FSN Ref: FSN2604031239-1 FSCA Ref: FSCA2604031239-1

Date of issue: 2026-09-22

Urgent Field Safety Notice
PLS Track Coupling, Safety Lock, Trolley DUO LeviCare Klamra

For Attention of*:Facility Risk Manager/Facility Administrator, Chief Executive Facility Administrator, Facility Engineer, Vigilance Manager, Biomedical Engineering, Medical Device Liaison Officer, QA manager at distributor, Head of Technicians at distributor.

Contact details of local representative (name, e-mail, telephone, address etc.)*
You can find the contact information of your local distributor on: https://www.patientliftingsolutions.com/en/dealers

FSN Ref: FSN2604031239-1 FSCA Ref: FSCA2604031239-1

Urgent Field Safety Notice (FSN)
PLS Track Coupling, Safety Lock, Trolley DUO LeviCare Klamra
Risk addressed by FSN

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	-Track Coupling -Double Coupling -Safety Lock -Trolley
1.	2. Commercial name(s)
	-PLS Track Coupling -PLS Double Coupling -PLS Safety Lock -Trolley DUO LeviCare Klamra
1.	3. Unique Device Identifier(s) (UDI-DI)
	Track Coupling Basic UDI-DI: 8720165793R20000V6
1.	4. Primary clinical purpose of device(s)*
	The purpose of the Coupling is to connect a traverse rail of an X-Y system to a straight rail in a PLS Rail System. This allows the ceiling hoist to pass from the X-Y system to a straight rail or vice versa. The Safety Lock is the part that allows the traverse rail to be blocked at the end when the X-Y system is in use to prevent a ceiling hoist from inadvertently exiting the rail. When the coupling is coupled it allows for an opening for the trolley of the ceiling hoist to pass through to the straight rail or vice versa. The double coupling is meant for a situation where two couplings are placed adjacent to each other to connect two X-Y systems. It provides a link for the couplings to function even though there is a limited stretch of straight rail between them. The purpose of the Trolley DUO LeviCare Klamra is to be pulled through the rail with a ceiling hoist attached to it.
1.	5. Device Model/Catalogue/part number(s)*
	1025, 1032, 1026, 1084
1.	6. Software version
	N/A

FSN Ref: FSN2604031239-1 FSCA Ref: FSCA2604031239-1

1.	7. Affected serial or lot number range
	All Safety Locks used in couplings built between 2022-04-03 and 2026-08-30 are possibly affected. Safety Locks built between 2022-04-03 and 2023-07-02 represent an elevated risk and should receive priority in the execution of the Corrective Action. All Trolley DUO LeviCare Klamra
1.	8. Associated devices
	PLS Rail system

FSN Ref: FSN2604031239-1 FSCA Ref: FSCA2604031239-1

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	The welded connection between two steel parts can be of a strength below the design specification. In the coupling and safety lock this can result in the Blocking arm becoming detached. This means that the trolley of a ceiling hoist is not protected from inadvertently leaving the rail at the end of the traverse rail. In the Trolley DUO LeviCare Klamra this could theoretically lead the ceiling hoist to becoming detached from the trolley.
2.	2. Hazard giving rise to the FSCA*
	The greatest hazard the FSCA is intended to mitigate is death or bodily harm due to a ceiling hoist falling, either while transferring a person or not. Either the fall itself and/or the impact of the falling device (possibly with accessories attached) onto a user and/or a patient can have severe consequences. When the Corrective Action has been performed a device is fitted with a replacement part that is made from different materials and of which the strength of the welded connection surpasses the design specification. As such there is no residual risk after the Corrective Action.
2.	3. Probability of problem arising
	The probability of this problem arising is low but dependant on intensity and frequency of load on the welded part.
2.	4. Predicted risk to patient/users
	The probability of occurrence is low, but severity is potentially very high as failure of a welded connection can result in a ceiling hoist falling which in turn can result in death or bodily harm to patients or users of the device.
2.	5. Further information to help characterise the problem
	The Trolley DUO LeviCare Klamra has been shown in testing to be well within the design specification. However this product consists of the same material combination that has caused welding faults to occur in the Safety Lock. Therefore out of an abundance of caution we are incorporating the Trolley DUO LeviCare Klamra in the FSCA.
2.	6. Background on Issue
	Earlier this year PLS was made aware by one of our Distributors that an incident had occurred where a Ceiling Hoist had inadvertently fell from the end of a traverse rail of an X-Y system. In this particular situation the wall charger had been installed in such a location that the trolley bumped into the blocking arm of the safety lock every time the hoist was charged. As such there was excessive daily wear to the blocking arm. The root cause was determined to be a change in type of steel which the blocking arm is made of. This type of steel is known to be difficult to properly weld due to sulphur that is present in the chemical composition. This can lead to a weld that is prone to crack as a result of fatigue or repetitive blows. The FSCA is limited to the blocking arm of the Safety Lock and not the blocking arm of the coupling itself as the blocking arm of the coupling rarely sees wear as opposed to the blocking arm of the Safety Lock due to the different use case of both products.
2.	7. Other information relevant to FSCA
	The Corrective Action Instructions document entails the specifics of the corrective action to replace affected parts.

FSN Ref: FSN2604031239-1 FSCA Ref: FSCA2604031239-1

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Contact your local representative to schedule a maintenance visit.	
3.	2. By when should the action be completed?	ASAP
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Distributor** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None For specifics see the Corrective Action Instructions FSCA2604031239-1	
3	6. By when should the action be completed?	Safety Locks produced between 2022-04-03 and 2023-07-02 should be replaced within 6 months of the date of issue of this FSN. Safety Locks produced between 2023-07-02 and 2026-08-30 should be replaced at the latest at the second planned yearly maintenance visit counting from the date of issue of this FSN. This means that the longest possible period could be 3 years from the date of issue of this FSN.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? N/A Choose an item.	

FSN Ref: FSN2604031239-1 FSCA Ref: FSCA2604031239-1

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	
	b. Address	
	c. Website address	
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * The Health and Youth Care Inspectorate has been notified.	
4.	9. List of attachments/appendices:	-Corrective Action Instructions FSCA2604031239-1
4.	10. Name/Signature	

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.