

URGENT - FIELD SAFETY NOTICE

ARJOHUNTLEIGH SARA COMBILIZER



Date:	June XX, 2016
Product Issue:	Sara Combilizer tipping hazard
Affected Product:	Sara Combilizer mobilizing aids of model number APA1000-WW, manufactured between 2014-May-16 and 2016-Mar-17
Resolution:	Upgrade Sara Combilizer mobilizing aids with updated design of lock arm and lift yoke.
Affected Serial Nos:	Refer to Attachment A
Field Correction Notice:	FSN/POZ/002-2016
Pages:	3

Dear Customer,

Our records indicate that you purchased one or more Sara Combilizer aid from ArjoHuntleigh, between May 2014 and March 2016.

This letter is to inform you of a field safety corrective action that will be performed to prevent hazard to persons and equipment.

ArjoHuntleigh investigated the issue and concluded that a device tipping hazard may occur on the current Sara Combilizer lifting mechanism, providing a potential for risk to the patient or the caregiver.

The tipping phenomenon has been found during the device testing performed internally; there have been no adverse events or customer complaints on this problem registered to date. The tipping hazard may occur when fully loaded Sara Combilizer in "stretcher mode" is lifted to the highest position (approximately 984 mm \approx 38 3/4") and tilted backwards to the angle of 25°-28°. Although such scenario has been defined as highly unlikely to occur during use with patients, we take this matter seriously and advise you about the further steps.

The device may stay in use until the upgrade will be performed, on the condition that the tilt angle in the device "stretcher mode" will be no greater than 15° and the device is not loaded over 330 lbs (150 kg).

Please also refer to the attached **Addendum to the Instruction For Use** which provides a recommendation not to use such device position to ensure patient safety.

The problem can be corrected by the device upgrade, which involves the replacement of two parts of the lifting mechanism to ensure the device full stability.

Next steps:

1. Ensure that all caregivers and users of the ArjoHuntleigh Sara Combilizer aid are made aware of this Field Safety Notice (FSN) and all devices at your facility would be available for the upgrade during the service technician visit.
2. Ensure that all caregivers and users of the ArjoHuntleigh Sara Combilizer receive a training on the Addendum to the Instruction For Use provided with this Field Safety Notice.
3. Complete and sign the enclosed Customer Response Form and return this form to ArjoHuntleigh.

Note: ArjoHuntleigh will contact the designated facility representative listed on the Customer Response Form to schedule service to inspect and upgrade your device, free of charge.

Distribution of this Field Safety Notice:

This Field Safety Notice must be distributed to those individuals who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

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

We deeply regret any inconvenience that this Field Safety Notice may cause, however we appreciate your understanding as we take actions to ensure patient safety and customer satisfaction.

The undersign confirms that the notice has been notified the appropriate Regulatory Agency.

Additional Comment

If you have any further questions or require assistance completing the Customer Response Form, please contact ArjoHuntleigh at _____ or via email at _____

ATTACHMENT A

ArjoHuntleigh Sara Combilizer

Affected Serial Numbers of units in use with German customers:

P0296131

P0296315

P0298465

P0319583

P0333285

P0333288

P0339264

P0343583

P0343584

P0343585

P0343684

P0344174

P0353246

P0364628

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