

Field Safety Notice

Permobil M- & F- Corpus series models - Control Recline with incorrect bushing

*A **Bushing** is a small protective sleeve that reduces friction and vibration between moving parts.*

2025-12-05 / Version 1 / Ref. FSCA CAPA GR8465

Dear Valued Customer,

The purpose of this letter is to inform you of a voluntary medical device field correction involving Permobil M- & F- series power wheelchairs with a Power Control Backrest assembled within the period 2025/07/10 to 2025/07/25.

Reason for Field Correction:

It has been identified that an incorrect bushing was used during the assembly of this device. The use of an incorrect bushing may reduce the chair's structural integrity under hard impact, although the likelihood is low it can lead to a hazardous situation. The most affected feature is the integrated neck injury protection mechanism which is designed to mitigate neck injuries in the event of a front-end impact.

According to our risk assessments, the probability of failure is determined to be low but since we still have identified an increased risk, we will perform a re-work on all affected units.

Actions Required:

Our records indicate that you own one of the affected chairs, and you will be contacted by your local provider to arrange the required re-work of the device.

While you are waiting for the re-work to be performed, we suggest avoiding car transportation to minimize any risk of injury.

Contact Information:

If you have any questions, please contact your provider, or Permobil Customer Support at +46 60 787 90 60 or customer_support_se@permobil.com

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer using the address: incident.report@permobil.com , as this provides important feedback.

We are voluntarily issuing this Field Safety Notice and the applicable Competent Authorities have been notified of this action.

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,

Monika Östlund
Vice President, Quality Assurance and Regulatory Compliance

Appendix A – Affected Serial Numbers

Country	Model	Serial Number
SE	M3 CORPUS	428002066
SE	M3 CORPUS	428002093
SE	M3 CORPUS	428002119
SE	F5 CORPUS VS	491001548
SE	F5 CORPUS VS	491001564
SE	F5 CORPUS	483000647
SE	F3 CORPUS	425001017
SE	F3 CORPUS	425001024
PT	M CORPUS VS	492000907
PT	F5 CORPUS VS	491001536
PT	F5 CORPUS VS	491001540
PT	F5 CORPUS VS	491001543
PT	F5 CORPUS VS	491001541
PT	F5 CORPUS VS	491001545
PT	F5 CORPUS VS	491001555
PT	F5 CORPUS	483000643
PT	F3 CORPUS	425001014
NO	M5 CORPUS	486000737
NO	M5 CORPUS	486000746
NO	M5 CORPUS	486000747
NO	M CORPUS VS	492000904
NO	F5 CORPUS VS	491001544
NO	F5 CORPUS VS	491001570
NO	F5 CORPUS VS	491001578
NO	F5 CORPUS	483000646
NO	F5 CORPUS	483000648
NO	F3 CORPUS	425001016
NO	F3 CORPUS	425001025
NO	F3 CORPUS	425001030
NO	F3 CORPUS	425001035
NL	M5 CORPUS	486000738
NL	M5 CORPUS	486000742
NL	M5 CORPUS	486000753
NL	M5 CORPUS	486000757
NL	M3 CORPUS	428002064
NL	M3 CORPUS	428002076
NL	M3 CORPUS	428002075
NL	M3 CORPUS	428002085
NL	M3 CORPUS	428002083

NL	M3 CORPUS	428002082
NL	M3 CORPUS	428002098
NL	M3 CORPUS	428002089
NL	M3 CORPUS	428002107
NL	M3 CORPUS	428002130
NL	M3 CORPUS	428002141
NL	M3 CORPUS	428002140
NL	F3 CORPUS	425001018
NL	F3 CORPUS	425001022
KR	M3 CORPUS	428002092
KR	M3 CORPUS	428002090
KR	F5 CORPUS VS	491001560
KR	F5 CORPUS VS	491001561
IT	M3 CORPUS	428002096
IT	M3 CORPUS	428002065
IT	F5 CORPUS	483000650
IT	F5 CORPUS	483000645
IT	F3 CORPUS	425001015
IS	F3 CORPUS	425001036
IL	F3 CORPUS	425001021
IE	M5 CORPUS	486000734
GR	M CORPUS VS	492000911
GB	M5 CORPUS	486000749
GB	M5 CORPUS	486000748
GB	M3 CORPUS	428002097
GB	M3 CORPUS	428002094
GB	M3 CORPUS	428002112
GB	F5 CORPUS VS	491001553
GB	F3 CORPUS	425001027
FR	M5 CORPUS	486000743
FR	M5 CORPUS	486000752
FR	M5 CORPUS	486000751
FR	M5 CORPUS	486000758
FR	M3 CORPUS	428002062
FR	M3 CORPUS	428002068
FR	M3 CORPUS	428002074
FR	M3 CORPUS	428002084
FR	M3 CORPUS	428002091
FR	M3 CORPUS	428002114
FR	M3 CORPUS	428002120
FR	M3 CORPUS	428002133
FR	M3 CORPUS	428002142

FR	M CORPUS VS	492000906
FR	M CORPUS VS	492000910
FR	M CORPUS VS	492000912
FR	M CORPUS VS	492000918
FR	F5 CORPUS VS	491001557
FR	F5 CORPUS VS	491001574
FR	F5 CORPUS	483000662
FR	F3 CORPUS	425001023
FR	F3 CORPUS	425001032
FI	M3 CORPUS	428002069
FI	M3 CORPUS	428002143
FI	F5 CORPUS	483000649
FI	F3 CORPUS	425001020
ES	M5 CORPUS	486000736
ES	M5 CORPUS	486000744
ES	M3 CORPUS	428002063
ES	M3 CORPUS	428002067
DK	M5 CORPUS	486000735
DK	F3 CORPUS	425001019
DE	M5 CORPUS	486000741
DE	M5 CORPUS	486000750
DE	M5 CORPUS	486000754
DE	M5 CORPUS	486000755
DE	M5 CORPUS	486000756
DE	M CORPUS VS	492000905
DE	M CORPUS VS	492000908
DE	M CORPUS VS	492000909
DE	M CORPUS VS	492000914
DE	M CORPUS VS	492000915
DE	M CORPUS VS	492000913
DE	M CORPUS VS	492000917
DE	M CORPUS VS	492000916
DE	M CORPUS VS	492000919
DE	M CORPUS VS	492000921
DE	M CORPUS VS	492000922
DE	M CORPUS VS	492000923
DE	F5 CORPUS VS	491001538
DE	F5 CORPUS VS	491001539
DE	F5 CORPUS VS	491001535
DE	F5 CORPUS VS	491001542
DE	F5 CORPUS VS	491001537
DE	F5 CORPUS VS	491001546

DE	F5 CORPUS VS	491001552
DE	F5 CORPUS VS	491001551
DE	F5 CORPUS VS	491001550
DE	F5 CORPUS VS	491001549
DE	F5 CORPUS VS	491001556
DE	F5 CORPUS VS	491001554
DE	F5 CORPUS VS	491001558
DE	F5 CORPUS VS	491001559
DE	F5 CORPUS VS	491001571
DE	F5 CORPUS VS	491001568
DE	F5 CORPUS VS	491001567
DE	F5 CORPUS VS	491001566
DE	F5 CORPUS VS	491001565
DE	F5 CORPUS VS	491001575
DE	F5 CORPUS	483000644
DE	F5 CORPUS	483000651
DE	F5 CORPUS	483000652
DE	F5 CORPUS	483000653
DE	F5 CORPUS	483000658
DE	F5 CORPUS	483000660
DE	F5 CORPUS	483000661
DE	F5 CORPUS	483000663
DE	F3 CORPUS	425001026
CZ	M5 CORPUS	486000733
CY	F5 CORPUS VS	491001576
CH	M5 CORPUS	486000740
CH	M5 CORPUS	486000739
CH	M5 CORPUS	486000745
CH	M3 CORPUS	428002070
CH	M3 CORPUS	428002125
CH	M3 CORPUS	428002124
CH	M3 CORPUS	428002135
CH	M3 CORPUS	428002132
CH	M3 CORPUS	428002127
CH	M3 CORPUS	428002126
CH	M3 CORPUS	428002137
CH	M CORPUS VS	492000920
CH	M CORPUS VS	492000924
CH	F3 CORPUS	425001033