
URGENT – Field Safety Notice (FSN)

Product: Tenor without scale
Serial Numbers: All devices manufactured since Tenor was placed on the market in 2004, not equipped with scale
Issue Date: 2014-04-08
Type of action: Safety Notice / Change the spreader bar without scale to the spreader bar with scale.
Ref: FSN/POZ/001-2014

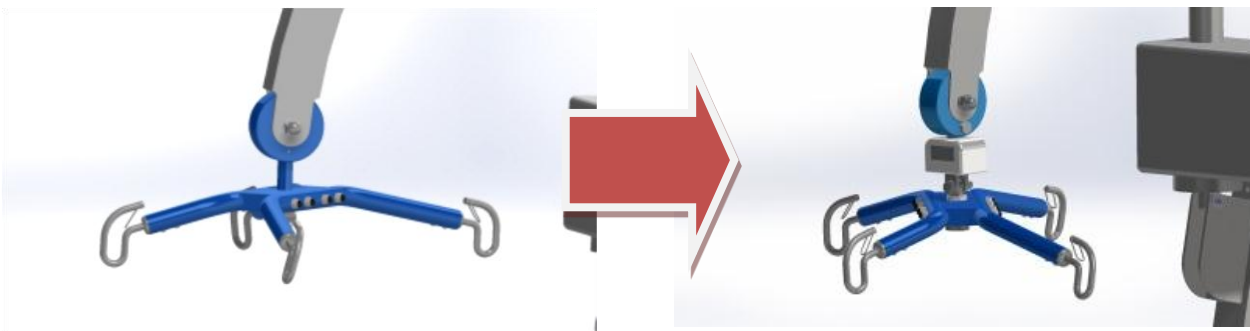
Dear Customer,
Dear Tenor users,

As part of our continuous monitoring of the complaints, we have found a remote risk concerning the breakage of the spreader bar bolt connection part # TEN.018.

During use, the bolt (part# TEN.018) when used in a Tenor **without** scale is subjected to mechanical forces, which may lead to breakage. This is due to the design of the connection between spreader bar and lifting arm jig, which in long term use can cause metal fatigue in this part and the formation of micro-cracks in the thread of the bolt.

Please note that to date; we have received 3 event reports where the bolt broke and the patient fell. There were no serious injuries related to these incidents. We perform this field action as part of our vigilance efforts and our strategy of continuous product improvement.

The assembly replacement shown below is **only** related to the Tenor devices **without scale**. The Tenor devices with scale have a different design that avoids sideward stress on the scale unit and spreader bar assembly, and is not involved in this field action.



Our records indicate that your facility has purchased one or more of the ArjoHuntleigh Tenors involved in this field action. For these Tenors, ArjoHuntleigh offers you free of charge a new spreader bar including scale to replace the spreader bar currently on your device.

Advice on actions to be taken by the user.

1. Please make sure that a copy of this field safety notice (FSN) is placed with the instructions for use for the products listed in this notice.
2. It is very important that the form in Appendix A of this FSN (see next page) is completed and returned to the ArjoHuntleigh Sales and Service office (SSU) or ArjoHuntleigh representative as soon as is reasonably possible.
3. The ArjoHuntleigh Sales and Service office shall arrange for an ArjoHuntleigh service technician to visit your facility to carry out these updates - retrieve and destroy the old spreader bar and replace it with the new one with scale.

Transmission of this Field Safety Notice

Please pass this notice to all those who need to be aware within your organisation and/or to any organisation where the equipment may have been transferred to.

Please maintain the action by filling in the table below the serial numbers of Tenor's devices without scales which you have in your facility and send signed list back to the sender.

Please perform that action for an appropriate period which is a maximum **two weeks** from the time receiving this letter to ensure effectiveness of the corrective action.

In cases where customers opt not to proceed with completion of these actions, regrettably ArjoHuntleigh cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond by the closure date of the field action.

We regret any and all inconveniences that this Field Safety Notice may cause; however we ask that you please see this preventive action as extended resident safety vigilance.

Contact reference person

Should you have questions or require additional information, please contact your local ArjoHuntleigh Sales and Service office or representative.

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



Anna Isaksson – Product Quality Director

Appendix 1 - Completion Notification FSN/POZ/001-2014

Our records indicate that your facility has purchased one or more of the ArjoHuntleigh Tenor lift without scale. An ArjoHuntleigh representative will visit you in the near future or during the next planned preventive maintenance to conduct the correction in the nearest future.

DEAR CUSTOMER, YOU WILL RECEIVE A NEW SPREADER BAR WITH SCALE ONLY IF YOU RESPOND TO THIS LETTER

Please record the serial numbers of all Tenor's at your location in the table below (continue on a separate sheet if necessary).

Serial number	Serial number	Serial number	Serial number	Serial number	Serial number

The number of Tenor lift affected by this FSN at this location is _____.

Please tick the box below:

- We have read the attached FSN and understand the communication.

To show compliance with this notification, please fill in the details below and e-mail or fax the signed copy of this notification to your local ArjoHuntleigh Sales/Service Unit (SSU) or representative.

Customer signature _____ Print name _____

Name of facility _____

Address of facility _____

Postcode _____ Date _____