carecentrix

Provider Newsflash
November 2022

FDA Recall –Insulet Omnipod DASH

Purpose of this communication:

- We are writing to inform you that the FDA has issued a Class I recall of the Insulet Omnipod DASH Insulin Management System Personal Diabetes Manager (PDM) after receiving reports of PDM battery issues, including battery swelling, fluid leakage from the battery and extreme overheating that may pose a fire hazard. The recalled products include all serial numbers of the 18239 ASM Omnipod DASH PDM, the PT-000010: Assembly, DASH Final PDM U100, mg/dL, and the PT-000011: Assembly, DASH Final PDM U100, mmol/L distributed from July 27, 2018 to August 31, 2022. Users could be exposed to battery fluid and extreme heat, including the potential for an explosion and/or fire, which could lead to serious injury or death.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/insulet-recalls-omnipod-dash-insulin-management-systems-personal-diabetes-manager-pdm-risk-battery?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.