Mass General Brigham
Health Plan

Omnipod 5 Pods medical device correction

On March 13, 2026, Insulet, the manufacturer of Omnipod 5 pods, issued a letter to distributors, health care providers, and affected customers recommending that Omnipod 5 pods be removed from where they are used or sold.

The recall was issued due to the discovery that certain Pods from specific 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. If insulin is not delivered properly, you 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, you may receive a hazard alarm to notify you to remove your Pod. It is important that you change your Pod immediately to resume full insulin delivery. When changing your Pod, confirm the new Pod is not from an affected lot. This risk of under-delivery increases if you use more than one affected Pod in a row.

What do you need to do?

Determine if your current or unused pod(s) are affected by visiting Omnipod's "Check Your Pod Lot" site.

- If you are currently using or have an Omnipod 5 pod that has been confirmed as potentially affected on Omnipod's "Check Your Pod Lot" site, or by a customer service representative, immediately discontinue use and dispose of the affected pod(s).
- You can request a replacement for any potentially affected pod(s) on Omnipod's "Check Your Pod Lot" site, or by calling their dedicated product support line at 800-641-2049.
- If you have pods that are *not* included in the lot(s) impacted by the recall, you may continue to use those pods.
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For more information, please contact Insulet's Product Support line at the number below. Please report any adverse events or quality problems experienced with the use of this product to Insulet, or you can report to the FDA's MedWatch Program.

Insulet's Product Support Line (For medical questions or to report adverse events):

1-800-641-2049 (available twenty-four hours per day, seven days a week)

Insulet Customer Support (live chat feature available Monday-Friday, 8am-10pm ET)

To report an adverse event to the FDA Med Watch Program

Online: http://www.fda.gov/MedWatch/report.htm

Regular Mail or Fax: Download form http://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program or call 1-800-332-1088 to request a reporting form. Complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.