

# URGENT FIELD SAFETY NOTICE

**Reference:** FSN/16/01

**Date:** 27.09.2016

**Product Name:** Steiss Activate Hoists

**Type of action:** Product Safety Notice

## Incident:

It has been reported that an end user has suffered an injury to their leg due to a location pin handle on the hoist mast being in the upright position on the Steiss Activate Hoists.

## Details of affected devices:

### Description

Steiss Activate 18 Hoist

Steiss Activate 13 Hoist

### Product Code(s)

PH-096-55

PH-096-56

## Description of the issue:

The fixing handle securing the mast location pin which are situated on either the side of the hoist mast through the chassis yoke were facing **upwards** (see photo 1) resulting in an end user unexpectedly suffering a severe gash on the leg.

This is the first reported incident since these hoists were placed on the market in 2013. Our quality monitoring system has however identified a medium risk as these handles are required to be facing **downwards** (see photo 2) as they were when the hoists are originally assembled.



Photo 1



Photo 2

## Action to be taken by the user:

1. Immediately identify the Steiss Activate models 18 and 13 currently in use and ensure that the handles are facing **downwards**. This is a simple operation that can be undertaken by the

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operator by turning the handles to face **downwards**. They are sprung loaded to enable this action at any tension. Simply pull the lever slightly outwards and rotate to the **downward** position. (photos 1 and 2).

2. Carry out the replacement of these handles with knobs (provided by the manufacturer) as described below. This is a simple operation to remove these handle by unscrewing. The locating pin will remain in position (photo 3), and the replacement knobs can simply be screwed into place. Please ensure that these knobs are evenly tightened and are tightly secured. (photos 4 & 5).



Photo 3



Photo 4



Photo 5

### Action to be taken by manufacturer:

An alternative to the handle will be provided in the form of a knob to hold the locating pin. Where required, service visits will be made by Nursing Hygiene Group engineers and all affected locating pin handles will be replaced accordingly.

### Contact reference person:

If you are unsure about any of the information given in this bulletin, or would like to discuss this issue in more detail please contact Nursing Hygiene Quality Manager on 01403 825825.

The undersigned confirms that this notice has been notified to the appropriate regulatory agency, MHRA.



Ken Morren  
HR and Operations Team Leader  
Nursing Hygiene Group

# FIELD SAFETY NOTICE – RETURNS ACKNOWLEDGEMENT



27<sup>th</sup> September 2016

Dear Sir / Madam

Please find enclosed a copy of a Field Notice that has been created due to a potential safety issue with the Steiss Activate 13 and 18 Hoists.

Our records indicate that you have received these Hoists and we would therefore be grateful if you could check your stock as per the FSN, and complete this acknowledgement slip as indicated below. This should then be returned by e-mail or fax and will enable Nursing Hygiene Group keep a complete record that will be forwarded to MHRA.

Customer Name: .....

Evidence of affected Hoists in stock:

 Yes No

How many would be in daily use? .....

If yes to the above, please contact Nursing Hygiene Group who will make the necessary arrangements (as per the FSN)

Name: .....

Signature: .....

Date: .....