

FIELD CORRECTIVE ACTION NOTICE

Leica M525 F20 Microscope System

FCA Identifier: CAPA-HER-MD-18-001

Enhancement of instructions for use and additional markings to prevent inadvertent tipping

Customer Name

Heerbrugg, August 20th, 2018

Institution

Leica Microsystems (Schweiz) AG

Address

Dear [•] Insert Customer Name:

This letter is to inform you about a field corrective action involving all Leica M525 F20 Microscope Systems (see Figure 1) to replace the instructions for use with an enhanced revision and to fix additional markings onto the device.

You are receiving this letter because you are the holder of a product that is subject to this field action according to our data. This letter contains important information that needs your attention.

Description of the Problem:

At Leica Microsystems, we are dedicated to providing the highest standards of quality to our customers. Part of this dedication is proactively responding to quality issues when they occur.

Leica Microsystems received five customer complaints stating that users inadvertently tipped over their Leica M525 F20 Microscope System. In four cases it was confirmed, that the issue occurred when users handled the microscope while the swing arm was in fully extended position (see Figure 3). In all cases the Leica M525 F20 did not cause or contribute to serious injury. The five complaints occurred in five different countries over a timeframe between the years 2010 and 2017. The Leica M525 F20 was introduced in the year 2009 with more than 1000 instruments distributed globally up to date.

Leica Microsystems identified an area of improvement in the instructions for use and markings as root cause for the reported issues. The existing instructions for use and markings on the device need to be elaborated in an enhanced manner to ensure all users will position and handle the Leica M525 F20 as intended with an angle of approximately 90° between horizontal arm and swing arm (see Figure 2). When the Leica M525 F20 is positioned with an angle of approximately 90° between horizontal arm and swing arm it is unlikely that the instrument is inadvertently tipped over by a person handling the instrument.



Figure 1: Overall view of Leica M525 F20 Microscope

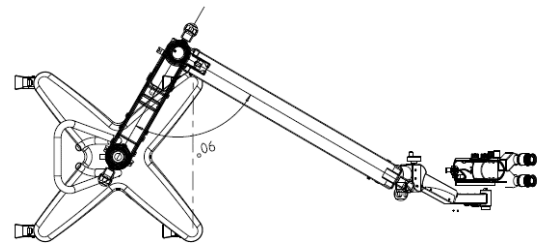


Figure 2: Top view of Leica M525 F20 Microscope

Intended correct positioning:

~ 90° between horizontal arm and swing arm

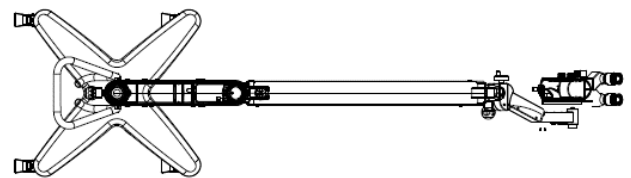


Figure 3: Top view of Leica M525 F20 Microscope

Unintended incorrect positioning:

Horizontal arm and swing arm fully extended

Leica Microsystems has initiated a field corrective action to provide enhanced instructions for use and additional markings for each Leica M525 F20 in the field. Details of the enhancements in the instructions for use and the additional markings are shown in Attachment 1 (see Page 4 and 5).

Leica Microsystems will provide you an update package containing the enhanced instructions for use and additional markings together with detailed instructions on how to fix the stickers onto your instrument within the next 3 months.

A Leica Microsystems representative will contact you to ensure users are sufficiently trained to position and use the Leica M525 F20 as intended.

Advice on action to be taken by the user:

- You can continue to use the system pending availability of the enhanced user manual and the additional markings as described in Attachment 1:
 - Ensure that your Leica M525 F20 is positioned and handled with an angle of approximately 90° between horizontal arm and swing arm during surgery as well as during set-up and preparation (see Figure 2 and Attachment 1).

- Ensure adherence to the current instructions for use, in particular for transportation:
 - For transportation always move the Leica M525 F20 into the transport position.
 - Never move the stand while the unit is extended.

Transmission of this field notice:

This notice must be passed on to all those within your organization who need to be aware of it and to any organization where the affected devices have been sold, rented, leased or otherwise transferred.

Please confirm receipt of this notice by signing, dating and returning the attached 'Acknowledgement Form' (see Page 6) back to us by email to:

M525F20-IFU-Update@Leica-Microsystems.com

within 10 working days after receipt of this field correction action notice.

The national competent authority has been informed of this field action.

We sincerely apologize for any inconvenience this field action may have caused.

For over 150 years, Leica stands for excellence in product quality, customer satisfaction and technological innovation. We strive to maintain these attributes in all our business activities and are committed to respond quickly to any deterioration in product quality.

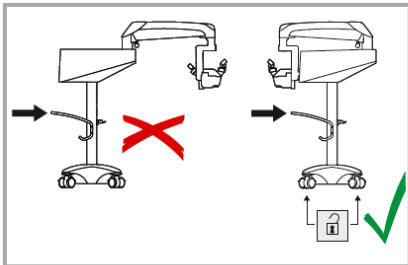

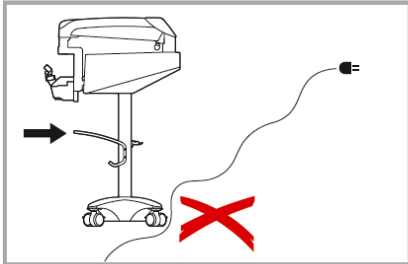

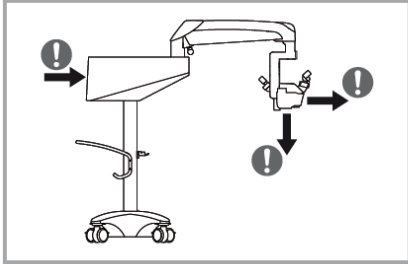

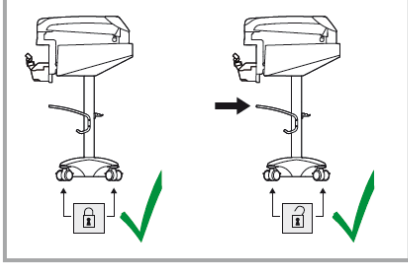

Sincerely,

Roland Jehle
Regulatory Affairs/Quality Assurance Manager
Leica Microsystems (Schweiz) AG

**ATTACHMENT 1
to FCA Notice - CAPA-HER-MD18-001 - M525 F20**

Enhanced Instructions for Use and Additional Marking

The enhanced revision of the Leica M525 F20 instruction for use will include the following additional information and warnings related to tipping hazards:

Tipping hazards	
	 <p>Never move stand in the extended position.</p>
	 <p>Never roll over cables lying on the floor.</p>
	 <p>Do not allow vertical and horizontal forces to the stand in the extended position.</p>
	 <p>Always lock the foot brake when you are not moving the system. Always open the foot brake when you are moving the system.</p>

ATTACHMENT 1
to FCA Notice - CAPA-HER-MD18-001 - M525 F20 - continued

The enhanced revision of the Leica M525 F20 instruction for use will describe the intended positions of the Leica M525 F20 in the OR as shown in Figure A and B below.

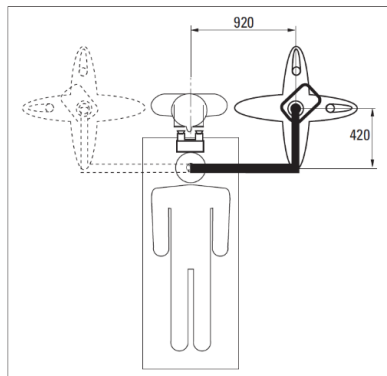


Figure A: Intended positioning- Option 1

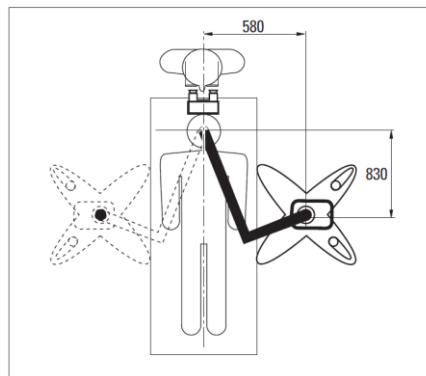


Figure B: Intended positioning – Option 2



Figure C: Scale Indicator

An additional marking with a scale indicator and arrow as shown above in Figure C will assist Leica M525 F20 users to position the horizontal arm and swing arm with as intended with an angle of approximately 90°:

- The yellow arrow pointing to the green area shows that the device is set up as intended.
- The yellow arrow pointing to the red area shows that the device is not set up as intended and special care is needed to prevent inadvertent tipping when handling the device.

Four additional warning markings (see Figure E) will be placed on the Leica M525 F20 to make users aware of tipping hazards when handling the device as shown below in figure D and F:

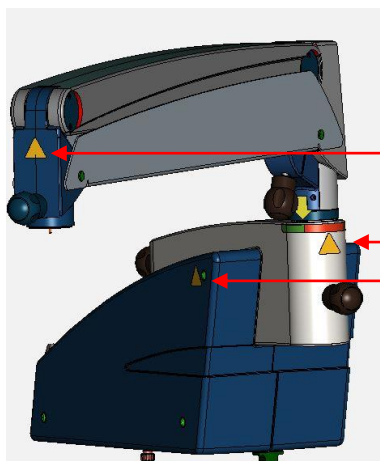


Figure D: Position of new Warning Label



Figure E: New Warning Label

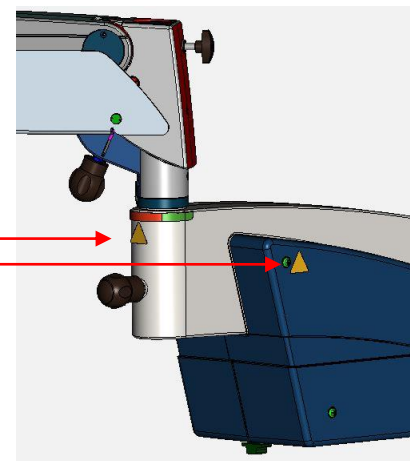


Figure F: Position of new Warning Label

ACKNOWLEDGEMENT FORM
to FCA Notice - CAPA-HER-MD18-001 - M525 F20

Leica M525 F20 Microscope System

FCA Identifier: CAPA-HER-MD-18-001

Enhancement of instructions for use and additional markings to prevent inadvertent tipping

Serial Number(s): _____

I hereby acknowledge receipt of the Field Corrective Action Notice involving Leica M525 F20 Microscope Systems regarding enhanced instructions for use and additional markings to address tipping hazards.

Contact Person (Please Print)

Signature

Date (day-month-year)

Facility Name (Please Print)

Please fill in, sign, scan or take a picture and send to:

M525F20-IFU-Update@Leica-Microsystems.com