

«Name_1»
«Name_2»
«Anrede» «Vorname» «Ansprech_partner»
«Straße»
«PLZ» «Ort»
«Land»

Gebrüder MARTIN GmbH & Co. KG
Operating Lights / Camera Systems /
Ceiling Pendants Product Management

August 2009

Werner Eisele
Product Management
Phone: (49) 7461 / 706453

Important Safety Notice

Inspection of the frontal joint of Ondal Acrobat 2000 spring arms used from March 2003 in our ML, marLUX and marLED operating light suspensions as well as in our arm systems for cameras, monitors and other equipment

Dear Customers and Users:

In the light of our global product surveillance and following a safety tip from our supplier Ondal Industrietechnik GmbH, we feel bound to inform you about risks to patients and users which may occur when using affected Gebrüder MARTIN products as specified in Annex 3, due to the Ondal spring arm Acrobat 2000 (AC2000) being part of those products.

So far, Gebrüder MARTIN has not received any reports from its markets regarding incidents involving this defect in Acrobat 2000 spring arms used in connection with operating lights and suspension arms placed on the market by Gebrüder MARTIN.

However, our supplier has reported some rare cases of weld fracture on the frontal joint of said spring arm, as well as the occurrence of a fatigue failure, i.e. a fracture developing over an extended period of time.

The investigation report made available to us by Ondal indicates that, in case of joint breakage, the light or device head will most likely be caught and restrained by the internal cable of the spring arm. Although Ondal's investigation report cites a failure probability of less than 0.05%, it cannot be ruled out, however, that the light head or device head will slip down in a swinging motion, or that it might even fall off if the cable breaks. In such a case, there is a big risk of the patient and anybody else in the direct vicinity being injured.

Recommendations on safety and handling until corrective measures are taken:

Based on what we know so far, it is to be assumed that spring arm joint fracture could occur mainly when the arm is put under load in the course of handling or positioning the light or other device suspended on it. To minimize risks, we therefore urgently advise you to move the light head (or other terminal device) and the spring arm with care, avoiding undue force. Pressure on the lower rotary joint of the spring arm should be kept to a minimum when swiveling the light or device towards the central axis of rotation. Especially when the horizontal rigid extension arm and the spring arm are fully extended – and thus in line with each other, creating a maximum radius – no additional force must be applied either centrally (in the direction of the central bearing shaft) or radially (opposite direction). Instead, make sure that the angle between the rigid extension arm and the spring arm is less than 180° (“folded position”) before continuing to position the light head or other device.

We kindly request you to appreciate that, given the large number of installations that are affected, it will take a little time to prepare adequate, possibly more extensive corrective measures.

To minimize risks in the meantime, Gebrüder MARTIN must ask you to inspect all affected Ondal AC 2000 spring arms as soon as possible as a preventive measure. This should be based on a check all of the units delivered to you by Gebrüder Martin.

The Ondal serial numbers of the affected Ondal Acrobat 2000 spring arms are specified in Annex 2.

For the item numbers of potentially affected Gebrüder MARTIN products, please refer to Annex 3.

An invoice overview regarding all potentially affected products delivered to you is provided in Annex 4 for your convenience.

Please make sure that your customers (if you are a specialized dealer) or your users, as well as all staff members involved in this matter, are duly informed about this Safety Notice and the instructions contained therein.

If no cracks are detected during the inspection according to Annex 1, the spring arms can be kept in use. However, should cracks or fissures be found, the respective spring arm must be withdrawn from service at once. In such a case, please inform our service department as soon as possible.

Please confirm receipt of our Safety Notice by completing the reply form attached and faxing it to the following address: +49 7461 706 193.

Should you have any queries, please do not hesitate to contact our service department under +49 7461 706 316.

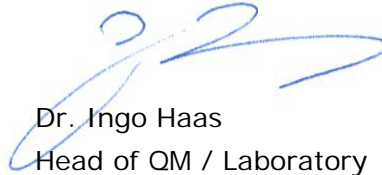
We sincerely apologize for all the inconvenience we are causing you. The measures outlined are preventive, the aim being to ensure the safety of both patients and users.

Yours faithfully,

Gebrüder Martin GmbH & Co. KG
A Company of the KLS Martin Group



W.
Head of Product Management
Operating Lights / Camera Systems /
Ceiling Pendants



Dr. Ingo Haas
Head of QM / Laboratory

Enc:

Reply Fax Form

Annex 1: Instructions for checking the frontal joint of Acrobat 2000 spring arms manufactured between 2000 and 2006 – Doc. no. 1539761, issued 06/2009, version 1

Annex 2: List of Ondal serial numbers of affected Acrobat 2000 spring arms

Annex 3: List of item numbers of affected Gebrüder MARTIN products

Annex 4: List of invoices of delivered Gebrüder MARTIN products

**Reply FAX to: +49 7461 706-193
Gebrüder MARTIN GmbH & Co. KG**

**Customer: «Name_1» «Name_2» «Ort»,
Customer-No: «Regulierer»**

«Betreff»

We hereby confirm

- 1) receipt of Gebrüder MARTIN's "Important Safety Notice" letter dated August 2009, including Annexes 1–4.
- 2a) As specialized dealer:

that we will pass on the "Important Safety Notice", complete with Annexes 1–4, to our customers immediately in order to have all the delivered and affected Acrobat 2000 spring arms inspected in accordance with the instructions provided in Annex 1.
- 2b) As user:

that we will immediately inspect all the delivered and affected Acrobat 2000 spring arms in accordance with the instructions provided in Annex
- 3) that we will inform our national authority according to national regulations (not required within the European Community and Switzerland)

Place, date:

Name/position of signatory:

Company/stamp and signature:
