

Urgent Field Safety Notice

Field safety corrective action

concerning

Ceiling Unit CU 5001/3 and CU 3-21/23

for ceiling mounted operating microscopes manufactured by MÖLLER-WEDEL

xx.02.2017

Sender

MÖLLER-WEDEL GmbH & Co. KG
 Rosengarten 10
 22880 Wedel

Receiver

Doctors and clinic personal,
 Distributors of MÖLLER-WEDEL GmbH & Co. KG

Dear Sir or Madam,

The MÖLLER-WEDEL GmbH & Co. KG has initiated a safety relevant and corrective action concerning the below listed products. The microscope arm of the mentioned ceiling units can be electrically driven from the parking position into the operating field of the surgeon by an electromotive lifting column. Abrasive wear of the drive assembly can occur by exceeding a higher life time of the devices which could cause a slide-through of the telescopic column into the lowest stop.

Our records show that at least one of the below listed ceiling units for ceiling mounted operating microscopes have been supplied to you:

Identification of affected medical devices

Product	Manufacturing Date	Reference No.	Serial No.	
			from	Up to
CU 5001	1993-2000	604 105	P51	274
CU 5003	1993-2000	604 106	P51	127
The prime series of the successor product is also affected:				
CU 3-23	2000	604 650	P51	P58
CU 3-21	2000	604 700	P51	P60

Description of the problem including the determined cause

The microscope arm can be moved up- and downwards with a levitation height of 40 cm by a motorized adjusted telescopic column. The analysis of a customer device with 19 years of operation has shown that the spindle driven with shaft joint fatigues additionally the supporting spindle nut shows a loss of stability due to abrasive wear. If severe abrasive wear occurs the lifting column can slide, during lifting procedure, downwards up to 40 cm into the integrated lowest mechanic limitation.

Possible Risk

The above described problem can occur if the lifting column has not been driven into the lowest working position before surgery. The lifting column could slide into the lowest working position if unrecognized abrasive wear of the spindle nut occurred and the lifting column is used in a different position other than the lowest working position or if the microscope is positioned via the lifting column and not as intended via the suspension arm during surgery which could cause injuries on patient or operator.

Up to date only one customer device has shown this failure while no patient or operator got injured. We are not aware of defective equipment or even injuries while clinical usage. This security information is a preventive action in field in order to prevent a possible patient hazard.

What actions are to be taken?

1. Move the telescope column to the lowest position. The ceiling unit is now in the safe working position and can be used without restrictions.
2. Keep the ceiling unit in the lowest and thus safe working position until the ceiling unit has been serviced.
3. Use the enclosed labels on the ceiling unit to indicate that the lifting column is not to be used anymore (see annex).
4. Order the maintenance of your ceiling unit at your local representative office.
5. Please return the enclosed reply form to us as soon as possible.

Transmission of the information

Please ensure that all users of the products mentioned are aware of and receive this urgent safety information. If you have passed the products to third parties, please forward a copy of this information and inform the below mentioned contact person.

Parking position of the lifting column

If you still want to move the telescope column to the upper parking position, ask for maintenance or, as the case may be, a replacement of the telescope column via your country representative. We would like to draw your attention to the fact that due to the age of the equipment no claims for warranty services apply.

Contact Details

For questions concerning this procedure, please contact, Phone: +49 (0)4103 709-04, Fax: +49 (0)4103 709-355, Email: vigilance@moeller-wedel.com

Please keep this information at least until the action has been closed accordingly.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Field Safety Notice". In addition, national authorities of the country have been informed in accordance with the European directives.

We apologize for any inconveniences caused to you by this safety action and thank you in advance for your support in the timely handling.

Yours Sincerely,

MÖLLER-WEDEL GmbH & Co. KG

Director Quality Management

Response / confirmation form
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We hereby confirm that:

- The telescope column is driven to the lowest position until maintenance. Additionally the device has been marked not usable and the ceiling unit is only used in the lowest and thus safe working position.
- The telescope column was checked / exchanged.
- We are not interested in maintenance and operate the ceiling unit exclusively in the lowest working position / the ceiling unit is taken out of operation.

REF / Serial number of the Device: REF: _____ SN: _____
(see annex)

Name of facility: _____

Address: _____

Additions to address: _____

City: _____ ZIP Code: _____

Country: _____

Contact details: _____

Local Distributor: _____

Name of Employee: _____
(in printed letters)

Date and Signature: _____

Please return this form completed and signed via e-mail to:
vigilance@moeller-wedel.com or by fax to + 49 (0) 4103 709 355

Annex
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Identification:

Identification plate with reference number (REF/Typ) and serial number (SN/Nr)
on the upper edge of the ceiling body



Labeling:

2x labels on the left/right underneath the column

