

March 2015

Re: Field Safety Notice – Update to Laser-over-Inlay Product Bulletin

Dear KAMRA™ Inlay Distributor:

This letter is to inform you that AcuFocus, Inc. is issuing an update to the Laser-over-Inlay Product Bulletin originally issued November 12, 2013. This update includes an additional Precaution regarding use of lasers with the KAMRA Inlay in place. While no issues have been reported, removal of the inlay prior to any laser-based glaucoma therapy is recommended.

ACTION TO TAKE: Please distribute the enclosed Field Safety Notice/Product Bulletin Update to all customers who have purchased the KAMRA Inlay in your assigned region.

If you have any questions about this Field Safety Notice, please call your AcuFocus Account Manager or contact AcuFocus Customer Service at customerservice@acufocus.com. AcuFocus remains fully committed to serving our customers and their patients with safe and effective products. We appreciate your assistance in expediting the distribution of the attached Field Safety Notice/Product Bulletin Update and apologize for any inconvenience this action creates.

Sincerely,



Sandra Selvaggi
Senior Director, Quality and Manufacturing Systems

AcuFocus Product Bulletin

LASER USE AFTER INLAY IMPLANTATION

UPDATE March 2015

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Urgent Field Safety Notice

AcuFocus KAMRA™ Inlay Field Safety Advice given by Manufacturer regarding use of the device:

LASER USE AFTER INLAY IMPLANTATION

Dear KAMRA Implanting Physician:

This update is being issued to the attached Product Bulletin to include guidance for laser glaucoma procedures in KAMRA patients. The Product Bulletin now includes:

“While no issues have been reported, removal of the inlay prior to any laser-based glaucoma therapy is recommended.”

Please pass this Field Safety Notice to all those who need to be aware of it within your organization.

AcuFocus confirms that this notice has been provided to the appropriate Competent Authority.

Please contact AcuFocus Customer Service at customerservice@acufocus.com or by telephone at (US) +1-949-585-9511 with any questions.



Sandra Selvaggi
Senior Director, Quality and Manufacturing Systems

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LASER USE AFTER INLAY IMPLANTATION

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AcuFocus is aware of reports of some cases involving use of ophthalmic laser applications in eyes containing KAMRA™ inlays. As a result of these case reports, this notice is being issued to keep you up to date on new information relative to the application of various ophthalmic laser procedures with a KAMRA inlay in situ.

CAUTION RECOMMENDED:

Excimer Laser Use Over an Inlay: To date, a few patients have been treated with a hyperopic PRK enhancement with the inlay in place. In these cases, the inlay and surrounding tissue appear to be unaffected by the laser.

Nd:YAG Laser: The Nd:YAG laser produces highly collimated laser energy that can be focused through the center of the KAMRA inlay and focused on the posterior capsule. Just as the Nd:YAG can create focal cracks and damage to an IOL if not properly focused, care must be taken to keep the beam well centered within the central aperture of the inlay. To date, there have been no published reports of Nd:YAG damage to the inlay when performing a posterior capsulotomy.

DO NOT RECOMMEND:

Femtosecond Laser Flap Creation Over an Inlay: A case was reported to us of a patient presenting for a LASIK enhancement months after implantation of a KAMRA inlay. A femtosecond laser was used to create the flap above the implanted inlay. After the procedure, the inlay appeared to have been reduced in dimensions circumferentially from its original size and showed evidence of surface pitting with focal areas of discoloration. The inlay was removed and the patient has recovered.

As a result of the case described above, creation of a LASIK flap using a femtosecond laser with the inlay in place is not recommended.

Retinal Laser Photocoagulation: A case of retinal laser photocoagulation in the presence of a KAMRA inlay was reported¹ in 2013. Six months after inlay implantation a chronic central serous retinopathy (CSR) was diagnosed, unrelated to the inlay. Photodynamic therapy was used to treat the retinopathy. After treatment, significant thermal damage to the inlay and secondary damage to the cornea – resulting in a scar - was observed. As a result of the case, AcuFocus recommends removal of the inlay prior to performing any unfocused laser photocoagulation.

Laser Glaucoma Procedures: While no issues have been reported, removal of the inlay prior to any laser-based glaucoma therapy is recommended.

Please contact AcuFocus Customer Service with any questions at (US) 949-585-9511.

¹Corneal heat scar caused by photodynamic therapy performed through an implanted corneal inlay. Mariko Mita, MD, PhD, Tomomi Kanamori, BS, Minoru Tomita, MD, PhD. J Cataract Refract Surg 2013; 39:1768–1773
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