Policy Number: 010-2004-06-03.02
Approval Date: June 3, 2004
(Existing reformatted)

ACADEMY OF LASER DENTISTRY

DISCLOSURE OF UNLABELED AND/OR INVESTIGATIONAL PRODUCT USAGE OR NONCOMPLIANCE WITH MANUFACTURER'S DIRECTIONS FOR USE

(NOT A NEW POLICY – FORMAT CHANGES ONLY WITH THIS REVISION)

The Academy of Laser Dentistry requires all authors and presenters to disclose (1) whether any product or device discussed in their manuscript or presentation is unlabeled for the use discussed or is investigational, or (2) whether any procedure described does not follow manufacturer's directions for use.

Definitions

Unlabeled: Any use of a product or device for purposes other than those specifically stated by the manufacturer and approved or cleared by the U.S. Food and Drug Administration.

Investigational: Any product or device that has not yet received approval or clearance for general use by the U.S. Food and Drug Administration.

Manufacturer's Directions for Use: Directions specified by a product or device manufacturer with respect to such factors as clinical indications for use; patient selection and management; proper diagnosis and treatment planning; proper device parameter settings (e.g., laser wavelength, delivery system, emission mode, fluence, power, energy, pulse rate, duration of exposure, etc.); useful shelf life, expiration date; technique, sequence, quantity, range, intensity, and other characteristics; postoperative instructions and follow-up care; management of complications; precautions and contraindications; record keeping and reporting.