

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Insulet Corporation OmniPod Insulin Management System May Fail to Deliver Insulin

Recall Class: Class I

Date Recall Initiated: July 13, 2015

Device:

- [Affected Lot Numbers \(/Safety/Recalls/ucm460169.htm\)](/Safety/Recalls/ucm460169.htm)
- Manufactured from: December 2013 to March 2015
- Distributed from: December 2013 to March 2015
- Devices Recalled in the U.S.: 40,846 boxes (10pods/box)

Use: The OmniPod Insulin Management System is an insulin pump used to deliver insulin to people with diabetes. The insulin pump "Pod" is a small adhesive pump that sticks directly on the body. Insulin is delivered through a small port holding a tube that is inserted into the skin.

Recalling Firm:

Insulet Corporation
600 Technology Park Drive Suite 200
Billerica, Massachusetts 01821

Reason for Recall:

Insulet has identified two issues with these devices.

1. The tube either fails to fully insert into the skin or completely retracts after insertion. This failure occurs without an alarm and the Pod will continue to pump insulin.
2. The Pod will provide an audible alarm signal and display a failure. Once the alarm occurs, the Pod will not pump insulin.

Both failures can result in inaccurate dosage of insulin which can lead to high blood sugar (hyperglycemia). If left untreated, hyperglycemia can cause life-threatening conditions or even death.

The firm has received nine reports in which the device has malfunctioned, including five injuries and no reports of deaths.

Public Contact:

Customers can contact Insulet Customer Care by calling 1-855-407-3729, 24 hours a day, 7 days a week.

FDA District: New England

More Information about this Recall:

Insulet notified customers on July 13, 2015 via email notification or Federal Express. Customers that did not respond to the email or Federal Express received follow-up phone calls.

Insulet provided the following instructions for customers:

1. If you have Pods from any of these lots, set them aside. Insulet will replace them at no charge.
2. Arrange for return and replacement from Insulet by choosing one of the following methods:
 - Complete the online form at <https://www.myomnipod.com/podinfo> (<https://www.myomnipod.com/podinfo>) (fastest method).
 - Return a reply card.
 - Contact Insulet Customer Care by calling 1-855-407-3729 (any time day or night).

About Class I Recalls

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) online, by regular mail or by FAX.

Other Resources

- [Firm Press Release \(/Safety/Recalls/ucm460169.htm\)](/Safety/Recalls/ucm460169.htm)
- [FDA MedWatch Alert \(/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm460197.htm\)](/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm460197.htm)

More in [Medical Device Recalls](/MedicalDevices/Safety/ListofRecalls/default.htm)
(</MedicalDevices/Safety/ListofRecalls/default.htm>)

[2015 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm429489.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

[2014 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm384921.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)