

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. There have been 13 reported injuries. There have been no reports of death. Impacted part numbers are MX2-3DCK and MX2-3DC that were manufactured from August 17, 2023 to November 21, 2024.

What do I need to do?

- Please review the following recall notice: 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
- 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.

Thank you in advance for your cooperation and continued partnership.