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Arnsberg (Germany), January 2018

Urgent safety information

Safety information regarding the affected products of the Aurinio L 110, L 120, L 150 and L 160, Aurinio OR lights series

Dear Sir or Madam,

We herewith would like to notify you of a safety-related corrective measure that affects the products of the Aurinio OR lights series Aurinio L 110, L 120, L 150 and L 160, of Trilux Medical GmbH & Co. KG (formerly Trilux GmbH & Co. KG).

The affected products delivered to you are listed in Annex I.

1. Description of the problem:

In the context of our worldwide product monitoring, we have determined that a formation of tears can occur in the support structure of the aforementioned lights. This results in a situation where the load-bearing capacity may potentially no longer be ensured and may lead to a material breakage at the welding seam of a component of our OR lights.

Investigations have shown that a fracture may not only occur during application but also during cleaning activities. Especially in case of extensive use of the OR light and a positioning of the light's head that is conducive for potential breakage, a breakage of the light's connection may occur.

In case of such a failure, the light's connection of the product breaks, which may lead to injuries to the patient, users, or third parties due to the turning down of the light. Also, to date we were not able to reproduce any spontaneous breakage of the light's connection. Based on our research, the breakage of the light's connection is preceded by the formation of a tear of the

paint on the surface. This can be checked via a visual inspection. The gap that occurs is increasing slowly.

To date, in no known case has a crashing-down or a complete separation between the head of the light and the light's connection occurred since the wires fed through have held the light's head or the light was still held on one side by the component of the light's connection.
Due to the cases known to use, the probability of occurrence has to be categorised as extremely low.

The breakage is preceded by the formation of tears in the construction, see Figure 1-3.

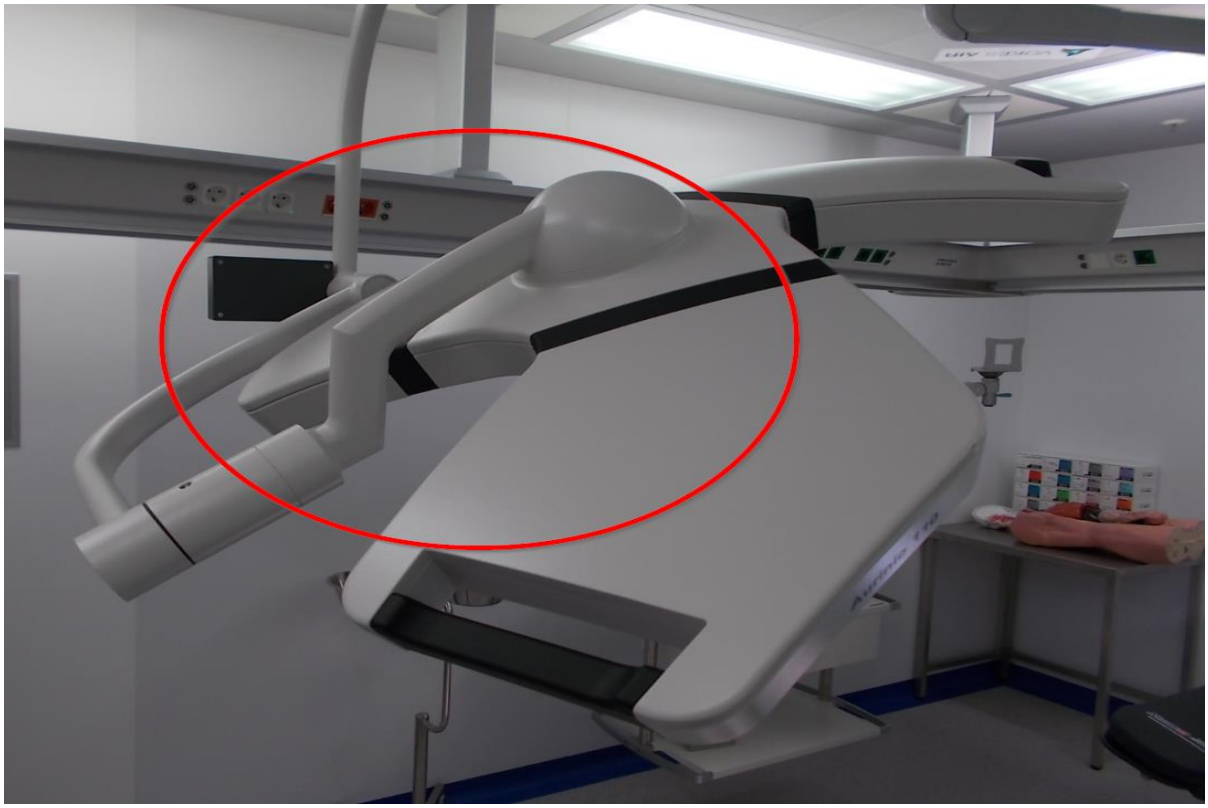

Figure 1: Overall system of the Aurinio OR light – affected component marked

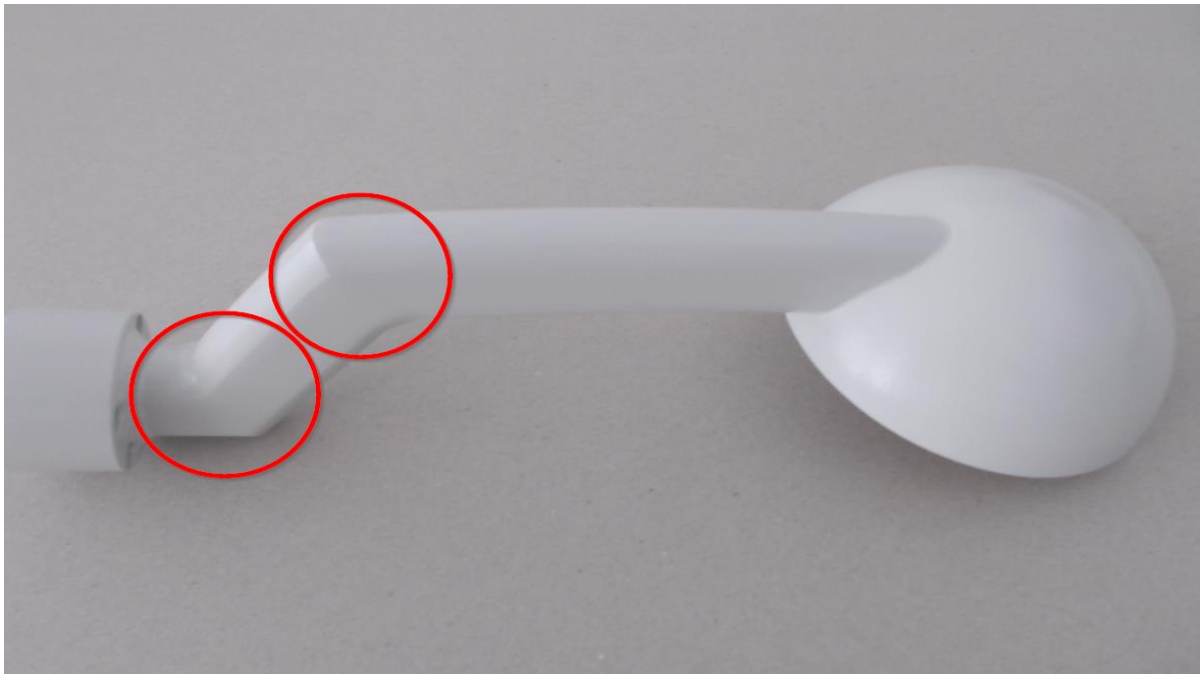

Figure 2: Light’s connection – potentially affected areas

The following figure shows the affected component (light’s connection) with the formation of tears to be potentially observed.

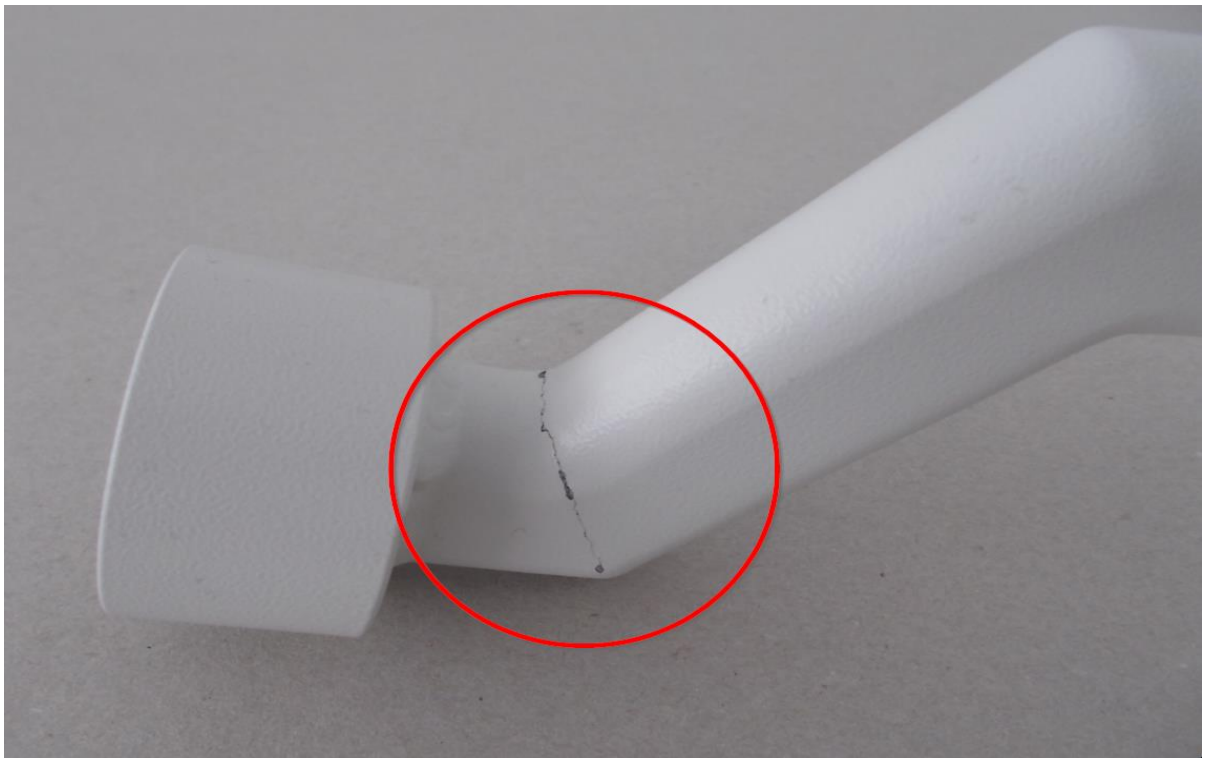

Figure 3: Light’s connection – tear observable

2. Measures to be taken by the consumer:

In order to avoid risks for patients, users, or third parties, the OR lights should not be moved with considerable force against the existing limit stops. Even if your OR lights turn out to be inconspicuous in the inspection, the OR lights must, on principle, be positioned and operated conscientiously.

Until the corrective measure has been carried out, the affected component (light's connection) of the Aurinio OR light must be subjected to a daily visual inspection for a potential tear formation, in accordance with the marked areas of Figure 2.

In this inspection, please bear in mind that the inspection for the formation of tears must be carried out all around.
Unless, taking into consideration the recommended inspection, something else results, the use of the OR lights can be continued until the implementation of the corrective measure.
Where applicable, please check your stockpiled products immediately and match them to the information in this letter.

With this letter, you are receiving the material necessary to be able to carry out the corrective measures.
The following figures are depictions of the installation as well as of the installed safety device set. The whole installation of the safety device set is described in the installation instructions.

Figure 4: Installation of the safety device set

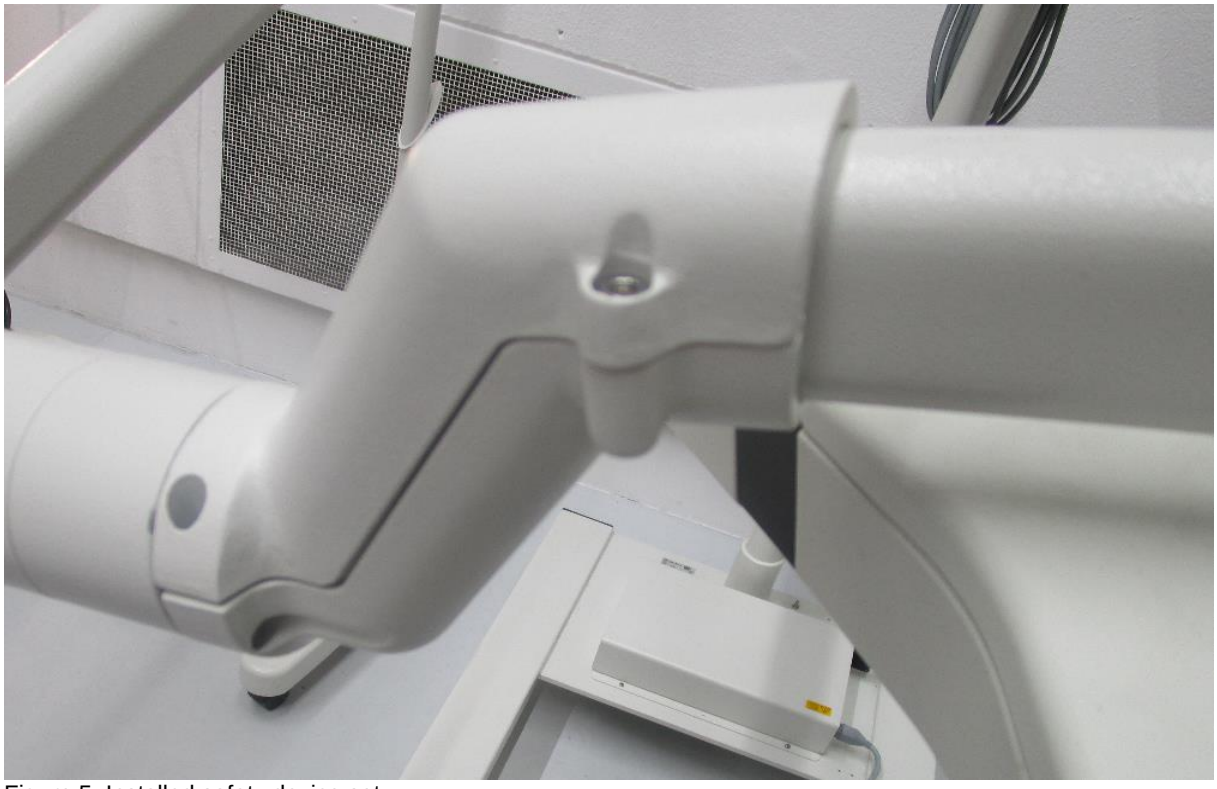
Figure 5: Installed safety device set

Please complete the attached response form (Annex III) regarding receipt of this letter and return it to us by email not later than one week after receipt of this letter.

The affected products should be corrected immediately in accordance with the installation instructions.

If you have resold affected products, please inform your customers immediately of this letter regarding safety-related measures in the field and provide your customer with the material we have made available to you for implementation of the corrective measure.
We recommend you include this letter with the message to your customer.

Please monitor the corrective measures and report back to us regarding this, no later than 15th of April 2018, with the response form regarding the implementation of the safety information (Annex IV), which is included with the material provided.

Please ensure that, within your organization, all users of the aforementioned products as well as other persons to be informed obtain knowledge of this urgent safety information.
Please retain this information at least until the measure has been completed.

We apologize for any inconveniences this action may be causing, but consider this a preventative measure in the interest of the safety of users and patients.
Thank you very much for your cooperation.

In case of questions regarding this letter, please contact us at any time at the following contact address:

email: spoon@trilux-medical.com
Phone no.: +49 2932/9214 214

Best regards,

[redacted] (Director Sales Operations)

[redacted] (Safety Officer for Medical Products)

Attachments:

Annex I: Products delivered to you

Annex II: Installation instructions (included with the material provided)

Annex III: Response form for acknowledgement of the safety information

Annex IV: Response form for implementation of the safety information (included with the material provided)