

Field Safety Notice

Date: 12/07/2018

Type of action: Instructions for safe use / Preventive maintenance procedure and notification of maintenance protocol update

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 lighting systems manufactured by Dr. Mach GmbH &Co. KG consisting of flange tubes and lights from Dr. Mach and the associated suspension system (heavy central axis, extension arm and spring arm) from the suspension system manufacturer.

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 above-mentioned products have not fully carried out all the maintenance procedures in accordance with our maintenance protocol and those of the manufacturer of the suspension system. In particular, our technicians found lighting systems whose screw connections had not been regularly maintained and consequently had worked loose after prolonged use over several years. It is particularly important to check the screw connection between the flange tube and the heavy central axis and the screw attaching the safety sleeve to the spring arm, and if necessary to tighten them, in accordance with the maintenance protocols.

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 lighting 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 lighting system 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 if the lighting system, or components thereof, were to fall down.

What action should be taken?

In order to maintain the safety and quality of the lighting systems, Dr. Mach GmbH & Co. KG has updated the maintenance protocol, and we are sending you this letter to draw your attention once again to the need for regular and thorough maintenance. Only in this way is the safety and performance of the products you have purchased assured in the long term. The maintenance procedures, which must be carried out according to the guidelines in the maintenance protocols and which include in particular the screw connections of components, relate both to our lights and to the suspension system manufacturer's suspension system supplied with them. Maintenance should be carried out only by trained staff familiar with the operating instructions and maintenance protocols. Here once again is the link to Dr. Mach's and the suspension system manufacturer'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 the maintenance protocols for the lighting and the support-arm systems and carries out regular maintenance procedures accordingly. The screw connections in particular should be checked regularly to make sure they have not worked loose and should be tightened, if necessary, to 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

Tel: +49 8092 2093-0

E-mail: info@dr-mach.de

Please send us the enclosed letter of reply by fax or e-mail by 10/08/2018 and confirm that you have received, understood and duly noted the content of this letter.

Kind regards,



Dr. Peter Kohrs
Technical Director



Dr. Martin Hyca
Divisional Director

Please reply by fax or email to:

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

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

Confirmation of receipt of the Field Safety Notice*

concerning lighting systems manufactured by Dr. Mach GmbH & Co. KG **consisting of flange tubes and lights from Dr. Mach and the associated suspension system (heavy central axis, extension arm and spring arm) from the suspension system manufacturer**
dated 12/07/2018

Name of customer:

- We confirm receipt of this urgent safety information and confirm that appropriate action will be taken.
- We confirm receipt of this urgent safety information and will pass it on to our customers.
- We confirm receipt of this urgent safety information and have not purchased any 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 no longer have the medical device mentioned.