IRISH MEDICINES BOARD
SAFETY NOTICE

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Femtosecond Laser System

IMB Safety Notice: SN2011(34)
Circulation Date: 19 December 2011

MANUFACTURER/SUPPLIER
AMO Manufacturing USA, LLC

TARGET GROUPS
Ophthalmologists
Laser Eye Clinics
Risk Managers
Hospital CEO's

ISSUE
A discrepancy may exist between the user-set depth of corneal tissue incisions and the actual depth of those incisions whilst performing procedures with Femtosecond Laser Systems.

BACKGROUND
AMO recently circulated a field safety notice (see attached) outlining a discrepancy they identified between the user-set depth of corneal tissue incisions and the actual set depth of those incisions.

AMO noted that non-penetrating corneal incisions deeper than 300µm are more significantly affected by this discrepancy. AMO advised users that cuts should be programmed to leave at least 125µm of posterior cornea intact, by selecting a maximum depth at least 125µm less than the thinnest pachymetry measurement. AMO has confirmed that all affected Irish devices have been recalibrated to reduce the effect of this discrepancy.

The Irish Medicines Board (IMB) is issuing this safety notice to emphasise the risk associated with this issue in terms of performing deep corneal incision procedures. The IMB is highlighting that this discrepancy poses greatest risk during deep corneal incision procedures such as corneal ring procedures, arcuate incisions and IEK procedures for example. The IMB advises users of this device to ensure they fully understand the information outlined in the attached field safety notice. If users have any concerns regarding this issue and the effect of the discrepancy on deep corneal incision procedures please contact the manufacturer for further guidance. Contact details for the manufacturer are provided with this safety notice.

ACTION OR RECOMMENDATIONS

1. Ensure that the relevant personnel in your organisation are made aware of this issue.

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2. If you require further details relating to this discrepancy and its impact on deep corneal incision procedures, please contact AMO for further guidance and information regarding this issue.

3. If you have an affected device confirm that the recommended actions have been completed.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Manufacturer / Authorised Representative:

AMO Ireland
Block B,
Liffey Valley Office Campus
Quarryvale
Co. Dublin

Telephone: +353 1643 6045
E-mail: DU-Regulatory@amo.abbott.com

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie