

Provider Newsflash April 2025

FDA Recall – Max Mobility/Permobil

Purpose of this communication:

- We are writing to inform you Max Mobility/Permobil is recalling the Speed Control Dial component used with the SmartDrive MX2+ Power Assist Device due to a circuit board issue that may cause the motor to be unresponsive to the user. Specifically, the device may continue to drive, move on its own without user input, lose power, or fail to start driving. The use of affected product may cause serious adverse health consequences for users and bystanders, including skin irritation, minor cuts, bruises, muscle or ligament strain or tear, bone fractures, concussion, and death. Impacted part numbers are MX2-3DCK and MX2-3DC.
- As of March 27, 2025, Max Mobility/Permobil has received 781 complaints associated with the Speed Control Dial with five (5) serious injuries have been reported for this issue. The reported serious injuries include a fractured hip, fractured tibia, fractured malleolus bone, broken ribs, and a concussion. This recall, as expanded, impacts all Speed Control Dials manufactured and distributed between the dates of August 17, 2023, through March 10, 2025.

What do I need to do?

- Please see the updated recall notification here: <u>https://www.fda.gov/safety/recalls-market-</u> <u>withdrawals-safety-alerts/max-mobility-permobil-expands-nationwide-recall-smartdrive-speed-</u> <u>control-dial-due-motor-being?utm_medium=email&utm_source=govdelivery</u>
- Review the following original recall notice: <u>https://www.fda.gov/medical-devices/medical-device-recalls/power-assist-device-recall-max-mobilitypermobil-removes-speedcontrol-dial-component-used-smartdrive?utm_medium=email&utm_source=govdelivery</u>
- Notify impacted patients and facilitate the replacement 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.