Field Safety Notice

Date: 12/07/2018

Type of action: Information on safe use/ operation

Dear customers and sales partners,

This letter contains urgent safety information intended for operators and users of lights manufactured by our company, Dr. Mach GmbH &Co. KG.

Identification of medical devices concerned:

All lights manufactured by Dr. Mach GmbH & Co. KG including suspension tubes supplied by Dr. Mach and "heavy central axis" manufactured by Ondal for ceiling mounting

Description of the problem including identified cause:

It was noted during repair work by our service technicians that the maintenance procedures specified in the operating instructions have not been followed or rather that individual operators of the abovementioned products have not fully carried out all the maintenance procedures according to our and Ondal's maintenance protocols. In particular, suspension systems were found whose screw connections had not been regularly maintained and consequently had worked loose after prolonged use over several years.

Signs of wear are inevitable with heavy use of both the lights and the suspension system. The resulting deformation, damage to paintwork, cracking and loose screw connections in the suspension systems can be safely detected and rectified during scheduled maintenance before the system poses a hazard.

Potential risk:

If maintenance is not carried out or not performed properly, screw connections in the mounting can wear and work loose with prolonged use over several years. This could affect the safety and reliability of the products you have purchased which, in the worst case scenario, may even cause serious injury to patients and/or users through the lighting system falling down.

What action should be taken?

This letter is sent to remind you of the need to maintain our products regularly and completely in accordance with our guidelines and those of Ondal in order to ensure their safety and quality. Only

Dr. Mach GmbH & Co. KG Medizintechnik · Flossmannstraße 28 · D-85560 Ebersberg
Tel +49(0)8092 2093-0 · Fax +49(0)8092 2093-50 · www.dr-mach.de · info@dr-mach.de

by doing so the safety and performance of the products you have purchased is assured in the long term. The maintenance procedures, which must be carried out according to the guidelines in the maintenance protocols and which include the components' screw connections in particular, relate both to our lights and to Ondal's suspension systems supplied with them. Maintenance should only be carried out by trained staff familiar with the operating instructions and maintenance protocols.
Here once again is the link to Dr. Mach's and Ondal's maintenance protocols:
www.dr-mach.de/en/downloads/maintenance.html

Circulating the information given here:
In your organisation please ensure that your maintenance technician / service company or other business responsible for maintaining the above mentioned medical devices is aware of the operating instructions and maintenance protocols for the lighting and for the suspension systems and carry out regular maintenance procedures accordingly. The screw connections in particular should be checked regularly to make sure they have not worked loose and tightened, if necessary, with the specified torque.

If you have handed the products over to a third party, please pass on a copy of this information sheet to them without delay.
Please keep this information sheet with the operating instructions.
The Federal Institute for Drugs and Medical Devices has received a copy of this "Field Safety notice".

Contact person:
Dr Peter Kohrs
T: +49 8092 2093-0
Email: info@dr-mach.de

Please fax back or email us a scanned copy of the attached form by July the 19th confirming that you have received, understood and taken note of this letter.

Kind regards,

Dr. Peter Kohrs
Technical Director

Dr. Martin Hyca
Area Manager

Please respond by fax or email to:

Dr. Mach GmbH & Co. KG
Flossmannstrasse 28
85560 Ebersberg

Fax: +49 (0) 8092 / 2093 – 50
Email: info@dr-mach.de

Confirmation of receipt of the Field Safety Notice*

concerning lights manufactured by Dr. Mach GmbH &Co. KG including Ondal suspension systems, dated 12.07.2018

Name of customer: …….

- We confirm receipt of this Field Safety Notice and confirm that appropriate action will be taken.
- We confirm receipt of this Field Safety Notice and will pass it on to our customers.
- We confirm receipt of this Field Safety Notice and have purchased none of the products concerned.

……., ……. 2018 ……
Place Date Signature / Stamp

* Please complete this confirmation of receipt in full and tick the appropriate boxes. Please also inform us if you should no longer hold the medical device mentioned.