

Ihr Schreiben vom

Unser Zeichen

Ansprechpartner

Datum / Durchwahl

27. Januar 2015

DW -

Safety Information referring to TRILUX Medical Examination Light L 50, ceiling-mounted version

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 L50 examination light with the connected spring arm and the extension arm due to a manufacturing defect. This manufacturing defect is due to the fact that in some cases an insufficient portion of safety adhesive for screws has been applied. This was found out during respective tests of completely assembled ceiling fixations out of our finished goods store as well as out of the field.

We have found out that in rare cases during use of the light Aurinio L50 a connection in the ceiling fixation of the lighting system might loosen.

When turning around the light head with the connected spring arm / extension arm around its own axis a plug in sleeve might loosen due to a possible insufficient application of safety adhesive. When continuing the rotation by more than 10 turns (11 threads) the threaded sleeve might unscrew out of the tube of the ceiling fixation and might abruptly fall down. A complete drop down is prevented due to the inside cabling, so that the light is swinging at the wiring cable. Under disadvantageous circumstances this swinging light might cause injuries to persons and damage to properties.

Wall mounted or mobile systems of the examination light Aurinio L50 are not affected!

To ensure that the light with the spring arm / extension arm may not fall down, we strongly recommend the inspection of the respective junction of the ceiling fixation of the examination light system.

Enclosed to this letter please find the respective accessory as well as the respective installation guide therefore.

We ask for your respective feedback on the enclosed form sheet as soon as the inspection of the examination lights has been effected. This allows us to register these inspections in our product records and to create a summary on all activities.

TRILUX Medical GmbH & Co. KG

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

Order confirmation No.

8XXXXXXX

Invoice No.

9XXXXXXX

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 examination light systems 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.



Aurinio L50 SD / PM Ausführung Deckenmontage

Montage und verkleben der Steckhülse Assembly and glueing of the plug-in sleeve

1. Nachrüstsatz bestehend aus Retrofit Kit existing of

- | | |
|---------------------|-----------------------|
| 1.1. Sicherungsring | Artikel-Nr.: 10062128 |
| Snap-in ring | Item no. |
| 1.2. Kleber, | Artikel-Nr.: 10125425 |
| Glue | Item no. |
| 1.3. Hakenschlüssel | Artikel-Nr.: 50142004 |
| Hook wrench | Item no. |

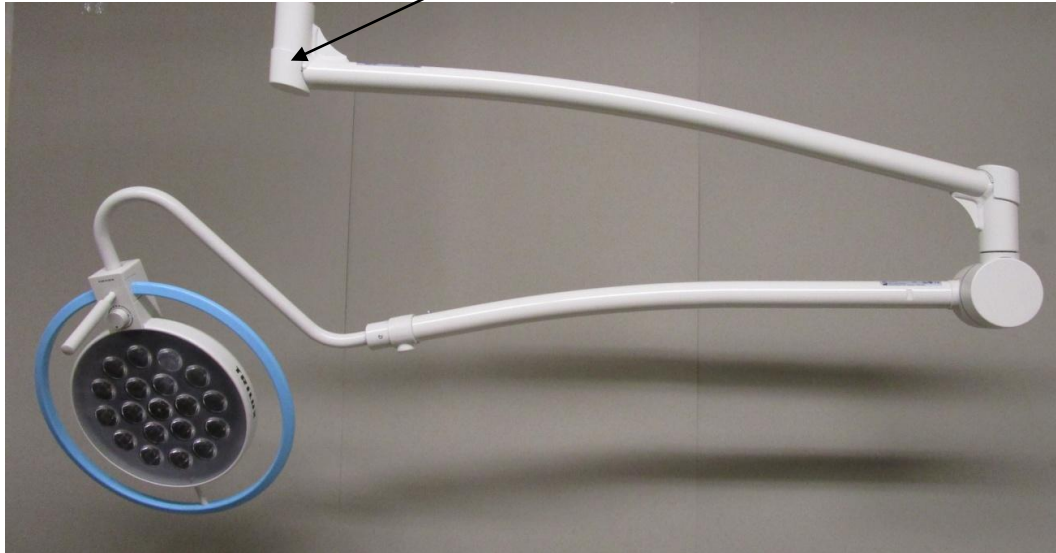


2. Benötigtes Montagewerkzeug/Required assembly tools:

- | |
|----------------------------|
| 2.1. Kreuz-Schraubendreher |
| Phillips screwdriver |
| 2.2. Sicherungsringzange |
| Snap-in ring pliers |
| 2.3. Hakenschlüssel |
| Hook wrench |

3. Demontage vom Ausleger/ Dismantling of extension arm

Auslegerabdeckung / Cover extension arm



- 3.1. Befestigungsschraube entfernen / Remove fixing screw
- 3.2. Sicherungsring entnehmen / Remove the snap-in ring
- 3.3. Ausleger demontieren / Remove the extension arm

Klebeverbindung der Steckhülse zum Außenrohr mit Hakenschlüssel durch Handkraft prüfen. Bei fester Klebeverbindung Ausleger wieder montieren.

Check adhesive bonding of the plug in sleeve to the outer tube with hook key by hand pressure. In case of permanent adhesive bond reassemble the extension arm.



Bei loser Klebeverbindung, Steckhülse herausdrehen und festhalten, mit Papiertuch reinigen und auf halber Gewindebreite umlaufend Kleber auftragen. Die Steckhülse mit Handkraft eindrehen, überflüssigen Kleber mit Papiertuch gut entfernen und die Steckhülse fetten. Die Trocknungszeit des Kleber ist **min. 3 Stunden**, danach kann die Montage des Auslegerarms erfolgen.

In case of a loose adhesive bond, unscrew the plug in sleeve, cleaning with a tissue and apply the glue to the half-length of the screw thread circumferential. Screw in the plug in sleeve by hand, remove needless glue with a tissue and lubricate the plug in sleeve with grease. The glue needs **min. 3 hours** drying time, after that, the extension arm can reassembled.





4. Montage des Auslegerarm / Assembling of the extension arm



Auslegerarm auf Steckhülse schieben, Unterlegscheiben einlegen, mit neuem Sicherungsring montieren. Auslegerabdeckung aufstecken und mit der Schraube sichern.

Assemble the arm on the plug in sleeve, insert washers, assemble with new snap-in ring. Attach the extension arm cover and secure it with the screw.