
URGENT – Field Safety Notice (FSN)

Product: Encore, Chorus and Sara Plus Standing Aids
Issue Date: May 14, 2012
Type of action: Warnings / Update to Instructions for Use
Ref: FSN003/2012/PHD

Attention: All those involved in the use of the above standing and raising aids. In particular: Nurses, occupational therapists, physiotherapists and care givers.

Description of the problem:

ArjoHuntleigh has recently been made aware of an unfortunate serious accident. During exercise, an Encore Standing and raising aid was used to support the patient to stand. The knee pad had been removed. However the support bracket holding the proactive knee pad support had not been removed as described in the instructions for use manual. This results in a vertical square section end of the metal support bracket becoming exposed.

It would appear that the patient fell onto the metal bracket causing severe trauma. This accident could have been avoided if the support bracket assembly had been removed with the proactive knee pad support.



It has been identified that this issue could occur on 3 similar devices;
The **Encore** (No longer in production)
The **Chorus** (No longer in production)
The **Sara Plus**.

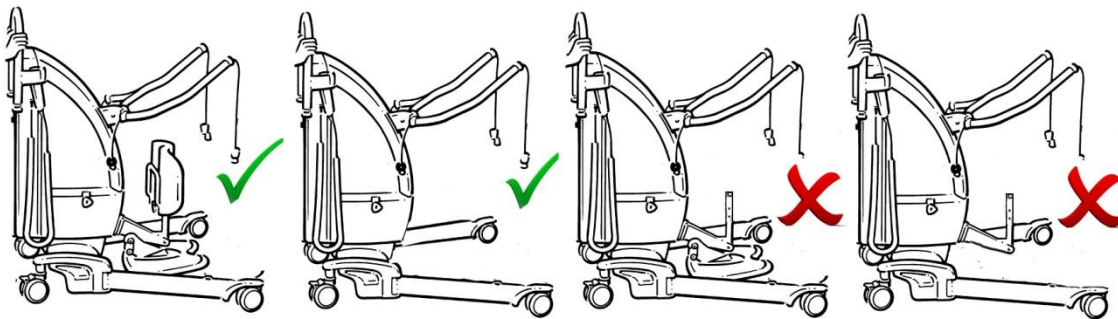
ArjoHuntleigh would like to remind users that the entire knee pad **and support bracket assembly must** be removed when required to do so for exercise.
An additional warning statement shown below will be added to the instruction for use manual and included with future purchases of these units.

Additional Warning

Warning!

The Pro-Active knee pad assembly can be removed to allow exercise. Ensure that when the knee pad is removed, the adjoining support bracket is **always** removed before therapy begins. When refitting, ensure the pad is reinserted, retightened and covers the support bracket.

Failure to do so could lead to serious injury.



IDENTIFICATION OF THE AFFECTED LIFTS



Sara Plus



Chorus



Encore

Field Safety Corrective Action Requirements

Action to be taken by users of these devices:

- Ensure that the knee pad support bracket is never left on the device without the knee pad being in place to prevent the bracket from being exposed.
- Ensure that this field safety corrective action notice is brought to the attention of all users of these devices.
- Ensure that a copy of this field safety corrective action notice is placed with the instructions for use manuals for the products listed in this notice.
- Ensure that this safety corrective action notice is available to all users.
- Where applicable, include this requirement in the training and refresher training of staff and care givers.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

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

Upon completion of the actions noted above, ensure that you have confirmed back to us using the appropriate form supplied.

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

Please contact your local ArjoHuntleigh representative should you have additional questions or comments in this matter.

Contact reference:

(To be entered by SSUs on translation)

Contact reference person:

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



FSN 003/2012/PHD 15th May 2012

Jonathan Smith – Group Vigilance Manager.