

ARJOHUN TLEIGI-1

GETINGE GROUP

URGENT - FIELD SAFETY NOTICE

ARJOHUNTLEIGH CONCERTO BASIC SHOWER TROLLEY

Date: December 09, 2015

Product Issue: Possible unscrewing of the balts under the stretcher.

Affected Product: Concerto & Basic Shower Trolleys - manufactured between March 7, 2014 and April 20, 2015

Resolution: **Inspect Concerto Basic Shower Trolley to ensure product is performing according manufacturer specification.**

Affected Serial Nos.: Please see page 3

Field Correction Notice: FSN/POZ/001-2015

Pages: 3

Dear Customer:

Our records indicate that you purchased one or more Concerto & Basic Shower Trolley from ArjoHuntleigh, March 2014 to April 2015.

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

ArjoHuntleigh investigated the issue and concluded the stretcher mounting balts or stretcher tilting mechanism can become loose which may make the device unstable, providing a potential for risk to the patient or the care giver.

As part of our post market surveillance (complaint reporting) monitoring, ArjoHuntleigh received a limited number of complaints where the balts under the stretcher became loose. There were no serious injuries related to these incidents, however we see it as a potential long term hazard.

Complaint investigation indicated that there may be an issue with a batch of devices manufactured between *ih* March 2014 and 20th April 2015. The devices involved are limited to those listed on the last page.

ARJOHUNTLEIGH TLEIGI-1

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Next Steps:

1. Ensure that all caregivers and users of the ArjoHuntleigh Concerto or Basic Shower trolley are made aware of this Field Safety Notice (FSN) and all devices at your facility would be available for the inspection during the service technician visit.
2. Complete and sign the enclosed Customer Response Form and return this form to the local ArjoHuntleigh Regulatory Department. 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.
3. Please note that per Instruction for Use delivered with the device it is requested to check all mechanical attachments of the Concerto Shower Trolley regularly. Visually check mechanical attachments are to be performed every week. If you have any concerns about the functionality of the shower trolley, notify ArjoHuntleigh without any delay".

Distribution of this Field Safety Notice:

This Field Safety Notice needs to 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 this inconvenience, but we appreciate your understanding as we take actions to ensure patient and customer safety and satisfaction. If you have any further questions or require assistance completing the Customer Response Form, please contact ArjoHuntleigh.

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

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Affected Serial Nos.:

List of the affected units per Netherlands:

P0249643, P0249851, P0278916, P0283500, P0283487, P0283488, P0289028, P0291310,
P0295021, P0295022, P0314900, P0317669