IRISH MEDICINES BOARD

Notice Information: - Advisory
19 December 2011

Part 1. Product Information

a)	Title:	Femtosecond Laser System
b)	Product Name/Type:	Femtosecond Laser System
c)	Reference:	SN2011(34)
d)	Manufacturer/Supplier:	AMO Manufacturing USA, LLC

Part 2. Target Audience

a)	Target Audience:	Ophthalmologists Laser Eye Clinics Risk Managers Hospital CEO's

Part 3. Problem/Issue

a)	Problem/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.

Part 4. Background Information

a)	Background Information:	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.

Part 5. Action to be taken

a)	Action to be taken:	1. Ensure that the relevant personnel in your organisation are made aware of this issue. 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.

Part 6. Enquiries

a)	All enquiries should be made to:	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 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 Please click here to download a copy of

Please click here to download a copy of the field safety notice

Please click here to download the PDF version of the Safety Notice