

Urgent Field Safety Notice

Title: Carbon fiber side guards with untrimmed edge

Contact information: Conny Hallberg, se_box_service_spanga@permobil.com

Background:

This Field Safety Notice (FSN) concerns carbon fiber side guards (table 1) distributed by Panthera AB between December 1, 2023, and March 15, 2024. The side guards have been found to potentially be untrimmed causing one of the edges to be sharp, see figure 1 for description of affected area. The investigation of the root cause concluded that the supplier of the side guards has not trimmed the edges correctly.

There is to date, one (1) reported case where an incident has occurred related to this identified risk.

Affected order numbers are presented in Appendix 1.

Side guards delivered before and after the period mentioned are not affected.

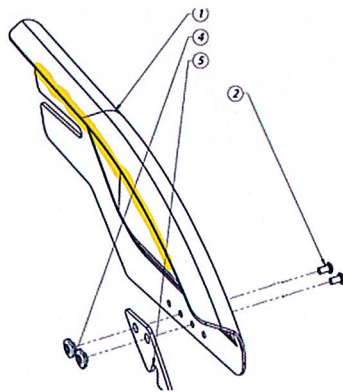


Figure 1. Edge of side guard that potentially can be untrimmed.

Article number	Name
4422033	Side guard carbon fiber small left
4422034	Side guard carbon fiber small right
4423033	Side guard carbon fiber large left
4423034	Side guard carbon fiber large right

Table 1. Article numbers that are affected by the FSN

Hazard giving rise to the FSN: Health Hazard Evaluation reports that the risk of getting hurt on the side guards is low (based on reported events) but given that fully operational hands are critical for the safe use of the device a market action is initiated.

Recommended actions for distributor and user: Our records indicate that you have purchased one or more of the potentially impacted units.

- Based on the information provided, please identify the impacted customers and/or users that need to be made aware of this information.

- Notify all impacted customers and/or users directly by forwarding this Urgent Field Safety Notice.

To identify if the edge is sharp, use the upper side of your thumbnail and gently slide from the inside out on the underside of the marked edge, see figure 1. If the edge is sharp, we recommend as an initial immediate action, that the sharp edge is taped either by you as a distributor or by the user. Then immediately contact Panthera, who will take permanent action to avoid risk to users.

Contact us at, se_box_service_spanga@permobil.com

Distributors are kindly asked to notify Panthera AB when this FSN has been distributed to the affected users (use the same email address as above).

Distribution and communication: Continue to report any relevant incidents to Panthera and relevant authority. This Field Safety Notice has been distributed to concerned parties including Medical Device Agencies.

Sincerely,



Linda Arebo
Site Quality Manager, Panthera AB

Appendix 1: Affected orders

Order
R280195