Urgent Medical Device Correction

Max Mobility/Permobil SpeedControl Dial utilized with SmartDrive MX2+ Power Assist Device

[MONTH DAY], 2024
[CONSIGNEE NAME]
[ADDRESS]
[CITY, STATE, ZIP]
[PROVIDER ID]

Dear Valued Customer,

The purpose of this letter is to inform you of a voluntary medical device field correction involving the **Max Mobility/Permobil Speed Control Dial component utilized with the SmartDrive MX2+ Power Assist Device**. All Impacted serial number products that were manufactured between August 17,2023 through November 21, 2024.

Reason for the Voluntary Field Correction:
The **Max Mobility/Permobil** Speed Control Dial is a wired control option for the SmartDrive power assist device. Through market feedback and subsequent investigation, **Max Mobility/Permobil** has identified a material change with the printed circuit board assembly (PCBA) in the SpeedControl Dial. This material change has resulted in performance issues with the SpeedControl Dial. The following are scenarios that some users may experience:

- **Continued drive:** The SpeedControl Dial does not fully stop the drive unit when rotated to zero position.
- **Involuntary movement:** Unintended activation of the SmartDrive motor without intentional user input while the SpeedControl Dial is at zero position and dial light is flashing in stand-by-mode.
- **Loss of power:** When the SpeedControl Dial is rotated forward from zero position, SmartDrive motor movement is initiated, and then the SpeedControl Dial unexpectedly shuts down.
- **Failure to start driving:** When the dial is rotated forward from zero position, no SmartDrive motor activation occurs.

Risk to Health:
If an individual is using an impacted **Max Mobility/Permobil** SpeedControl Dial, they may experience one of the above performance issues. This could result in the SmartDrive motor continuing to run, unexpectedly initiating movement, or stopping unexpectedly. Depending on the scenario, this could lead to serious injury.

Affected Product:
The specific model numbers impacted by this issue are shown below:

Part Number
MX2-3DCK

MX2-3DC

Actions Required:
Our records indicated that you have purchased one or more of the impacted units. A list of impacted purchase orders is shown in ATTACHMENT 1. To correct the affected products, you will need to request replacement SpeedControl Dial units to replace any impacted SpeedControl Dial units in the field.

Please use the QR code to access the field action portal at:
https://hub.permobil.com/smartdrive-scd-voluntary-field-action

1. Click on the link or scan QR code to enter the portal.
2. Once you enter the portal, you will be asked to enter your contact information, select if you are a dealer or end user, and acknowledge that you have read and understood the Urgent Medical Device Correction letter.
3. If you are a dealer and have distributed the affected product to someone else, you will be asked to select a transmission method. You may either (a) notify your end users directly and include a copy of this notice with your communication and the provider ID OR (b) provide end user contact information to **Max Mobility/Permobil** through the online portal and we will contact them for you.
4. If you are an end user, you will need to complete the end user portion of the requested information within the field action portal linked above.
5. After acknowledgement, instructions for obtaining replacement SpeedControl Dial units will be provided. You will need the associated provider ID provided in ATTACHMENT 1 of this letter when requesting SpeedControl Dial replacement(s).
6. Once the replacement SpeedControl Dial has been issued, you will be asked to verify that the correction was completed via the field action portal and destroy or return the effected SpeedControl Dial(s) to **Max Mobility/Permobil**.

If at any time you need assistance, the portal will provide you with access to the **Max Mobility/Permobil** technical support team at (800) 736-0925.

While a user is waiting to receive their corrected SpeedControl Dial, the following actions can be taken immediately to reduce the likelihood of a hazardous situation:

- Discontinue use of the SpeedControl Dial and utilize an alternate wired controller (SwitchControl buttons or SwitchControl with mono jack and mechanical switch) or wearable controller (compatible Apple Watch or Samsung Galaxy Watch once Wear OS app is released).

- Possible actions for each performance issue include:
    - **Continued drive:** Press the face of the SpeedControl Dial. This is an alternative stop option to disengage power assist.
    - **Involuntary movement:** Press the face of the SpeedControl Dial. This is an alternative stop option to disengage power assist.
    - **Loss of power:** Rotate the SpeedControl Dial back to the zero position and reengage power assist.
    - **Failure to start driving:** No in-field action, a replacement is required.
    - Another potential action to the above issues is to swap the switch on the rear of the dial from" R" (right) to "L" (left). While this results in the controls of the dial performing opposite of what it does when set to "R," this has been shown to address performance issues in some scenarios.

Contact Information:
If you have any questions, please contact Permobil at 1-800-736-0925 or

Any adverse events experienced with the use of this product may be reported using one of the following options:

- Online: By completing and submitting the report online at https://www.accessdata.fda.gov/scripts/medwatch

- Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

We are voluntarily issuing this Urgent Medical Device Correction, and the U.S. Food and Drug Administration has been notified of this action.

Max Mobility/Permobil considers patient safety and customer satisfaction our top priorities. We apologize for any inconvenience this may cause you and thank you in advance for assistance in implementing this correction.

Sincerely,

Mark Elliott
Vice President, Quality Assurance and Regulatory Compliance

ATTACHMENT 1
List of Purchase Orders / Marked For

[PO NUMBER] [SERIAL NUMBERS] [Marked For]
[PO NUMBER] [SERIAL NUMBERS] [Marked For]
[PO NUMBER] [SERIAL NUMBERS] [Marked For]