

URGENT FIELD SAFETY NOTICE

Leica M525 F40 Surgical Microscopes

FSCA-Identifier: CAPA-2017-05-001-H

Adherence to Warnings required during Transportation and Positioning in the OR of the M525 F40

Customer Name

Institution

Address

05. May 2017
Leica Microsystems

Dear [*] Insert Customer Name:

Our goal at Leica Microsystems is to provide you with the best quality products and services to ensure highest customer satisfaction. Our Quality Management process has identified that instructions for use and warnings are not always followed by the users of the Leica M525 F40, in particular for transportation and positioning in the OR.

This is to inform you that Leica Microsystems has introduced additional warning stickers on the Leica M525 F40 (refer to picture 1a, 1b, 1c). In addition, Leica Microsystems provides a „quick reference guide for transportation and positioning in the OR“ for the M525 F40 which can be attached to the instrument (refer to Appendix 1).

Purpose of these measures is to ensure, that all M525 F40 users will transport and position the instrument in the OR as intended and according to the instructions for use.

If you are receiving this letter you have received a product that is subject to this field safety notice.
This letter contains important information that needs your immediate attention.

Description of the Problem:

The Leica M525 F40 complies with all applicable norms and regulations including requirements for stability and to prevent tilting. Using the M525 F40 improperly during transport and positioning, i.e. other than required by the warnings on the device and other than described in the instructions for use, can have an adverse effect on the stability of the device. In extreme cases, improper use during transport and positioning can cause tilting of the M525 F40. Leica Microsystems received information on two (2) cases where a M525 F40 started tilting due to improper handling. In one (1) out of the two (2) cases this caused a bruise on the shoulder of the nurse trying to position the instrument in the OR.

Advice on action to be taken by the user:

A Leica Microsystems representative will be contacting your facility to determine the needed number of warning stickers and “quick reference guides for transport and positioning in to OR” and to arrange the fixation of the warning stickers on your instruments.

You can continue to use the system according to your M525 F40 User Manual. Please ensure, that only trained staff will be using your M525 F40 in order to ensure the instrument is transported, positioned and used as intended according to the instructions for use (refer to pictures 1a, 1b, 1c and 2a, 2b).

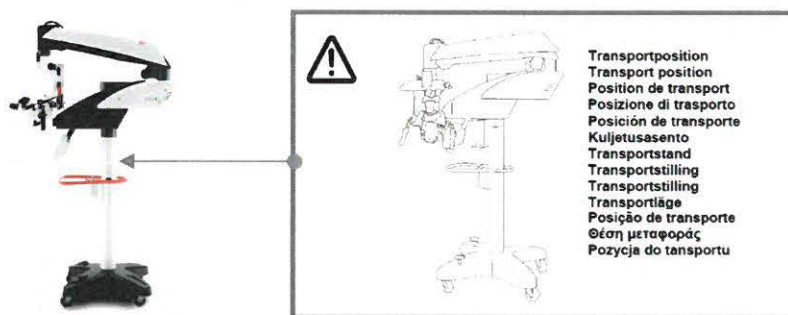
New, additional warning stickers for positioning in the OR (i.e. for minor distances, e.g. within a room):



Picture 1a: M525 40 in use position

Picture 1b & 1c: Warning labels for Leica M525 F40 positioning in the OR (new, in addition)

Existing warning label for transportation (i.e. over significant distances, e.g. from one room into another):



Picture 2a: M525 F40 in transport position

Picture 2b: Warning label Leica M525 F40 transport position (existing)

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.

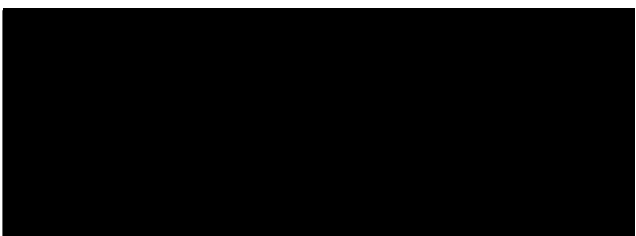
Please confirm receipt of this notice by signing, dating and returning the attached 'Acknowledgement Form' back to us by email to:

md.quality-assurance@leica-microsystems.com

within 10 working days after receipt of field safety notice.

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

Leica Microsystems (Schweiz) AG aims to provide you only with products of the highest quality.



Leica Microsystems (Schweiz) AG