

Gebrüder MARTIN GmbH & Co. KG

Product management surgical lamps / camera systems / Independant® Ceiling Pendants

January 2013

Sven Zehnder

Chief of product management (surgical lamps)

Tel.: +49 7461 / 706 453

Important safety notice

Inspection of our ML 301 examination lamp – danger to patients and users

Dear customer and user,

as part of our worldwide product surveillance and following a safety notice from our supplier Ondal Medical Systems GmbH, it is our duty to inform you of risks to patients and users that may arise in the use of certain Gebrüder Martin GmbH & Co. KG products which feature the Ondal Acrobat® Swing spring arm.

Our supplier Ondal Medical Systems GmbH reports that after an average usage period of seven years fatigue failure of the plastic joint may occur. The manufacturer has become aware that a joint on the spring arm may break either during use or when the spring arm is not in operation. If the joint breaks, the spring arm falls suddenly and without hindrance. In such a case there is a high risk of injury to the patient and other persons in the immediate vicinity.

Safety and procedural instructions, corrective action

In order to preclude unnecessary risks, Gebrüder Martin must ask you to carry out an inspection of all the Ondal Acrobat® Swing spring arms which have been delivered to you. Kindly inspect the units that have been delivered to you by Gebrüder Martin.

You will find a list of the products which have been delivered to you and may potentially be affected in Attachment 1.

If inspection in accordance with Attachment 2 reveals that an aluminium joint was used, there is nothing to be said against continuing to use the examination lamp.

If the joint is plastic, however, the spring arm must no longer be used. By continuing to use it you may endanger the life, limb and health of patients and users.

In this case, please inform our service department, Mr. Rupert Kohler Tel. +49 7461 706 332, immediately.

On request, we may also contact you directly. In this case please mention it on the attached return fax form filling in the telephone number and contact person and fax the form back to +49 7461 706 190.

Please make sure that your customers ('customers' refers only to specialist trade partners), users and / or any staff whom this may concern are informed of this safety notice and the instructions it contains.

We offer to replace the spring arm or arms concerned at a price of 140,- euros net plus VAT. Neither the costs of installation and removal nor those of further consequential loss or damage caused thereby are covered by this offer.

We are sorry for the inconvenience caused. The measures described here are of a preventive nature and aim to ensure the safety of patients and users.

Please retain this notice for at least as long as it takes to complete the measures.

Yours faithfully

Gebrüder Martin GmbH & Co. KG,
a company of the KLS Martin Group



Michael Martin
President Marketing
Safety officer Medical Device

p.p.



Sven Zehnder
Chief of Product management
Surgical lights

Return fax
Attachment 1:
Attachment 2:

Reply fax: to +49 7461 706-190
Gebrüder Martin GmbH & Co. KG

V.-ID: Customer:

We hereby confirm

- 1) that we have received the letter headed 'important safety notice' from Gebrüder Martin dated January 2013 with its Attachments 1 and 2
- 2) that we have understood the situation and the risk it involves
- 3a) as a specialist trade partner:
that we shall pass on the contents of the letter headed 'important safety notice' with its Attachments 1 and 2 to our customers immediately with the aim of ensuring that the Acrobat® Swing spring arms delivered and referred to here are subjected to inspection
- 3b) as a user / operator:
that we shall carry out an immediate inspection of the Acrobat® Swing spring arms delivered and referred to here in accordance with Appendix 2 and replace them if necessary.

Please contact me/us directly at:

Name:..... **Telephone:**

Place, date:

Name / position of signatory:

Company / stamp and signature:
