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Ettlingen, 14. October 2011

Urgent Field Safety Notice

Abbott Medical Optics (AMO) Femtosecond Laser Systems

Models 2, 3 and iFS

FSCA-identifier FSN2011-16

Type of action: Advisory notice

Dear AMO Femtosecond Laser Customer:

In an effort to help ensure the best possible outcomes for your patients, Abbott Medical Optics Inc. (AMO) is providing this Advisory Notice to make you aware of a discrepancy in cut depth that may affect deep corneal incisions (e.g., 300 µm or deeper) created using the AMO Femtosecond Laser System, and to describe actions you should take.

AMO has identified a minor discrepancy between the user-set depth of corneal tissue incisions and the actual depth of those incisions by way of *in vitro* testing. Because AMO field personnel routinely calibrate the user-set depth of flaps to individual user preference, the discrepancy is minimized when cutting corneal flaps. **Corneal flap depth, therefore, is expected to be virtually unaffected**. Additionally, full corneal penetrating incisions such as those used for IEK, should not be appreciably affected.

Non-penetrating corneal incisions deeper than 300 µm are more significantly affected by this discrepancy. In addition to cut depth, a number of contributing factors such as patient physiology and the accuracy of pachymetry can also influence the outcomes of deeper corneal incisions, which may rarely include endothelial perforations. For these deeper corneal incisions, the contribution of the cut depth discrepancy to undesired patient outcomes is unknown and likely to be small. However, as part of our commitment to continuous improvement, AMO will be contacting you in the near future to schedule a visit by a Field Service Representative who will adjust your AMO Femtosecond Laser to correct this cut depth discrepancy.

IntraLase Model 1 Femtosecond Lasers are not affected by this Advisory Notice. These lasers can be identified by their serial number. Serial numbers in the format XXXX-**1**NNNN, where the first digit after the hyphen is 1, are not affected. All other systems, where the first digit after the hyphen is 2 through 7, are affected by this Advisory Notice.

Sitz der Gesellschaft: Ettlingen
Amtsgericht Mannheim HRB 362585

Geschäftsführer:
Enzo Cangiolini, Valentine Yien

Action to Take by the User:

Continue to use your AMO Femtosecond Laser, without changes, to cut LASIK flaps.

AMO advises users performing deeper non-penetrating corneal incisions to exercise caution when making cuts that approach the corneal endothelium. Cuts should be programmed to leave at least 125 μm of posterior cornea intact, by selecting a maximum depth at least 125μm less than the thinnest pachymetry measurement. This recommendation applies to all deeper corneal incisions, even after your femtosecond laser has been adjusted to minimize the cut depth discrepancy.

We have enclosed an addendum to your Operator's Manual clarifying this recommendation. Please insert this additional information into your AMO Femtosecond Laser Operator's Manual.

For each surgeon at your site using the AMO Femtosecond Laser, complete and return the attached facsimile to AMO via fax at +353 1675 4660 within the next 3 business days as an acknowledgement of:

- Receipt of this Advisory Letter and Operator's Manual addendum, and
- Understanding of the information contained within this letter.

Your patients who have been previously treated with the AMO Femtosecond Laser require no additional follow-up. Any adverse events or complaints experienced with use of this product should be reported to AMO by calling +353 1643 6272.

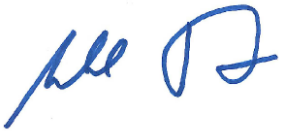
Please share the information in this Advisory Notice with your staff. Please ensure that all personnel who operate your AMO Femtosecond Laser are aware of this Advisory Notice. Please maintain awareness on this notice and resulting action to ensure effectiveness of the corrective action. The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

If you or your facility has transferred your AMO Femtosecond Laser to other persons or facilities, please promptly forward the recipients a complete copy of this Advisory Notice, including the fax acknowledgement form. In addition, please return the fax acknowledgement to AMO with the contact information for the facility to which the laser was transferred.

AMO appreciates your attention to this issue and we apologize for any inconvenience this action may cause. AMO is committed to providing you with state-of-the-art technology that allows you to perform the safest and most effective laser vision correction treatments possible and as such, we are constantly improving our technology and ensuring it always meets our mutual high quality standards. We appreciate your cooperation in these efforts.

If you have any questions regarding the information or recommendations in this Advisory Notice, please call +353 1643 6272 and you will be directed to an AMO representative.

Yours sincerely,
AMO Germany GmbH



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AMO Femtosecond Laser Acknowledgement Models 2, 3 and iFS

RETURN FAX TO: +353 1675 4660

Please read this acknowledgment and complete all information below.

I certify that I have been informed of the Advisory Notice related to AMO Femtosecond Laser Systems Models 2, 3 and iFS.

Femtosecond Laser Serial Number: _____

Account Name: _____

Physician Name: _____

Street Address: _____

City: _____

Postal Code: _____

Country _____

Signature: _____

Date: _____

Complete if appropriate:

☐ This Femtosecond Laser has been transferred to another facility:

Facility Name: _____

Street Address: _____

City: _____

Postal Code: _____

Country _____

Please return this fax acknowledgement to AMO within 3 business days.