Dear Partner,

Ensuring quality for our customers is an primary concern here at S.I.M.E.O.N. . We continuously monitor our product quality and the behavior of our products in the field. In accordance with this, we would like to inform you of a planned voluntary test of our central axis system. The central axes which are the subject of the test were produced between 01.03.2014 and 30.04.2016.

A report from the USA has drawn our attention to a risk of incomplete screw connections on central axis systems produced in this period.

This applies only to the extension arm on the central axis. The screws are used to fix the extruded section to the "bearing head (large)". As the extruded section is also glued in place, this is a redundant system.

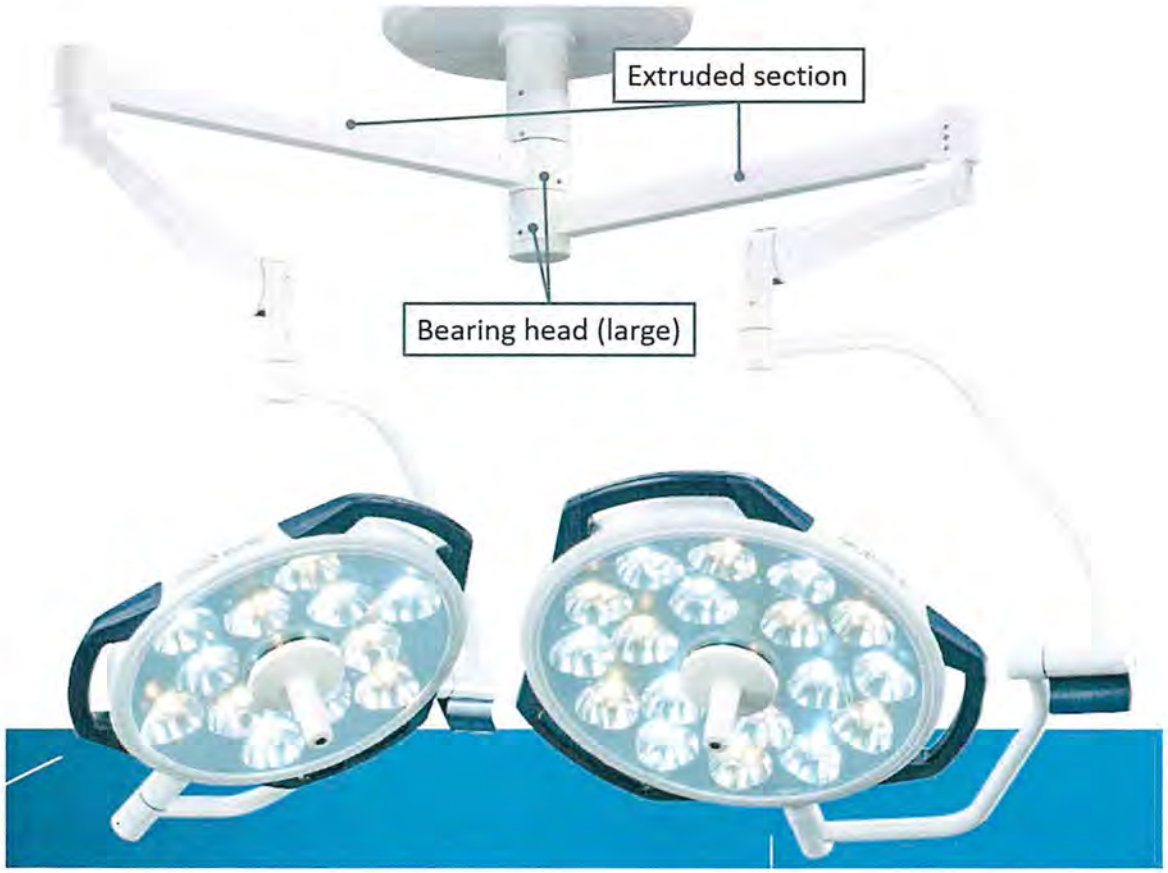

Fig. 1: Relationship of extruded sections and bearing head (large) in the lighting system

As a preventive measure, we have decided to test the central axes in question with a very simple magnet test devised by us. The test takes only a few minutes and can be performed by any person at the hospital.

We apologize for the possible inconvenience this may cause. You will understand that we take our responsibility for quality and patient safety seriously and that this is the reason for this preventive measure.
This notice must be shared with all relevant personnel in your organization, and with any organization to whom the potentially affected equipment has been provided.

Sincerely,

[redacted]

PUSHING TECHNOLOGY TO EXCELLENCE

Anticipated Field Corrective Action – Field Safety Notice

Inspection

Acknowledgement – Please fill out and send it via email or post to the following address:

S.I.M.E.O.N. Medical GmbH & Co. KG

Mr. Timo Steuer

In Grubenäcker 18

78532 Tuttlingen, Germany

Email: capa@simeonmedical.com

Telephone: +49 7461 90068 899

Name of organization

Address

Department

I hereby acknowledge the receipt of the sent information as well as the immediate and permanent attention and implementation of its content within the defined time.
I also confirm the inspection of affected central axes within the defined time period.

Name and function

Date

Signature