

TO WHOM IT MAY CONCERN

2020-03-19

Closure Notification for Field Action CAPA-HER-MD-18-001 Surgical Microscope Leica M525 F20

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

Preamble:

In August 2018 a Field Corrective Action (FCA) was initiated involving all Leica M525 F20 Microscope Systems to replace the instructions for use with an enhanced revision and to fix additional markings onto the device.

The FCA was initiated based upon five (5) complaints received by Leica Microsystems stating that users inadvertently tipped over their Leica M525 F20 Surgical Microscope System. In all cases the Leica M525 F20 did not cause or contribute to serious injury. The five (5) complaints occurred in five (5) different countries over an eight (8) year timeframe between the years 2010 and 2017. Since implementation of the countermeasures and initiation of the field action in 2018 Leica Microsystems did not receive any (0) further customer complaints stating that users inadvertently tipped over their Leica M525 F20 Surgical Microscope System.

Field Corrective Action:

Leica Microsystems identified an area of improvement in the instructions for use and markings as root cause for the reported issues. The original instructions for use and markings on the device were enhanced in a manner to ensure all users will position and handle the M525 F20 as intended. Leica Microsystems provided an update package containing the enhanced instructions for use and additional markings to affected customers.

Verification of Effectiveness for Field Corrective Action:

For verification of effectiveness of the field corrective action CAPA-HER-MD-18-001 a review of customer complaints in the timeframe between January 1st, 2018, and March 9th, 2021, was performed. It was found that there were no (0) customer complaints indicating that users inadvertently tipped over or nearly tipped over their Leica M525 F20 Microscope System within this three (3) year timeframe.

Before implementation of countermeasures, there were five (5) complaints which occurred in an eight (8) year timeframe between the years 2010 and 2017. With an average of 0.625 (5/8) complaints per year at least one (1) complaint would have been expected within a three (3) year time frame without implementation of countermeasures.

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After implementation of countermeasures the complaint review showed that there was no (0) similar complaint over a three (3) year time frame. Based on this evaluation the field corrective action CAPA-HER-MD-18-001 is verified to effectively prevent inadvertent tipping of the M525 F20 Surgical Microscope System by ensuring that all users position and handle the instrument as intended.

Field Action Closure:

Based on the verification of effectiveness Leica Microsystem considers the field action CAPA-HER-MD-18-001 as closed in all of the below listed countries:

Algeria, Australia, Austria, Azerbaijan, Belarus, Belgium, Bolivia, Brazil, Bulgaria, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Ecuador, Egypt, Finland, France, Gabon, Georgia, Germany, Greece, Great Britain, Hungary, India, Indonesia, Ireland, Israel, Italy, Jamaica, Korea, Kosovo, Kuwait, Lebanon, Malaysia, Mexico, Morocco, Country, Mozambique, Nepal, Netherlands, New Zealand, Norway, Pakistan, Peru, Philippines, Poland, Portugal, Russian Fed., Saudi Arabia, Shanghai, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Turkey, Unit.Arab Emir., Vietnam, Zimbabwe.

Note: In some of the above listed countries the field corrective action was already closed earlier in alignment with local competent authorities, e.g. Australia (TGA RC-2018-RN-01608), China (SMPA HSYJXZZ 2019-085), Great Britain (MHRA 2018/008/028/291/020) etc.

Transmission of this Field Action Closure Notification:

Kindly pass this Closure Notification for Field Action CAPA-HER-MD-18-001 to all those within your organization who need to be aware of the information.

Contact Point:

Please do not hesitate to contact me by phone at +41 71 726 3216 or per e-mail roland.jehle@leica-microsystems.com should you have questions regarding the information provided.

Sincerely,



19 March 2021

Roland Jehle
Manager Global PMS & CDT&R, PRRC