



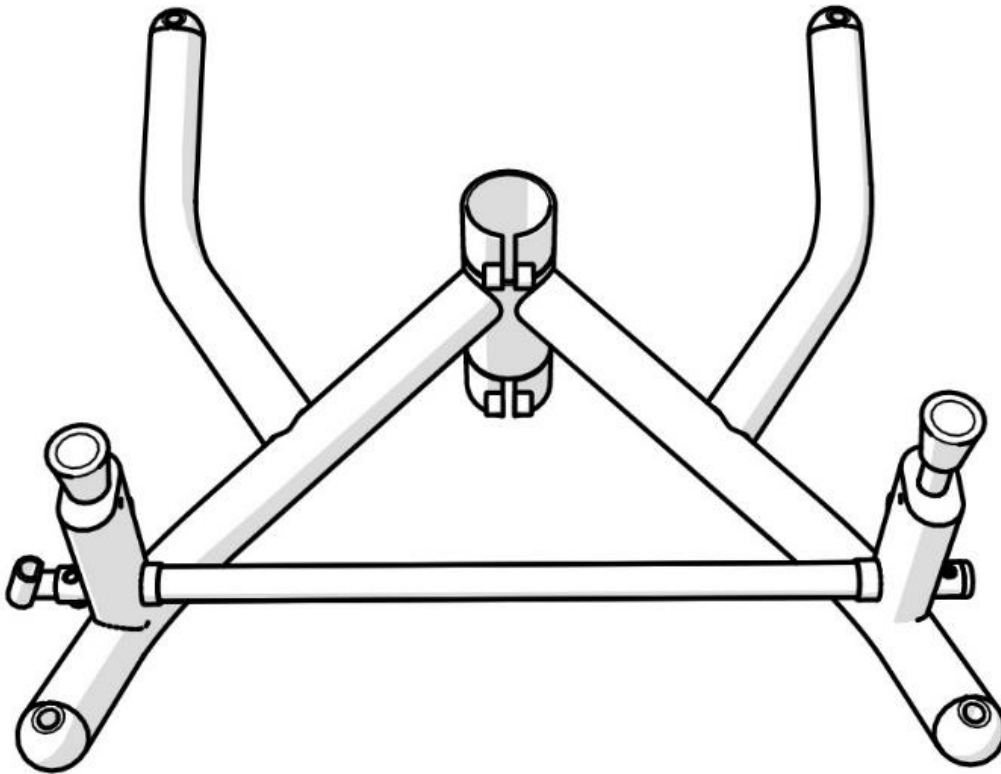
Date: 2020-03-16
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FIELD SAFETY NOTICE

Regarding frame REAL 9000 PLUS

ECR(s): S02461

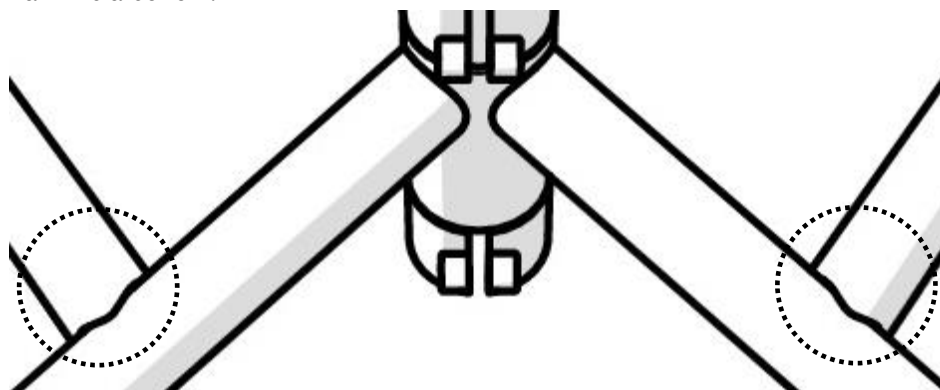


Picture 1 REAL 9000 plus frame from underneath

Background

To assure patient safety, we at Mercado Medic AB want to call for actions that may prevent future incidents. Mercado Medic AB have received four cases where one of the front support legs of the frame have been bent out of position. The frames have split in the weld between the front and rear support legs, see picture 2.

Mercado Medic AB clearly want to communicate that we don't see any reason to make a bigger effort than the proposed actions. The probability of material failure is low, and should it occur the risk of harm is also low.



Picture 2 The circles show where the frames split

Following actions should be taken

- The welds marked in picture 2 and the areas around should be checked by a technician when a chair is being reconditioned or repaired. Any cracks in the material or surface treatment should be considered a reason to replace the frame.
- If a chair has bad brake performance the frame should be checked for imbalance in addition to the standard condition check of the brake feet. If the chair doesn't stand on all four wheels in the unbraked position it must be taken out of use immediately. The check for imbalance should be performed at different places and in different directions to exclude that the imbalance is due to the floor.
- 10 years is the maximum life expectancy of the chair. After that both the CE mark and the warranty for the frame expires. Therefore the manufacturing date should be checked. All chairs older than that must be replaced, the alternative is to change all critical components. These are the frame, lift, seat frame and backrest mechanisms. Manufacturing date can be found on a label on the frame, year/week.

Affected article numbers

All chairs with REAL 9000 PLUS 48 frames need to be checked independent of the type of wheels the chair has. Or if the chair is front-, rear-, fourbraked or has frame extender.

Warranty for fund broken frames

If a frame is identified with cracks the following criteria's must be met for warranty.

- A case must be submitted on <https://mercado.se/feedback/> with pictures of the crack and the serial number of the chair.
- The chair can't be older than 10 years.

Timeline

To ensure patient safety Mercado Medic AB doesn't regard this as a short-term effort. Instead these actions must be implemented as a part of relevant routines immediately and practised for as long as the REAL 9000 PLUS adult chairs are used within your organisation.