Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-086-CG
November 17, 2022

FDA announced the following, Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), a **Medical Device Correction for the Omnipod® 5 Automated Insulin Delivery SystemExternal Link Disclaimer** because of an issue with the Omnipod 5 Controller charging port and cable. This does not impact the Omnipod 5 Pod, the Omnipod® DASH Insulin Management System, the Omnipod® Insulin Management System, or compatible Android smartphone devices that have the Omnipod 5 App installed. These actions are taken voluntarily with the knowledge of the FDA.

RECOMMENDATIONS

1. Omnipod 5 users are being notified by email with instructions on how to detect and reduce the risk of an issue with the charging port or cable.

2. Users who experience any issue should contact Insulet's dedicated Customer Care team at 1-800-641-2049, which is available 24 hours a day, 7 days a week.

3. Alternatively, Omnipod 5 users can utilize the FDA's MedWatch Adverse Event Reporting program either online **(www.fda.gov/medwatch/report.htmExternal Link Disclaimer)**, by regular mail, or by fax (1-800-FDA-0178).

4. Additional information, including instructions to customers to mitigate risk, can be found on the Company's website at **www.omnipod.com/insulet-alertsExternal Link Disclaimer.**

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

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

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
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FDA U.S. FOOD & DRUG ADMINISTRATION

Insulet Issues a Nationwide Voluntary Medical Device Correction for the Omnipod® 5 Controller

Summary:

Company Announcement Date:	November 14, 2022
FDA Publish Date:	November 15, 2022
Product Type:	Medical Devices
Reason for Announcement:	Issue with the Omnipod 5 Controller charging port and cable
Company Name:	Insulet Corporation
Brand Name:	Insulet Corporation Omnipod
Product Description:	Automated Insulin Delivery System

Company Announcement

ACTON, Mass.--(BUSINESS WIRE)--Nov. 14, 2022– Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), today announced a **Medical Device Correction for the Omnipod® 5 Automated Insulin Delivery SystemExternal Link Disclaimer** because of an issue with the Omnipod 5 Controller charging port and cable. This does not impact the Omnipod 5 Pod, the Omnipod® DASH Insulin Management System, the Omnipod® Insulin Management System, or compatible Android smartphone devices that have the Omnipod 5 App installed. These actions are taken voluntarily with the knowledge of the FDA.

Insulet has received 24 reports that the Omnipod 5 Controller charging port (USB-C port) or cable (USB cable) are melting, deforming, or discoloring due to heat generated by a poor connection between the cable and the port. The excess heat may cause minor burns if those areas of the Controller are touched or could lead to fire. No serious injuries have been reported to Insulet as a result of this issue.

Omnipod 5 users are being notified by email with instructions on how to detect and reduce the risk of an issue with the charging port or cable. Users who experience any issue should contact Insulet's dedicated Customer Care team at **1-800-641-2049**, which is available 24 hours a day, 7 days a week. Alternatively, Omnipod 5 users can utilize the FDA's MedWatch Adverse Event Reporting program either online **(www.fda.gov/medwatch/report.htmExternal Link Disclaimer)**, by regular mail, or by fax (**1-800-FDA-0178**).

Additional information, including instructions to customers to mitigate risk, can be found on the Company's website at **www.omnipod.com/insulet-alertsExternal Link Disclaimer.**

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