

Field Safety Notice

S1590005 spreader bars installed with MOLIFT Air and HITRAC ceiling hoists

Reference	NDS-2015-01-EN v1_2015-08-18
Action	Field safety notice informing the users of a plastic part problem that could affect the safety of the Air or HITRAC ceiling hoists
Date	18/08/2015
Concerns	Health facilities Directors, medical vigilance managers
Products object of the FSN	MOLIFT Air and HITRAC ceiling hoists equipped with a SCALEO Medical S1590005 spreader bar, with the exception of those equipped with a SCALIS® scale.

Dear Customer,

The purpose of this letter is to advise you that SCALEO Medical is issuing a field voluntary safety corrective action for the devices listed above.

Object :

We have been informed of a quality issue about the material used for the plastic cap of our S1590005 spreader bars installed on MOLIFT Air and HITRAC, ceiling hoists, with the exception of those equipped with a SCALIS® scale, delivered before the 16th of May 2015.

There have been no serious injuries or deaths related to these reports.

So we come to bring you information relating to the inspection of the installed devices, and the corrective action to perform if the security of the device is compromised.



Potential risk :



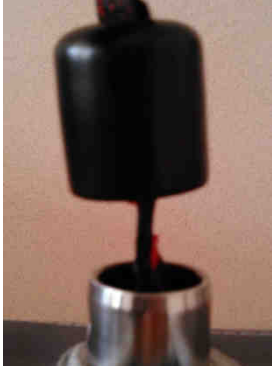
Due to the quality issue found on the plastic cap, the cap may be deteriorated or in a wrong position on the hoist sling. The security pin may then go to a wrong position, the sling may fall and the patient fall during the transfer.

A visual inspection may swiftly identify if the plastic cap is deteriorated or in a wrong position.

Inspection to be performed:

The visual inspection is to be performed on the plastic cap and its position, and therefore on the position of the safety pin.

In all case the safety pin MUST be properly installed between the two holes of the bottom metallic part.

<p>Conform : the plastic cap is not worn, the cap is in its right position, the safety pin is properly installed and cannot move</p> 	<p>NON CONFORM : the plastic cap is worn, the safety pin may go out of its axis</p> 	<p>NON CONFORM : the cap has moved up on the sling, the safety pin may go out of its axis</p> 
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Curative action :

If the visual inspection reveals a nonconforming spreader bad, or a deteriorated plastic cap, the S1590005 suspension must be replaced for a new one.

Corrective action :

SCALEO Medical has developed and validated a corrective solution to solve the issue: the material of the plastic cap has been changed, and a safety screw added to prevent the cap from moving on the sling. The corrective action is applied since the 16th of May 2015.

Actions you should take :

Please fill in and then send to us the form found below stating that you have been informed of this field safety notice, and have inspected or have inspected the devices listed above, and have informed SCALEO Medical of the result of the inspection.

This notification is being issued with the knowledge of the competent authorities.

Please send back the fulfilled form to SCALEO Medical.

For more information, contact us by phone : +33 (0)4 99 77 23 34 or by mail : info@scaleomedical.com

We sincerely apologize for any inconvenience this situation may cause you or your facility and thank you for your understanding and collaboration.

Sincerely,

Jean-Patrick Sanna
Quality and Medical Devices Vigilance Manager

Corrective Action Response

Name of the facility or distributor :

**Fiel Safety Notic ref : NDS-2015-01 relating to S1590005 spreader bars installed on
MOLIFT Air and HITRAC ceiling hoists**

Please acknowledge that you have received, read, understood and applied the actions to be taken by completing the information below.

Send your response to

SCALEO Medical 107 rue Dassin, PARC 2000, 34080 Montpellier FRANCE
Or by e-mail : info@scaleomedical.com ou by fax : +33 (0)4 99 74 01 79

I thereby certify that:

- I have received and read the NDS-2015-01 field safety notice from SCALEO Medical
- I have performed or have performed the inspection required by the field safety notice
- I have been informed that in case of a non conforming installation, SCALEO Medical has been informed in order to provide a replacement spreader bar.

Result of the inspections is the following:

Place	Inspection performed by	Date	Result

Facility or distributor name :

Name :

Title :

Facility or distributor adress :

Date and signature :
