



Firma XXXXX  
XXX XXXXXX  
XXXXXXXXXXXXXXXX XX

XXXXX XXXXXXXX

Ihr Schreiben vom

Unser Zeichen

Ansprechpartner

Datum / Durchwahl

26. Januar 2015

-

## **Safety Information referring to TRILUX Medical OT Lighting systems with cameras and monitor holders**

Ladies and Gentlemen,

in line with our product monitoring it is our duty to inform you about any possible risks for patients and users, that might arise during handling of the a.m. products.

Trilux Medical received a customer complaint about a drop of an Aurinio LED OT light with the connected spring arm due to improper use. The improper use was to move the light over the stop what lead to a derailing of the pivot bearing.

This risk upon improper use is only applying to lights which are equipped with a camera system with stop as well as with monitor holders with stop. These products are amongst others equipped with stops at the connection point between the spring arm and the boom of the central axis to avoid a rotation of more than 360°.

Aurinio OT Lights without camera systems are not affected!

The stop protects the inside cabling to avoid a damage of same when rotating more than 360°.

An excessive use of physical strength which may result in the shearing-off of the stopper pin may result in a minor possibility for the OT light with the spring arm (monitor holder) to fall down.

To ensure that the light with the spring arm (monitor holder) may not fall down, even when the stopper pin might have sheared-off, we strongly recommend the retrofit of a mechanical locking device that excludes any possible risk even upon improper use.

Enclosed to this letter please find this necessary mechanical locking device as well as the respective installation guide therefore.

We ask for your respective feedback on the enclosed form sheet as soon as the retrofit of the OT lights (monitor holders) has been realized. This allows us to register the retrofit in our product records and to create a summary on all activities.

**TRILUX Medical GmbH & Co. KG**

Hüttenstraße 21 · D-59759 Arnsberg · info-medical@trilux.de · www.trilux-medical.com

Commerzbank AG, Arnsberg · Konto 4 027 900 00 · BLZ 466 400 18 · IBAN DE70 4664 0018 0402 7900 00 · SWIFT COBADEFF466



Kommanditgesellschaft, Sitz Arnsberg, Arnsberg HRA 7043 · Persönlich haftende Gesellschafterin: TRILUX Beteiligungen GmbH, Sitz Arnsberg, Arnsberg HRB 7574 · Geschäftsführung: Johannes Huxöl, Rafael Muñoz



Following our sales records you have received the products in question with the following documents:

Order Confirmation No.

8XXXXXXXX

Invoice No.

9XXXXXXXX

Please ensure that within your organization all users of the a.m. products as well as any other relevant persons involved are being informed about this urgent and important safety information.

Should you have delivered these OT light systems (monitor holders) to any third party, please make sure that this information including the enclosures is passed on to this party/user.

Please keep this information at least until this measure has been finalized.

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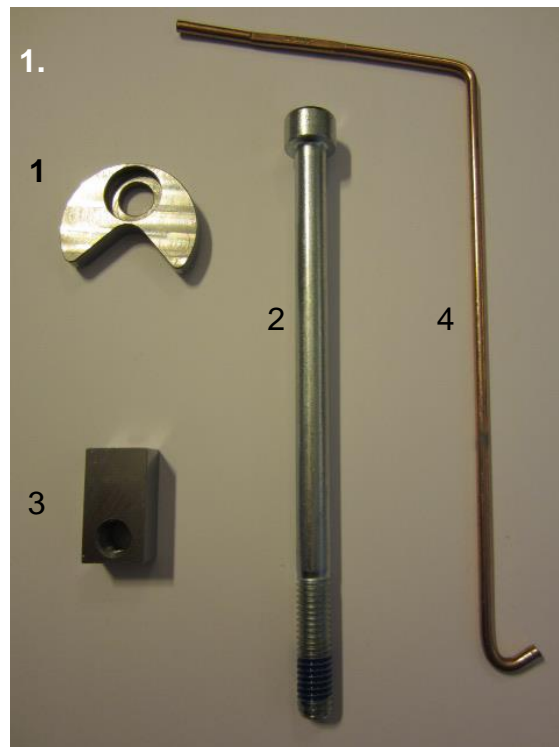


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## Montage redundante Sicherung/ Mounting redundant protection

### 1. Redundante Sicherung/ Redundante protection

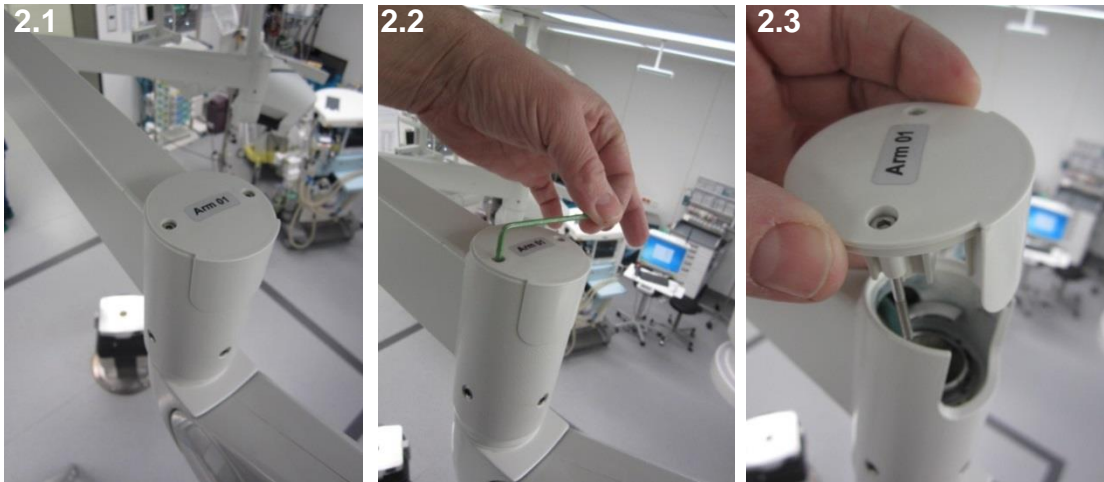
- 1. Sicherungsscheibe, Tk.-Nummer:10129143
- 2. Zylinderschraube, Tk.-Nummer:10129142
- 3. Sicherungsglasche, Tk.-Nummer:10129144
- 4. Demontage Tool Hülse, Tk.-Nummer:10129328



### Benötigtes Montagewerkzeug/Required assembly tools:

- 1. Innensechskantschlüssel 2,5mm und 6 mm  
Hex-wrench 2,5 mm und 6 m
- 2. Schraubendreher 5mm  
Screwdriver 5mm
- 3. Seitenschneider  
Side cutter
- 4. Drehmomentschlüssel >10 Nm mit Innensechskanteinsatz 6mm  
torque spanner >10 Nm with hexagonal socket 6mm

## 2. Demontage Deckel von Z-Achse/Disassembly cover of Z-axis



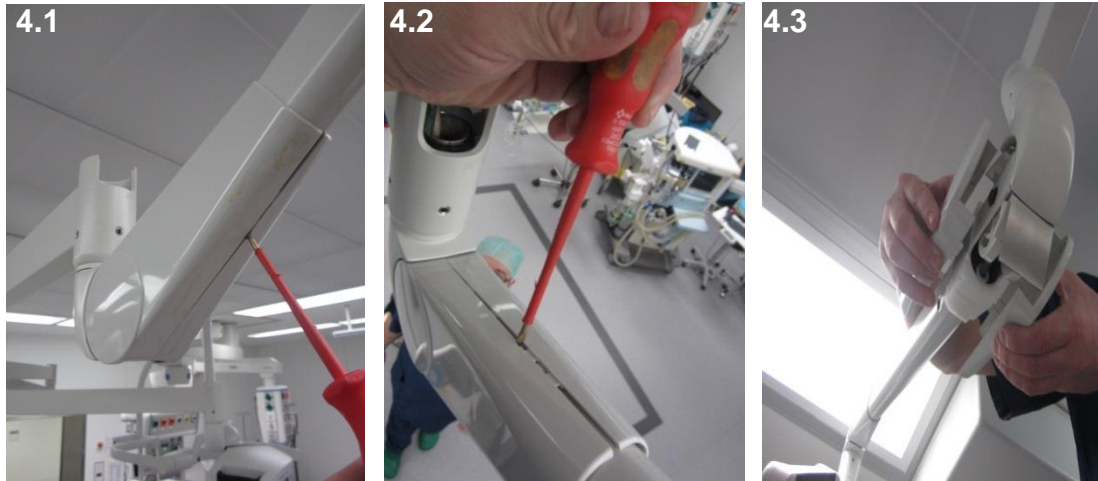
Beide Befestigungsschrauben am Ende des Auslegers lösen (Abb. 2.2)  
Unscrew both fixing screws on the upper end of the boom. (Pic 2.2)

## 3. Federarm positionieren/ position the spring arm



Federarm zur Montage der redundanten Sicherung in die oberste Position bringen (Abb 3.1).  
Bring spring arm for mounting the redundant protection to the highest position (Pic 3.1).

#### 4. Blende vom Federarm lösen/Remove panel from the spring arm



Durch vorsichtiges Hebeln mit einem Schraubendreher (Abb.4.1/4.2) in den beiden Nuten beide Kunststoff-Halbschalen auseinanderrücken (Abb.4.3) und abnehmen.

Press both plastic covers apart and remove via (Pic 4.3) careful levering with one screwdriver (Pic 4.1/4.2) within both grooves.

## 5. Kunststoffhülse aus Federarm entfernen/Remove the plastic sleeve spring arm

Durchverdrahtung vorsichtig aus dem Federarmgelenk herausziehen (Abb.5.1).

Through wiring carefully from the Pull spring arm hinge (Pic 5.1)



Kunststoffhülse mit Schraubendreher bündig (Abb.5.2) unter das Gußteil drücken.

Press plastic sleeve with a screwdriver flush (Pic 5.2) under the casting



Kunststoffhülse mit Hilfe des Demontagetools (Abb.5.3) aus dem Federarm herausziehen.

Pull out the plastic sleeve using the disassembly tools (Pic 5.3) from the spring arm.



## 6. Kunststoffhülse aus Federarm entfernen/Remove the plastic sleeve spring arm

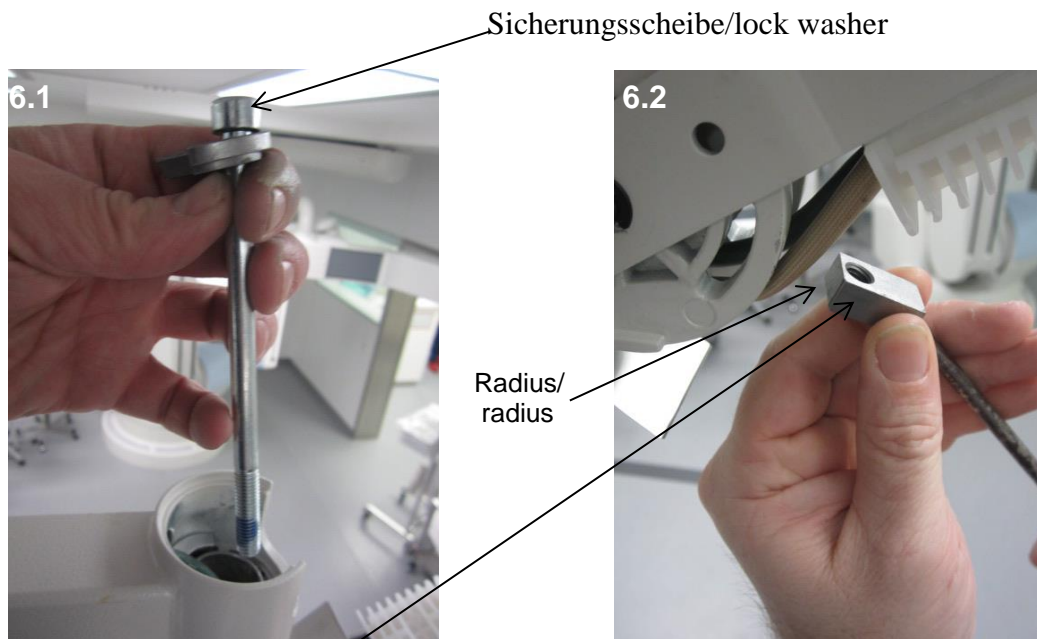


Hülse mit Seitenschneider (Abb.5.5) auftrennen und entfernen (Abb.5.6).

Sleeve with side cutter.  
Unpick (Pic 5.5) and remove (Pic 5.6).

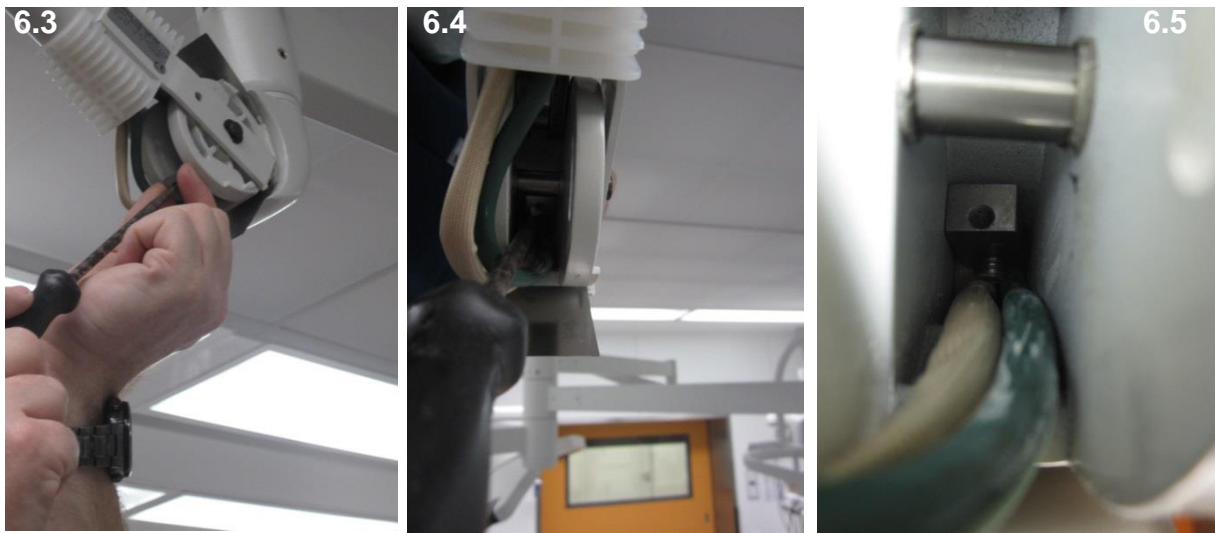


## 7. Redundante Sicherung montieren / Redundant protection set



**Achtung:** Sicherungslasche mit Radius nach unten montieren Abb. 6.2.

**Attention:** Install locking tab with radius down (Pic 6.2).



Sicherungslasche von unten in den Federarm einschieben, an der oberen Fläche entlangführen und dort halten (Abb.6.3/6.4).

Insert the Securing tab from bottom into the the spring arm, place it parallel to the upper surface, and hold it there (Pic 6.3/6.4).

Mikroverkapselte Schraube M 8,0x130,0 8.8 vz mit Sicherungsscheibe und Sicherungslasche im Federarm montieren (Abb.6.5).

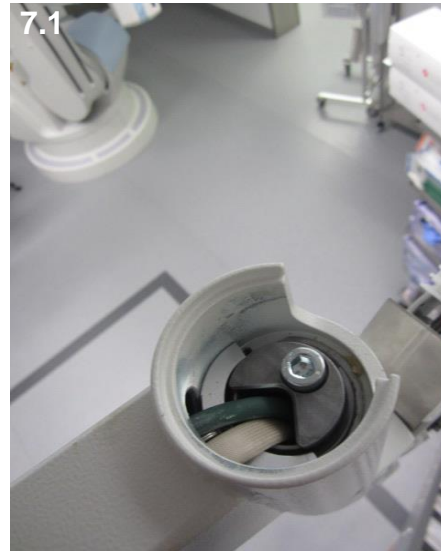
Microencapsulated screw mount M 8,0x130,0 8.8 vz with lock washer and locking tab in the spring arm (Pic 6.5).



## 8. Redundante Sicherung ausrichten und vormontieren/ Align and premount redundant protection

Sicherungsscheibe der redundanten Sicherung ausrichten (Abb. 7.1).

Lock washer redundant protection line up Pic (7.1).



Zylinderschraube mit Drehmomentschlüssel 12,5 Nm anziehen (Abb 7.2).

Tighten cylinder bolt with a torque wrench 12,5 Nm (Pic 7.2).



Blenden und Deckel in umgekehrter Reihenfolge montieren, dabei auf korrekte Lage der Blendenbleche im Federarmgelenk achten. Beide Kunststoff-Halbschalen nacheinander aufstecken und zusammendrücken, bis sie hörbar einrasten

Mount panels and lid in reverse order, Make sure the correct position of the aperture plates in spring arm hinge. Then fit both plastic covers in sequence and press tight until they are heard to snap in place