California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Insulet Corporation Recalls Omnipod 5 ACE Pump

Recall Date	Product Description	Recalling Firm	Recall Reason
4/10/2026	Omnipod 5 Pods Model/Catalog number: PT-001662 ASM 5PK Pod STRL OPS G6G7	Insulet Corporation Acton, MA	Due to a manufacturing defect, certain Omnipod 5 Pods from 49 lots have an internal soft cannula tear that results in insulin leaking into the Pod instead of being delivered to the user regardless of basal or bolus delivery.

Recall Class	Product Identification	Distribution	Affected Dates
I	Model/Catalog number: PT-001662 ASM 5PK Pod STRL OPS G6G7. UDI-DI: 10385083000527. Lot Codes: PH1U02252541, PH1U03282511, PH1U03282522, PH1U03312511, PH1U03312521, PH1U04012511,	1,240,115 Units Nationwide Nationwide including California	March 2026 and prior

	PH1U04012521, PH1U05052511, PH1U08162531, PH1U08182531, PH1U08182541, PH1U09242511, PH1U09242521, PH1U09242531, PH1U09252521, PH1U09252531, PH1U10152541, PH1U10162531, PH1U10162541, PH1U10172531, PH1U10172541, PH1U10182531, PH1U10182541, PH1U10202511, PH1U10202521, PH1U10202531, PH1U10202541, PH1U10212531, PH1U10212541, PH1U10222531, PH1U10222541, PH1U10232531, PH1U10232541, PH1U10242521, PH1U10242531, PH1U10242541.		

For additional information, please visit the FDA website