URGENT
FIELD SAFETY NOTICE (SAN)

ARJOHUNTLEIGH

Maxi Move Scoop Stretcher (KRA2210-20)
ID [090713AHE]
Instruction to test all Scoop Stretcher Safety Latches

Date:2009-07-21

Attention!
All users of Maxi Move Scoop stretcher model # KRA2210-20

Details on affected devices:
All KRA2210-20 models manufactured by Arjo Hospital Equipment AB, Eslöv Sweden with six digit batch numbers (fig 1)
and
All KRA2210-20 models manufactured by Arjo Hospital Equipment AB, Eslöv Sweden up to serial number **0812001186** (fig 2) sold together with Maxi Moves or as an individual accessory.

The units affected can be identified by the serial number label.

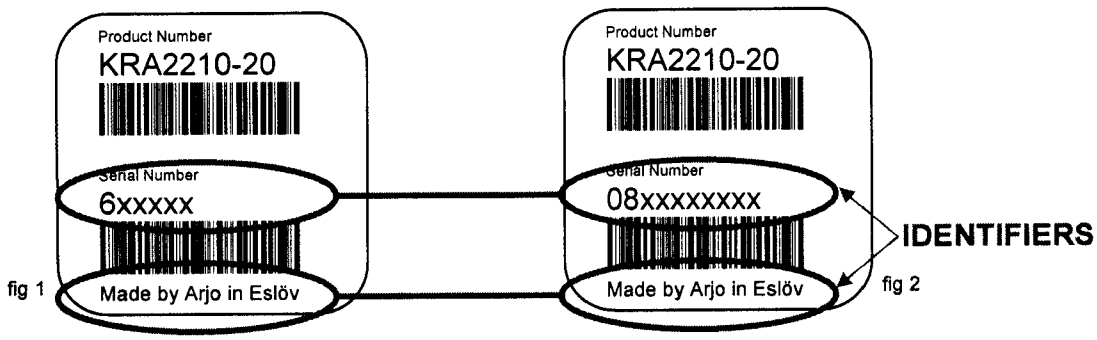


fig 1 fig 2

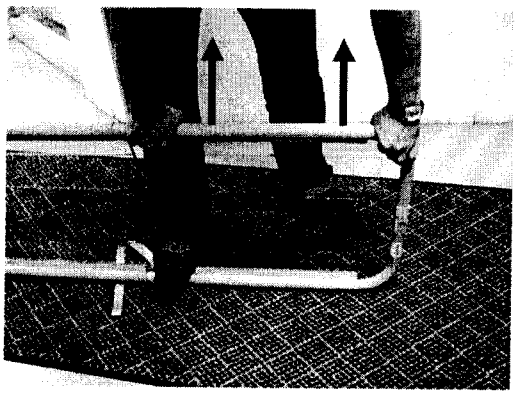
Description of problem
A Scoop stretcher is made up of two frames that are held together with two locking devices, one on each end. Each locking device contains a safety latch.

We have received one report of one safety latch unintentionally releasing when side frames were pulled for positioning. This could cause serious injury to both patient and caregiver should it occur during a transfer of a patient if the frame is used to position the stretcher.

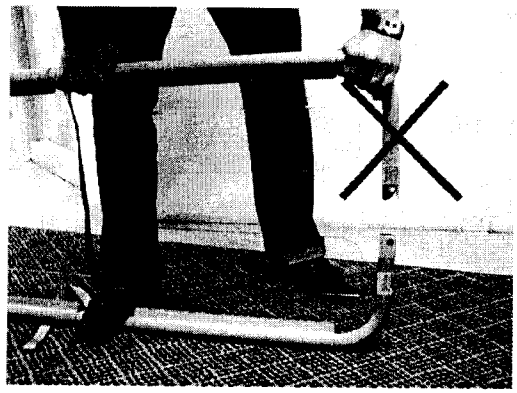
Instructions on action to be taken by the user:
Users must test the safety latches by placing the stretcher on the side on a non scratch surface and pulling the two sides apart with the latch engaged.
The latch must not release inadvertently. Make sure to test both head and foot end latches.

See pictures for reference.

Hold firmly to the floor with foot and attempt to pull sides apart



If latch unlocks from position when pulling, remove from use immediately



If the latch does release, allowing the frames to separate from each other, the stretcher must be taken out of service immediately and you must contact your local Arjo/ArjoHuntleigh representative.

If the latches do not release the scoop stretcher can be used.
The latches do not wear and a one time test is therefore sufficient.

All latches on affected devices described above will be replaced as a precautionary measure, however this test will verify that your stretcher is unaffected by the tolerance issue and that it is safe to use.
A local Arjo/ArjoHuntleigh representative will contact you within 12 weeks from distribution of this FSN to schedule a service call for the replacement of the safety latches.

Transmission of Field Safety Notice *(if appropriate)*

This notice must be provided to all those who need to be aware within your organisation or to any organisation where the potentially affected accessory has been transferred.

Please forward this notice to other organisations where this action has an impact.

Contact reference person:
Local organisation, address, and contact details.

The undersigned confirms that this notice has been submitted to the appropriate Regulatory Agencies

Eslöv 2009-07-21

[redacted]
Director of QA/RA
Arjo Hospital Equipment AB