

URGENT – FIELD SAFETY NOTICE
Arjo Disposable Repositioning Sling – risk of tripping in product straps

Date: 2021-MMM-DD

Product Issue: Potential trip hazard in Sling straps

Affected Product: Arjo Disposable Repositioning Sling (AHD001) manufactured between 2021-Jan-05 and 2021-Jun-16. For the list of impacted lot numbers please refer to Appendix 1.

Resolution: Field Safety Notice circulation to the customers

Field Safety Notice: FSN-DOM-001-2021

Pages: 3 & Customer Response Form

Single registration number of the manufacturer: SE-MF-000000696

Dear Customer,

Our sales records indicate that you have purchased within the past six months the Arjo Disposable Repositioning Sling (AHD001) manufactured between 2021-Jan-05 and 2021-Jun-16.

We are contacting you to provide information regarding a safety-related notification released by our company to address proactively an issue reported to Arjo in recently received customer complaints.

Note: This notice applies to the Arjo Disposable Repositioning Sling (AHD001) manufactured between January and June 2021 and their lot numbers in Appendix 1. No other Arjo Slings are affected by this issue.

Following the feedback received from the market, our company has determined that the straps of AHD001 Arjo Disposable Repositioning Slings manufactured between 2021-Jan-05 and 2021-Jun-16 (the lot numbers listed in Appendix 1) may cause a trip hazard to caregivers and visitors when straps hang over the side of the bed resting on the floor (please refer to Figure 1).



Figure 1

According to the performed risk assessment, the probability of occurrence of harm is rare. The potential hazardous situation related with the detected problem is caregiver/visitor fall, if their feet were to trip in the straps. The potential fall might result in a musculoskeletal injury, fracture, tissue loss and / or damage to internal organs.

Please note that the tripping hazard could occur with the Arjo Disposable Repositioning Sling (AHD001) loop straps after and in-between resident transfers when straps hang over the side of the bed. Therefore, we would like to recommend you extra caution when walking over the loop straps after and in-between transfers.

In order to mitigate the risk of tripping, we have identified also the additional instructions to be followed by caregivers:

- As an infection control best practice, slings straps should not be positioned to rest or drag on the floor.
- If possible, keep the bed at a position where the straps do not touch the floor.
- In cases where the bed height does not accommodate keeping the strap off the floor, we recommend tucking the straps between the mattress and the bed frame.

The product is safe for use when the above precautions are taken. There is no necessity to remove the Arjo Disposable Repositioning Sling (AHD001) from use or return it to Arjo.

Additionally, we are in the process of enhancing the design of the Arjo Disposable Repositioning Sling (AHD001) straps. The newly designed Arjo Disposable Repositioning Sling (AHD001) will be available in sales in coming weeks.

Arjo is taking this issue seriously as customer satisfaction and safety are essential. We regret any inconvenience that this Field Safety Notice may cause, however we greatly appreciate your understanding as we take actions to ensure the safety of our caregivers.

Next Steps

1. Forward a copy of this Field Safety Notice to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.
2. In order to confirm the Field Safety Notice reception, please complete and sign the enclosed Customer Response Form and return it to the Arjo address given in the Additional Comment section. Fill in the enclosed Customer Response Form and return it to: **<Arjo contact (address/e-mail)>**.
3. We would like to inform also that all adverse incidents relating to a medical device should be reported to the nearest Arjo office/representative or alternatively to the National Competent Authority in your country.

The notice has been submitted to the Regulatory Agency/National Competent Authority in your country **[insert name]**.

Additional Comment

If you have any further questions or require any further assistance, please contact Arjo at **[insert local phone number]** or via email at **[insert email]**.

Appendix 1

List of impacted lot numbers

Lot Number	Lot Number
DAG1300482	DCG1300510
DAG1300483	DCG1300511
DAG1300484	DCG1300513
DAG1300485	DCG1300514
DAG1300486	DCG1300515
DAG1300487	DDG1300516
DBG1300488	DDG1300517
DBG1300489	DDG1300518
DBG1300490	DDG1300519
DBG1300491	DDG1300520
DBG1300492	DDG1300521
DBG1300493	DAG1300522
DBG1300494	DDG1300523
DBG1300495	DDG1300524
DBG1300496	DDG1300525
DBG1300497	DDG1300526
DBG1300498	DEG1300527
DBG1300499	DEG1300528
DCG1300500	DEG1300529
DCG1300501	DEG1300530
DCG1300502	DEG1300531
DCG1300503	DEG1300532
DCG1300504	DEG1300533
DCG1300505	DEG1300534
DCG1300506	DEG1300535
DCG1300507	DEG1300536
DCG1300508	DFG1300537
DCG1300509	

Customer Response Form

FIELD SAFETY NOTICE FSN-DOM-001-2021

Reference: Arjo Disposable Repositioning Sling (AHD001) – risk of tripping in product straps

Our sales records indicate that you have purchased within the past six months the Arjo Disposable Repositioning Sling (AHD001) manufactured between 2021-Jan-05 and 2021-Jun-16 (the lot numbers indicated in Appendix 1 in the Field Safety Notice).

Field Safety Notice Receipt and Customer Response Form Completion

Please mark one of the appropriate boxes below:

☐ We have read the Field Safety Notice and we understand the communication of actions required per this document.

Facility Name & Address			
Contact Name / Title			
Signature of recipient		Date	

☐ We have already used the impacted Arjo Disposable Repositioning Sling (AHD001).

Facility Name & Address			
Contact Name / Title			
Signature of recipient		Date	

☐ We have sold/transferred the impacted Arjo Disposable Repositioning Sling (AHD001).

If marked: please provide new facility information below.

<u>New</u> Facility Name	
Contact Name / Title	
Full Address	

Post Code			
Phone Number		Fax	
E-Mail Address			
Signature of recipient		Date	

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>