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## **Urgent Field Safety Notice**

**Subject:** Arthrex Shoulder Suspension Tower  
**FSCA-identifier:** MOD1257  
**Type of action:** Field Safety Corrective Action

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**Date:** 20 January 2017

**Attention:** Arthrex Personnel

**Details on Affected devices:**

Production Dates: 01 March 2016 – 11 July 2016

Models: Arthrex AR-1650-01

Serial Numbers: In Germany: 501895, 501896, 510737, 510738, 510750, 510751  
In The Netherlands: 501822

**Description of the problem:**

Allen Medical Systems has recently become aware of a potential problem with the Arthrex Shoulder Suspension Tower (AR-1650-01) manufactured and distributed between 01 March 2016 and 11 July 2016. During use, there is a potential scenario which could allow screws that hold the plastic covers to fall out. This failure could potentially allow for a non-sterile screw to fall into the sterile field, possibly causing moderate injury to the patient. This potential defect is not apparent to the user. To date, there have been no injuries reported.

**Advise on action to be taken by the user:**

Immediately retrieve and segregate your Arthrex Shoulder Suspension Tower (AR-1650-01). All serial numbers are impacted and are listed above. Please return all Arthrex Shoulder Suspension Tower (AR-1650-01) to Arthrex at the following address:

Arthrex  
14550 Plantation Road  
Ft. Myers, FL 33912  
USA

Arthrex will then forward all returned product to Allen Medical Systems at the following address:

Allen Medical Systems  
100 Discovery Way  
Acton, MA 01720  
USA

In order to minimize this inconvenience, Allen Medical will inspect, repair or replace all Arthrex Shoulder Suspension Tower (AR-1650-01) devices as necessary at no cost. Allen Medical will make these corrective actions to the devices and return them to service as soon as possible.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.



Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**Contact reference person(s):**

Manufacturer:

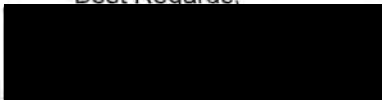
Scott Wright, QA/RA Director  
Allen Medical  
100 Discovery Way  
Acton, MA 01720  
USA  
+19782664280  
scott.wright@hill-rom.com

EU Authorized Representative:

Joe Fogel  
Hill-Rom SAS  
Z.I du Talhouet B.P 14  
56330 Pluvigner  
FRANCE  
+31203019207  
joe.fogel@hill-rom.com

The undersign confirms that the appropriate Regulatory Agencies have been notified of this notice.

Best Regards,



Joseph Fogel  
QA/RA Director  
Hill-Rom SAS