

URGENT FIELD SAFETY NOTICE

Arjo Flat Dynamic Positioning System (DPS) used with Clip Slings

Date: DD-MMM-YYYY

Product Issue: Risk of Sling Clip breakage while in use with obsolete Flat Dynamic Positioning System (DPS) Spreader bar

Affected Product: DPS spreader bar with the following model numbers: LBA1030-xx, LCA80563-xx, LCA81695-xx, KTX01440.xx, LBX05420-xx, LBX1033-xx and KTS0010 used with obsoleted lifters namely Trixie, Bianca and Bravo products

Resolution: Discontinue use of obsolete DPS units

Affected Serial No.: All DPS serial numbers belonging to the affected models above, starting with "GB"

Field Safety Notice: FSN-MAG-2020-03

Pages: 2

Dear Customer,

Our records indicate that you may have purchased an Arjo flat Dynamic Positioning Systems (DPS), which is a type of spreader bar used for patient transfers. These spreader bars were **manufactured between 1994 and 2006**, and were used in combination with our Trixie, Bianca and Bravo range of lifters, products which are also obsolete.

This letter is to inform you that any DPS spreader bar with a serial number starting with "GB" (Image 1) has exceeded its expected lifespan and is no longer produced nor supported. As a result, we recommend that these DPS systems are withdrawn from use and replaced with a new Arjo patient transfer solution.

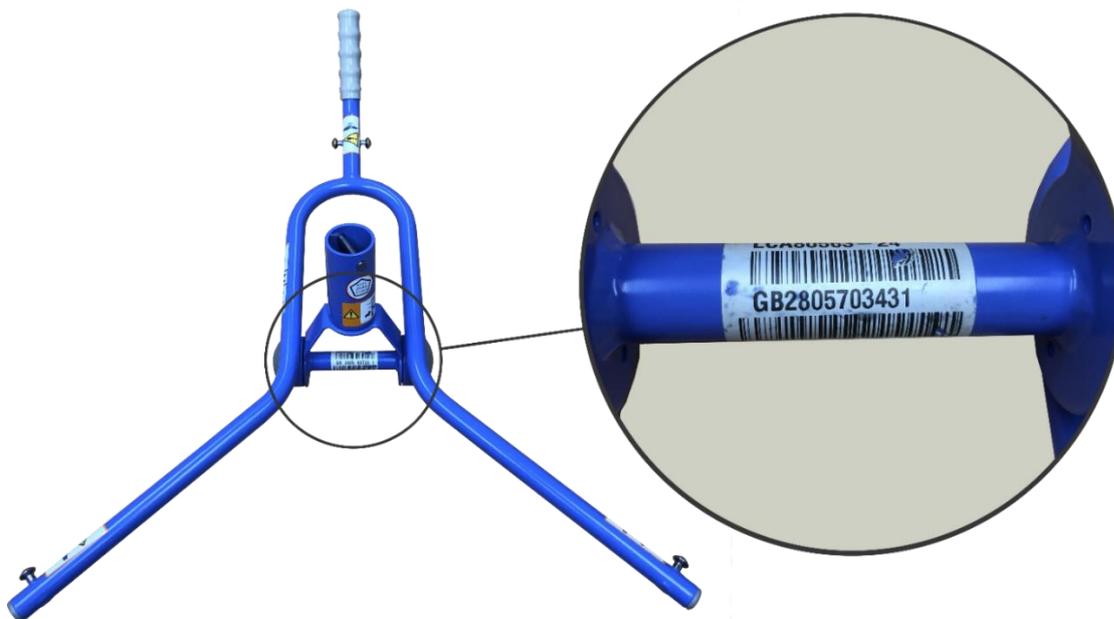


Image 1: Picture of the affected model

Arjo has also become aware that, there is the possibility of a sling clip break with continued use of these spreader bars on Arjo lifters (Image 2). This could lead to a sling clip detachment from the DPS, resulting in patient fall or drop from the sling with potential for injury to occur. Also if the DPS is used with a Clip Sling which has exceeded its expected lifespan as detailed in the sling IFU, the probability of a clip break increases.



Image 2: Picture of a broken sling clip

It is unlikely that these spreader bars are still in use due to our proactive product obsolescence program. However as product and patient safety is our priority, this communication is issued to ensure that if any devices are found to be still in use, we recommend that they should be removed from use.

Next Steps

1. Ensure this FSN is cascaded within your organization. Check your devices and any DPS spreader bar units to check if they within the obsoleted range. If any are found, they should be removed from use and disposed of with immediate effect.
2. Complete and sign the enclosed Customer Response Form and return this document to your local Arjo office without delay.
3. Contact your local Arjo office to discuss your obsolete device(s) and the best solution to meet your needs.

Transmission of this Field Notice

This Arjo flat DPS Field Safety Notice needs to be distributed to those individuals who need to be aware within your organization or to any organization where those devices have been transferred.

Arjo confirms that the Notice has been submitted to the National Competent Authority in your country (HPRA).

Additional Comment

If you have any further questions or require assistance completing the Customer Response Form, please contact Rachel Dempster at Arjo on 01809 8960 or via email at fieldactions.uki@arjo.com.

Customer Response Form

FSN-MAG-2020-03

Reference: Urgent Field Safety Notice, Arjo flat DPS Spreader Bars - models LBA1030-xx, LCA80563-xx, LCA81695-xx, KTX01440.xx, LBX05420-xx and LBX1033-xx

Our records indicate that Arjo flat DPS spreader bar(s) (models mentioned above) may have been delivered to your location. Please verify if you have any of the listed devices and complete the information below.

ArjoHuntleigh ORDER NO.	MODEL NO.	SERIAL NO.

Record the total number of affected devices currently located at your facility here please → ____.

Please check the appropriate boxes below:

We have read the Arjo flat DPS Field Safety Notice, understand the communication and confirm that the affected devices have been removed from use as required by this action.

If checked : please provide information where the affected devices are physically located.

Field Safety Notice Receipt and Customer Response Form Completion and Certification

<u>Current</u> Facility Name			
Contact Name / Title			
Address (including postcode)			
Phone Number		Fax:	
E-Mail Address:			

We have sold/moved our Arjo flat DPS (models referenced above) Field Safety Notice to another facility.

If checked : please provide new facility information below.

<u>New</u> Facility Name			
Contact Name / Title			
Address*			
Phone Number		Fax:	
E-Mail Address:			

We have read the Arjo flat DPS Field Safety Notice and understand the communication. The Arjo flat DPS spreader bar(s) (referred to above) was(were) not located nor found in use at our facility.

PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL

Arjo Ireland
 EA House,
 Damastown Industrial Park,
 Mulhuddart, Dublin 15,
 Ireland

CONTACT

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