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Advisory Memorandum

Date: Friday, January 30, 2004
To: All Wavefront-guided Excimer Laser Users
From: Glenn Hagele, Executive Director
re: Communication to Patients Regarding the
Limits of FDA Approval of Excimer Laser
Regarding Correction of High Order Aberrations

It has come to our attention that patients are commonly being told the wavefront-guided excimer laser proposed for LASIK surgery is approved by the Food and Drug Administration (FDA) to treat and correct high order aberrations (HOA), defined as those optical aberrations measured and expressed in Zernike polynomials level three and greater.

A review of the relevant documentation will find the FDA approvals do not include language that supports the contention that wavefront-guided excimer lasers are FDA approved to correct HOA.

Our organization's goal is to promote full and truthful communications between physician and patient in a positive and cooperative environment where patients are appropriately and accurately informed. In the interest of the dissemination of accurate information, we respectfully ask that you carefully compare the FDA-approved labeling for your laser system with your current patient information materials to affirm that the information you circulate accurately reflects FDA approval status regarding high order aberration correction for your particular laser.

The Council for Refractive Surgery Quality Assurance (CRSQA) is a nonprofit patient/consumer advocacy organization formed to provide balanced, objective, and factually substantiated information to the public regarding refractive surgery issues. Our 50 Tough Questions For Your Doctor have been a roadmap to a quality refractive surgeon for hundreds of thousands of patients. Additionally, CRSQA evaluates and certifies refractive surgeons based upon patient outcomes. For more information, visit www.USAeyes.org or contact me at 916/381-0769.

If you are not a user of a wavefront-guided excimer laser, please disregard this notice and accept our apologies for the intrusion.