

URGENT FIELD SAFETY NOTICE

Surgical Microscope Leica M220 F12
FSCA Identifier: CAPA-HER-MD-21-002
Additional Retention Fixture to secure M220 Optics Carrier



Customer Name

Institution

Address

Heerbrugg, November 2nd, 2021
Leica Microsystems (Schweiz) AG

Dear [•] Insert Customer Name:

Leica Microsystems is issuing this field safety notice as a corrective action for all Leica M220 F12 Surgical Microscopes that were manufactured since introduction in January 2009 until March 9th, 2017.

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 defects when they occur.

You are receiving this letter because according to our data you are the holder of a product that is subject to this field safety corrective action.

This letter contains important information that needs your immediate attention.

Description of the Problem:

In May 2021, Leica Microsystems received one (1) complaint pertaining to the M220 F12 Surgical Microscope system. There was no patient injury reported for this complaint. However, the identified defect carries some potential injury risk. In the event that this defect may occur, the M220 optics carrier may unintentionally drop into the surgical field, risking contact with the patient.

The identified defect is a mechanical part failure with the screw that connects the optics carrier to the free end of the swing arm (see Figure 1).



Figure 1: Leica M220 F12 Surgical Microscope

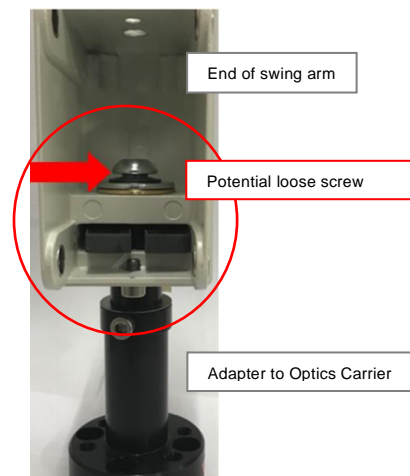


Figure 2: Potential loose screw connecting the swing arm with the optics carrier

Leica Microsystems has performed a thorough root cause investigation which has identified the cause of the observed issue to be insufficient securing of the screw that connects the swing arm with the optics carrier (see Figure 2). This screw was found to not be secured by an adequate amount of high strength thread adhesive to ensure a reliable connection of the swing arm with the optics carrier. This inadequate securing of the swing arm was not identified during production and final inspection of the M220 swing arms. These swing arms were then built into M220 F12 Surgical Microscopes manufactured before March 9th, 2017*. Due to this, the screw that connects the swing arm with the optics carrier has loosened over time (see Figure 2) and subsequently resulted in the optics carrier falling. Based on the results of the root cause investigation the probability of occurrence of this defect for the end user is very low.

*Note: For M220 F12 manufactured after March 9th, 2017, changes implemented in production and final inspection ensure reliable securing of the screw.

As a matter of precaution Leica Microsystems has chosen to initiate a field safety corrective action to provide a retention fixture (see Figure 3) to be added on all Leica M220 F12 Surgical Microscopes manufactured before March 9th, 2017 to ensure patient safety and customer satisfaction.

Your Leica Microsystems representative will provide you a retention fixture as an additional means of securing the M220 Optics Carrier free of charge.



Figure 3: Detailed view of the retention fixture as an additional means of securing the M220 Optics Carrier



Irrespective of the additional safety feature to be implemented on your M220, Leica Microsystems advises to immediately take action as described below.

Urgent and important mandatory action to be taken by the user:

Prior each use of your M220 F12, please perform the following mandatory inspection:

- If the gap between the black adapter and the white housing at the end of the swing arm becomes bigger than 3mm (see Figure 4) or a free rotation of the optics carrier is possible for more than 360° (see Figure 5): **→ Immediately stop using the device!**

In this case the M220 F12 can no longer be used.

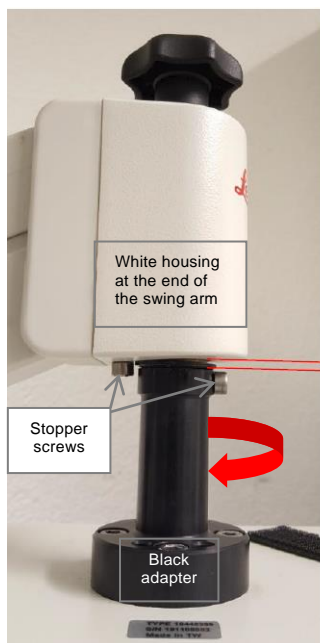


Figure 4: Detailed view of gap between black adapter and white housing of swing arm.



Figure 5: Detailed view of stopper screw when M220 F12 is faulty: Stopper screws are not effective and allow free rotation > 360°. **→ Immediately stop using the device!** The M220 F12 can no longer be used.

X A gap bigger than 3mm or possible free rotation of the optics carrier for more than 360° indicates that the screw holding the adapter is loose and there is a potential risk that the optics carrier becomes disconnected and potentially fall.

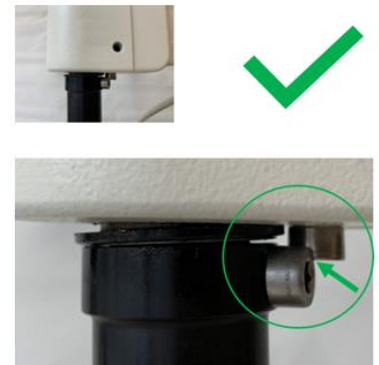


Figure 6: Detailed view of stopper screws when M220 F12 is according to specification: Stopper screws are effective and do NOT allow free rotation > 360°. **→ Instrument can be used as intended.** There is no risk for the optics carrier to disconnect from the swing arm and potentially fall.

✓ With a gap of less than 3mm, and it is NOT possible to rotate the optics carrier 360° the screw holding the adapter is NOT loose and the device can be continued to use as intended.

- If you notice any anomalies with your M220 F12 Microscope System before the additional retention fixture is attached to your instrument, please contact your Leica representative for relevant repair of your instrument.
- If the mandatory inspection performed prior using your M220 F12 does not result in an observed potential defect, you can continue to use the system pending fixation of the retention fixture.



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

We sincerely apologize for any inconvenience this field safety correction action may cause.

For over 150 years, Leica has stood 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 decrease in product quality.

Please acknowledge receipt of this Field Safety Notice with the digital acknowledgment form by either scanning the QR code in your mobile phone or with the following link:

<https://forms.office.com/r/4gCZx3hz16>

Note: All data provided will be handled according to the Leica Microsystems Privacy Policy: <https://www.leica-microsystems.com/company/privacy-policy/>



This Field Safety Notice must be distributed to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred to.

Please maintain awareness of this Field Safety Notice and resulting corrective action to ensure effectiveness of the correction.

Sincerely,



Roland Jehle
Manager Global PMS & CDT&R
Leica Microsystems (Schweiz) AG

