

## NOTIFICATION LETTER

QUALITY notice

SAFETY notice

Reference	QN-20220622-EN v3
Object	<b>Reminder of the proper use of the SLS device</b>
Date	2022/07/20
Recipients	Health professionals and SLS distributors
Product	Safe Locking System (SLS) for patient lifter

**This document contains important information about your product. Please ensure that all potential users in your facility are aware of this safety notice and the recommended corrective actions. Please retain this document for your records.**

Dear Madam, dear Sir, dear Client,

Please be advised that SCALEO Medical is taking voluntary corrective actions on the regarding the Safe Locking System suspension system installed on the patient lifts.

This corrective action is related to a potential misplacement of the straps in the SLS hook

**Problem description :**

We were informed of various incidents in early 2022, with a risk of patient falling as a result of the unhooking of the patient support strap.

Two SLS hooks were found to have a broken stop in the hook locking system.

The manufacturer's analysis of the production batches did not identify a systemic flaw in the hooks.

Further analysis revealed a possible incorrect placing of the sling in the hook when positioning the patient in the sling.

Until a force is not applied downwards, the automatic locking of the SLS is not closed or secured, which can cause the sling to come out of the hook in the event of significant patient movement.



In the previous described case and during the installation process, the sling may come out of the hook, and place itself on the white safety ring. This must be avoided since patient's weight on the hook stop, can cause the stop to break.


The breakage of the stop is therefore the result of the strap being stretched without first ensuring the locking of the SLS suspension white safety rings as described in the user's manual

This white ring is not designed to support the weight of a patient.



**Setting the scene:**

Situations	Risk of incident	Pictures	
Correct fitting of a strap on an SLS without any flaw	No risk		
Correct fitting of a strap on a SLS with a broken stop	No risk		

<p>Incorrect fitting of a strap on an SLS</p>	<p>High risk</p>	
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**Corrective action:**

The production batches incriminated in this notification do not present any particular defects. They may continue to be used under the normal conditions of use as described in the user manual.

However, we ask you to consider the following preventive measures:

**Preventive measure:**

**Reminder of the correct use of the SLS device in the context of a lift:**

- 1- Depending on the type of transfer (bed, chair, seat, toilet, diaper), install the straps according to the recommendations in the user manual.
- 2- Once the straps are positioned on the patient, install the straps in the SLS hooks according to the following recommendations:



The SLS hook is in open position.



The loop of the sling is inserted into the SLS.



Pushing the SLS with one hand locks the hook and the SLS system is locked and secured.

- 3- The straps must be in the back buckle in order to close the hook with the white locking ring.
- 4- Check that the white safety is properly locked.
- 5- Lift the patient carefully



***Reminder : It is strongly recommended to use the appropriate SCALEO Medical slings***

All this information is available in the user manual of your medical device.

This notice has been submitted to the relevant regulatory authorities.

If you have any questions or need additional information, our Technical and Quality departments are at your disposal by telephone on +33499772323 or by email : [info@scaleomedical.com](mailto:info@scaleomedical.com)

We thank you for your understanding and cooperation.

Yours sincerely

Quality Manager and Materials Safety Officer

**Response form**

**Name and address of the healthcare professional or distributor :.....**

**SAFETY NOTIFICATION LETTER**  
**SLS Strap Hook Safety System**

We kindly ask you to complete this reply form and return it as soon as possible to the following address

SCALEO Medical 107 rue Dassin, PARC 2000, 34080 Montpellier France

Or by email : [sebastien.moreau@SCALEOmedical.com](mailto:sebastien.moreau@SCALEOmedical.com) or [savsud.transfert@scaleomedical.com](mailto:savsud.transfert@scaleomedical.com) or  
[savnord.transfert@scaleomedical.com](mailto:savnord.transfert@scaleomedical.com) by phone +33 04 99 77 23 38

**I certify :**

- **I have received the notification reference : QN-20220622-FR v3**
- **I have forwarded this notification to our respective departments and customers concerned**
- **I have noted that in the event of non-conformity SCALEO Medical or SCALEO Medical must be informed as soon as possible in order to supply a replacement part.**

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Name of the person signing the reply form:

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Function of the signatory:

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Email address:

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Phone number :

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Date and signature :

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