Urgent Safety Information

Inspection of Mounting Bolts M10x30mm at the Ceiling Tube of the Suspension Systems MediBoom XL, MediLift XL und MediBoom XXL

Philips Medical Systems

[redacted]

Hünfeld, 11.07.2024

[redacted]

As a manufacturer of high-quality medical devices, Ondal Medical Systems is committed to strict quality control and continuous, worldwide product monitoring.
In this context, we have learned of an incident involving a MediLift XL.
As part of our ongoing commitment to the quality and safety of our products, we would therefore like to inform you of an important preventative measure we are taking in relation to our heavy-duty suspension arm systems MediBoom XL, MediLift XL and MediBoom XXL.

Identification of the affected Medical devices:
This safety information applies exclusively to products of the series MediBoom XL, MediLift XL and MediBoom XXL manufactured by Ondal Medical Systems in the period from April 2022 to June 2023.
The attached list (Appendix 2) contains the delivery information (part number, serial numbers, delivery number, ship date) of all products for which an inspection is necessary, unless it can be ensured beyond doubt that the respective installation was carried out correctly in accordance with the assembly instructions provided by Ondal Medical Systems GmbH.

Description of the problem including the identified cause:
Ondal Medical Systems has been informed of an incident in which a MediLift XL suspension arm system with monitor fell.
In this case, only property damage occurred and no personal injury was caused as no patient or clinical staff were present in the room. However, there is a risk of considerable personal injury in the event of a fall from the above-mentioned product series.
The fall occurred due to the failure of the bolt connection between the ceiling tube and the MediLift XL bearing.

The root cause analysis revealed that the fastening screws were not the specified length and were therefore not screwed in deep enough into the bearing unit.
We would like to point out that the affected system was not installed in accordance with the installation instructions provided by Ondal Medical Systems and was not installed by an authorized service technician.

The too short bolts, which were supplied with the suspension arm system as assembly accessories, would have been discovered if they had been properly installed in accordance with the assembly instructions provided by Ondal Medical Systems GmbH:

- All 10 bolts must be tightened to a tightening torque of 40Nm in accordance with the assembly instructions; this tightening torque cannot be achieved due to the screw being too short, as the threaded hole in the bearing unit tears out beforehand
- One bolt must also be fitted with a bracket for strain relief of the brake cable; this bolt cannot be tightened at all due to the screw being too short.

What measures should be taken to eliminate the potential risks of this problem?
To avoid possible endangerment to patients, users or third parties, the bolts must be inspected and verified unless it is absolutely certain that installation has been carried out correctly in accordance with the installation instructions provided by Ondal Medical Systems GmbH. We will provide you with a free spare parts kit with new screws.
Corresponding instructions for checking the bolts are enclosed with the replacement delivery.

What measures can the user take to reduce the potential risks of this problem until the fastening screws have been inspected?
If you notice a gap or misalignment at the interface between the ceiling tube and the bearing of the arm system (see Appendix 1), stop using the system and inform your contact person immediately.

Forwarding of the information described here.
Please ensure in your organization that all users of the above products and other persons to be informed are aware of this Urgent Safety Information. If you have supplied the products to third parties, please forward a copy of this information or inform the contact person listed below.

We apologize for the inconvenience caused by this action, but see this as a preventive measure in the interest of user and patient safety.
We thank you for your cooperation.

The German “Bundesinstitut für Arzneimittel und Medizinprodukte“ (Federal Institute for Drugs and Medical Devices) has received a copy of this "Urgent Safety Information".

We kindly ask you to return the acknowledgement of receipt and confirmation of inspection enclosed as Appendix 3 and Appendix 4 .

If you have any questions, please do not hesitate to contact Mr. Stub at +49 (0) 6652 81-166 or by e-mail at stub.christian@ondal.com.

Yours sincerely,
Ondal Medical Systems GmbH

Appendix 1: Inspection of the interface between the ceiling tube and bearing of the arm system
Appendix 2: List of all affected part numbers with serial number
Appendix 3: Acknowledgement of receipt
Appendix 4: Confirmation of Inspection