AMERICAN ACADEMY® OF OPHTHALMOLOGY
The Eye M.D. Association

POLICY STATEMENT

Unapproved Lasers and Software for Refractive Surgery

Policy
It is the American Academy of Ophthalmology's position that the use of a particular excimer laser and its software for refractive surgery is appropriate only when permissible under federal law. Lasers and software should be used for the correction of refractive errors only under the following conditions:

- The laser and software have been approved for sale by the U.S. Food and Drug Administration (FDA) and are operated consistently with the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), or

- The laser and software are operated under an investigational device exemption (IDE) in accordance with the provisions of the FD&C Act, and under an experimental protocol approved by a properly composed and operated Institutional Review Board

Background
Excimer lasers approved by the FDA have been marketed to treat refractive errors since 1995. The FDA has classified lasers used in refractive surgery as "significant risk" class III devices, which are subject to the highest level of regulatory control authorized under the FD&C Act, including stringent premarket approval evaluation.

Approval of a particular excimer laser by the FDA assures the public that the manufacturer has provided evidence with reasonable assurance that a particular laser is safe and effective when used as labeled. Approval of legally marketed excimer lasers by the FDA is not something that can be generalized and does not imply that the FDA approves other excimer and refractive lasers. The FDA also regulates the software used for specific refractive corrections. Use of software not approved by the FDA is illegal unless the software is used under an approved IDE.

Evaluation
Testing and operation of excimer lasers and software must be conducted in accordance with applicable regulations that ensure the safety and welfare of the patient. Patients should not be subjected to unnecessary risks from an experimental, untested excimer laser or software. Further, patients should be fully informed about the laser's approval status. It should be noted, however, that the practice of medicine permits a physician to use an approved laser and/or software in an off-label manner, if it is in the best interest of the patient. It is appropriate for the patient to be informed of such off-label use in these cases.

Recommendations
The Academy disapproves of the illegal use of excimer lasers and/or software for refractive surgery. Lasers and/or software that have not been approved by the FDA for specific refractive indication, or that may not otherwise be used in accordance with the FD&C Act, should not be used to perform refractive surgery. The laser and/or software also should not be promoted in a way that might lead patients to believe that the device has been approved or thoroughly tested, or is known to be safe or effective under federal law. It is FDA's

responsibility to enforce compliance with regulations pertaining to unapproved lasers and their software.

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American Academy of Ophthalmology, Board of Trustees, October 2001

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