Omnipod 5 Pods	PH1U03312511	10385083000527	PH1U10212531	10385083000527
Omnipod 5 Pods	PH1U03312521	10385083000527	PH1U10212541	10385083000527
Omnipod 5 Pods	PH1U04012511	10385083000527	PH1U10222531	10385083000527
Omnipod 5 Pods	PH1U04012521	10385083000527	PH1U10222541	10385083000527
Omnipod 5 Pods	PH1U05052511	10385083000527	PH1U10232531	10385083000527
Omnipod 5 Pods	PH1U08162531	10385083000527	PH1U10232541	10385083000527
Omnipod 5 Pods	PH1U08182531	10385083000527	PH1U10242521	10385083000527

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Device Name	Lot Number	UDI	Lot Number	UDI
Omnipod 5 Pods	PH1U08182541	10385083000527	PH1U10242531	10385083000527
Omnipod 5 Pods	PH1U09242511	10385083000527	PH1U10242541	10385083000527
Omnipod 5 Pods	PH1U09242521	10385083000527	PH1U08062421	10385083000527
Omnipod 5 Pods	PH1U09242531	10385083000527	PH1U08062411	10385083000527
Omnipod 5 Pods	PH1U09252521	10385083000527	PH1U08052431	10385083000527
Omnipod 5 Pods	PH1U09252531	10385083000527	PH1U08032411	10385083000527
Omnipod 5 Pods	PH1U10152541	10385083000527	PH1U08032421	10385083000527
Omnipod 5 Pods	PH1U10162531	10385083000527	PH1U07252421	10385083000527
Omnipod 5 Pods	PH1U10162541	10385083000527	PH1U05162431	10385083000527
Omnipod 5 Pods	PH1U10172531	10385083000527	PH1U05162421	10385083000527
Omnipod 5 Pods	PH1U10172541	10385083000527	PH1U05162411	10385083000527
Omnipod 5 Pods	PH1U10182531	10385083000527	PH1U05152421	10385083000527
Omnipod 5 Pods	PH1U10182541	10385083000527	PH1U05152411	10385083000527
Omnipod 5 Pods	PH1U10202511	10385083000527	PH1U05152431	10385083000527
			PH1U03212421	10385083000527

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