

**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)

**Affected Product:** 9048 DPS units of the following model numbers: LBA1030-xx, LCA80563-xx, LCA81695-xx, KTX01440.xx, LBX05420-xx and LBX1033-xx, KTS0010

**Resolution:** Discontinue use of obsolete device

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

**Field Safety Notice:** FSN-MAG-2020-03

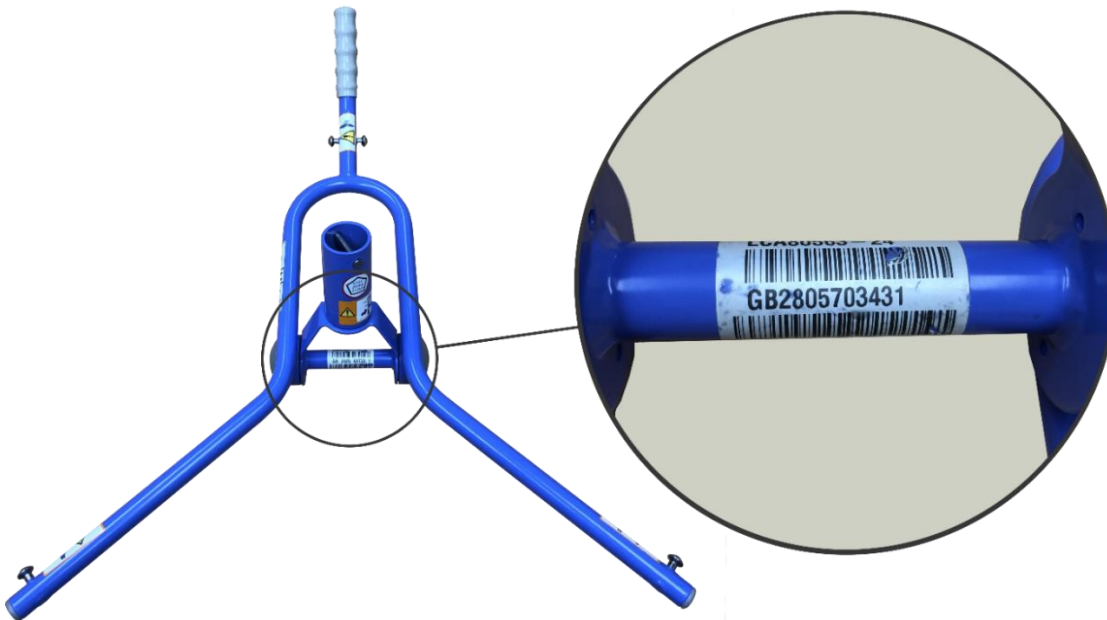
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**Dear Customer,**

Our records indicate that you may have purchased one or more Arjo flat Dynamic Positioning Systems (DPS), manufactured between 1994 and 2006.

This letter is to inform you that the DPS you may own, with a serial number starting with "GB" (Image 1) has exceeded its 7-year lifespan and is no longer produced. Therefore we recommend to withdraw obsoleted systems with a new patient transfer solution available in our offer.



*Image 1: Picture of the affected model*

Arjo has become aware that there is a likelihood that a sling clip may break (Image 2) when used with the models of spreader bars referenced above that are out of their lifespan (see note 1 below). The continued use of the obsoleted DPS can lead to complete clip breakage and subsequently to its detachment from the DPS attachment point. As a consequence, the resident may fall off and potentially sustain injuries.

Although the likelihood of a serious injury is limited, Arjo is taking this matter very seriously and recommends replacement of the obsoleted DPS on ceiling lift or floor lift systems.

**Note 1: The probability of the event may increase if the DPS is used with a Clip Sling that has exceeded its expected lifespan of 2 years or more than 1.5 years for Passive Clip Slings models MAA2080M, MAA2050M, MAA2040M, MAA2070M and MLAAS2000.<sup>1</sup>**

**Next Steps**

1. Verify whether you possess DPS within the range of this Notice and ensure that all caregivers and users of Arjo ceiling lift or floor lifts are made aware of this Field Safety Notice (FSN).
2. Complete and sign the enclosed Customer Response Form and return this document to your local Arjo office. Contact your local Arjo office to take the appropriate decision regarding your obsolete device(s) and select the best solution for your needs.

NOTE: Until you find with our Arjo representative the most appropriate solution for your patient transfer needs, the device may stay in use strictly if those two conditions are fulfilled;

- A. Before each patient transfer, ensure to follow the recommendation of the Sling Instruction for Use and check all parts of the sling are free of any damage (Image 2):



Image 2: Picture of the broken clip sling

- B. Ensure the sling used is within its intended lifetime (2 years or 1.5 years for Passive Clip Slings models MAA2080M, MAA2050M, MAA2040M, MAA2070M and MLAAS2000). In addition, if the label of the sling is faded, unreadable or damaged, ensure sling disposal as recommended in the product Instruction for Use.

**Transmission of this Field Notice**

This Arjo flat DPS Field Safety Notice needs to be distributed to those individuals who need to be made 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 – *[insert applicable competent authorities name]*.

**Additional Comment**

If you have any further questions or require assistance completing the Customer Response Form, please contact Arjo at *[insert phone number]* or via email at *[insert email address]*.

<sup>1</sup> As referred in the Passive Clip Slings *Instructions for Use* 04.SC.00-INT1 rev 6 and Toilet Slings *Instructions for Use* 04.ST.00-INT1 rev 6

## Customer Response Form

FSN-MAG-2020-03

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

Our records indicate that the Arjo flat DPS (models mentioned above) was 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.
<X>	<1>	<XXXX>
<Y>	<2>	<YYYY>

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 and we understand the communication and the required actions.  
**If checked : please provide information where the affected devices are physically located.**

### Field Safety Notice Receipt and Customer Response Form Completion and Certification

<b>Current Facility Name</b>			
<b>Contact Name / Title</b>			
<b>Address (no PO boxes, please)</b>			
<b>City, State, Zip</b>			
<b>Phone Number</b>		<b>Fax:</b>	
<b>E-Mail Address:</b>			

- 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.**

<b>New Facility Name</b>			
<b>Contact Name / Title</b>			
<b>Address*</b>			
<b>City, State, Zip</b>			
<b>Phone Number</b>		<b>Fax:</b>	
<b>E-Mail Address:</b>			

- We have read the Arjo flat DPS Field Safety Notice and we understand the communication. The Arjo flat DPS (models referenced above) has not been used or is not anymore used at our facility, therefore there is no product to withdraw.

**PLEASE RETURN YOUR COMPLETED FORM TO:**

**MAIL**

<local SSU address line 1>  
 <local SSU address line 2>  
 <local SSU address line 3>  
 <local SSU address line 4>

**CONTACT**

<contact address>@arjo.com  
 Tel: <SSU contact phone number>  
 Fax: <SSU contact fax number>