

POLICY STATEMENT

Use of Unapproved Lasers and Software for Refractive Surgery

Policy

It is the position of the American Academy of Ophthalmology that use of an excimer laser and its software for refractive surgery is appropriate only if the use of the particular excimer laser and software are 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 United States Food and Drug Administration (FDA) and are operated consistent with the provisions of the Federal Food, Drug and Cosmetic Act; or
- The laser and software are operated under an Investigational Device Exemption in accordance with the provisions of the Federal Food and Cosmetic Act, and under an experimental protocol approved by a properly composed and operated Institutional Review Board

Background

FDA-approved excimer lasers 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 federal Food, Drug, and Cosmetic Act, including stringent pre-market approval evaluation.

FDA approval of a particular excimer laser assures the public that the manufacturer has provided evidence with a reasonable assurance that the particular laser is safe and effective when used as labeled. FDA approval of legally marketed excimer lasers is not generalizable 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 it is used under an approved investigational device exemption.

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. Depending on the specific facts and circumstances, it may be appropriate for the patient to be informed of the off-label use.

Recommendations

The Academy disapproves of the illegal use of excimer lasers and/or software for refractive surgery. A laser 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 Federal Food, Drug and Cosmetic Act should not be used to perform refractive surgery. The laser and/or software should also not be promoted in a way that might lead patients to believe that it has been approved or thoroughly tested, or is known to be safe or effective under federal law. It is the responsibility of the FDA to enforce compliance with regulations pertaining to unapproved lasers and their software.

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P.O. Box 7424/ San Francisco, CA 94102/ 415.561.8500