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ALD SPEAKER PACKET

Thank you for sharing your knowledge and experience with the audience of this ALD event.

As a presenter, you are required to acknowledge the information shared in the following pages by completing the [online form](#). Below is a checklist of the documents contained in this packet.

You are acknowledging these documents for the following presentation(s):

Document Title
Speaker Acknowledgement of Copyright Guidelines
ALD Policy on Support of ADA CERP Criteria Related to Scientific Content, Clinical Efficacy and Public Safety
List of Scientific References
Speaker HIPAA Compliance Form
Antitrust Compliance Policies
Guidelines for Commercial Support & Conflict of Interest
Standard v. Commercial or Promotional Conflict of Interest (for Lasers used in Workshops) <ul style="list-style-type: none">• Standard V Regarding Uses of Lasers in Continuing Dental Education Activities• ALD's Policy Rules on Accepting Commercial Support for Any CDE Workshop Related Activities



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Continuing Dental Education

Speaker Acknowledgment of Copyright Guidelines

The Academy of Laser Dentistry is required to abide by the United States Law of 1976, as amended, (title 17, United States Code) ("Copyright Act"). Copyrighted material requires written permission from all authors in order to be printed/duplicated. If authorization is not provided to the ALD in a timely manner, the material will not be duplicated for participants or used during the Continuing Education presentation. If ALD is not able to duplicate published materials, they may still be included in the List of Scientific References that is distributed to each participant.

I verify I am in compliance with the "Copyright Act." I will provide written authorization from authors of any material that I wish to be duplicated by the ALD. It is further understood that if written permission is not obtained in a timely manner, the ALD will not duplicate published material where I am not the sole author.

Academy of Laser Dentistry Policy on Support of ADA CERP Criteria Related to Scientific Content, Clinical Efficacy and Public Safety

The ADA Commission for Continuing Education Provider Recognition approved revisions to the ADA Continuing Education Recognition Program (ADA CERP) Recognition Standards and Procedures to promote scientifically sound continuing dental education, effective October 2017. In compliance with this ADA CERP Recognition Standard, the Continuing Dental Education Program(s) of The Academy of Laser Dentistry re-affirms its compliance with ADA CERP Standards and adopts the following as official policies:

1. Instructors or presenters of programs/courses sponsored by the Academy of Laser Dentistry are responsible for ensuring that clinical and technical continuing dental education activities have a sound scientific basis and proven clinical efficacy in order to promote public safety. Instructors/presenters must attest that the images used in the CDE activity have not been falsified to misrepresent treatment outcomes. Instructors should caution participants about the potential risks of using limited knowledge when integrating new techniques into their practice.
2. Instructors/presenters are expected to implement these policies by communicating compliance with them to the ALD in writing *in advance of the presentation*.
3. Instructors/presenters who offer the same program on an ongoing or repeated basis must periodically review the content and update *every two years* as needed to ensure that it includes *current* scientific information and *assessments of benefits and risk*.
4. When programs present clinical/technical subject matter about which scientific evidence is limited or uncertain, the program *must include the level of scientific information that is available* and any *known risks and benefits*. In programs in which scientific evidence is limited or uncertain, instructors/presenters must also include information regarding the limitations of available scientific evidence. For example, instructors/presenters should disclose when *limited data or studies are available*, when results presented *are based on small sample sizes/small-scope studies*, or when *results are not duplicated in other studies*.
5. Instructors/presenters are required to provide a list of scientific references for each course, in electronic form, with references in standard format utilized in ***Index Medicus*** in advance of acceptance of the presentation and for duplication and distribution to all participants. References to manufacturers' websites or manufacturers' printed marketing materials are not acceptable for this purpose. ***Instructors/presenters are required to state in writing when no scientific references are available for each program.***
6. It is the policy of the Academy of Laser Dentistry that all visual images, electronic or otherwise, used during presentations do not misrepresent or falsify the treatment outcome. ***If corrections have been made to any images to better demonstrate an educational topic, these corrections must be fully explained and disclosed to the audience so as to ensure that no member of the audience believes that the image presented was not in its natural state.***
7. The Academy of Laser Dentistry reserves the right to cancel any presentation in which misrepresentations of scientific merit are made or perceived and final decisions involving the acceptability of documentation of the scientific content of any presentation will be made by ALD's Science & Research Committee or the committee's designee(s).
8. List of Scientific References is required and supplied.

I verify my presentation is based on scientific evidence and is in compliance with ALD Policies as described in items 1-8.

Please feel free to call ALD if you have any questions or need additional information. Once signed please return this form to the ALD, by electronic submission or by fax to 954-757-2598 or email to academyoflaserdentistry@gmail.com. Thank you for your participation in the ALD program(s).

Continuing Dental Education

List of Scientific References

Continuing Dental Education

Speaker HIPAA Compliance Form

The Health Insurance Portability and Accountability Act (HIPAA) states that patient records and photos used in teaching must be stripped of all "direct identifiers" such as name, address, social security number, patient ID number, identifiable photographic images, etc. or that you have written authorization from the patient to use his/her directly identifiable health information in this way. The Academy of Laser Dentistry requires you, as a presenter participating in a continuing dental education program, to verify by way of your signature below that your presentation materials meet these HIPAA standards. Presentation materials include, but are not limited to, handouts, slides, electronic presentations (for example: PowerPoint, Keynote), videos and reproductions of journal articles.

Once signed please return this form to the Academy of Laser Dentistry. Thank you for your participation as a speaker during an Academy of Laser Dentistry sponsored CE event noted below.

I verify I am in compliance with the HIPAA standards to protect the privacy of the patients discussed in my presentation(s). I have received written authorization from the patient or have removed any identifiable images or patient records from my presentation, or my presentation does not pertain to patient treatment.

ANTITRUST COMPLIANCE POLICIES

It shall be the policy of the Academy of Laser Dentistry (ALD) to be in full compliance with all Federal and State Antitrust laws, rules and regulations. Therefore:

- I. These policies apply to all meetings of the membership, Board of Directors, committee and other meetings sponsored by ALD.
- II. Discussions of fees/prices or costs are prohibited. Discussion of pricing methodology is permitted as long as there is no implication that dentists should adopt any specific methodology.
- III. It is a violation of antitrust laws to agree to not compete, therefore, discussion of limitations on the nature of business carried on or services/products sold are not permitted.
- IV. Boycotts in any form are unlawful. Discussion relating to boycotts is prohibited, including discussions about blacklisting a vendor.
- V. It is ALD's policy that a copy of these Antitrust Compliance Policies be posted on the ALD website and included in ALD's board orientation annually.

GUIDELINES FOR COMMERCIAL SUPPORT & CONFLICT OF INTEREST

Academy of Laser Dentistry

The Academy of Laser Dentistry, in planning continuing dental education (CDE) programming for the Academy's annual conference, will adhere to the following policies:

1. Program topic selection will be based on perceived needs for professional information and not for the purpose of endorsing specific commercial products, materials, drugs, treatments, services, or techniques.
2. Funds received from commercial sources in support of any educational programs shall be unrestricted and the Scientific Sessions Committee shall retain exclusive rights regarding the selection of presenters, instructional materials, program content and format, etc.
3. All commercial support received shall be acknowledged in program announcements, brochures, and the on-site program book.
4. Commercial support, if received, shall be limited to:
 - a. the payment of reasonable honoraria
 - b. reimbursement of presenters' out-of-pocket expenses
 - c. the payment of the cost of modest meals or social events held as part of an educational activity.
5. Presenters shall be instructed to avoid recommending any specific product by its trade name and to use generic terms whenever possible. The following guidelines will be enforced:
 - a. It is appropriate and expected to indicate the specific instrument(s) used (including manufacturer and model name) ONCE in the "Materials and Methods" section of the clinical or scientific presentation.
 - b. In the interests of full disclosure, it is appropriate and expected to acknowledge ONCE during the presentation the sources of any support received in carrying out the study.
 - c. If a particular clinical technique or methodology has been developed by or named after an individual (such as the presenter), it is appropriate and expected to indicate that ONCE during the presentation.
6. Product-promotion material or product-specific advertisement outside of the exhibit space is prohibited during CDE activities. Advertisements and promotional materials are not allowed to be displayed or distributed in the educational space immediately before, during, or after a CDE activity. Representatives of commercial interests are not allowed to engage in sales or promotional activities while in the space of the CDE activity.
7. Speakers will be required to disclose any potential bias toward commercial supporters of any activity related to the Academy of Laser Dentistry conference. Disclosure of relevant financial relationships, in-kind commercial support, other special interest, or potential bias must be provided as part of the abstract submission process, before the start of the continuing education activity, and in the conference program, publicity materials, course materials, and the presentation itself. If any conflict develops

between the time the disclosure form is completed and the educational activity, the presenter must notify the Academy in writing and disclose the additional conflict of interest.

The Scientific Sessions Committee shall:

1. Be responsible for the content, quality, and scientific integrity of all CDE activities.
2. Assure that presentations give a balanced view of all therapeutic options.
3. Assure that arrangements for commercial exhibits and advertisements do not influence planning or interfere with the presentation of CDE activities.
4. Be responsible for making ultimate decisions regarding funding arrangements for CDE activities.
5. Assure that commercially supported social events at CDE activities do not compete with or take precedence over the educational events.
6. Have a policy on conflict of interest and assure that all CDE activities conform to this policy.

Disclosure Policy Regarding Dual Commitment and Conflict of Interest Academy of Laser Dentistry

Definitions

The expression "dual commitment" describes the dilemma faced by persons (or persons' institutions) when their responsibility to remain unbiased may be compromised, or perceived to be compromised, by a simultaneous commitment to commercial or other interests related to the subject of a specific educational activity or scientific endeavor. "Conflict of Interest" refers to a degree of dual commitment that may be strong enough to produce questions or reservations regarding potential loss of objectivity.

Policy

It is the policy of the Academy of Laser Dentistry (ALD) that persons who submit or review manuscripts or materials for publication or presentation disclose any proprietary, financial, professional, or other personal interests that may influence or be perceived to influence positions presented in, or the review of, the manuscript or presentation. This policy is intended to ensure balance, independence, objectivity, and scientific rigor in educational activities and scientific endeavors. ALD acknowledges that the potential for conflicts of interest can occur for financial and other reasons, such as personal relationships, academic competition, and intellectual passion. This disclosure requirement includes relationships with biomedical device manufacturers or distributors, pharmaceutical companies, or others whose products or services may be considered to be related to the subject matter of the educational activity or scientific endeavor. The intent of requiring disclosure is not to prevent an author with dual commitments from submitting a manuscript or presentation. Disclosure is requested so that the readers may reasonably formulate their own judgments regarding the article or presentation in the light of full disclosure of related information.

Operating Principles Governing Disclosure of Dual Commitment and Potential Conflict of Interest

1. Dual commitments that are governed by the ALD's Conflict of Interest and Disclosure Policy (and that affect the presenter, the presenter's immediate family, or a trust of which the presenter or member of the presenter's immediate family is a beneficiary) include **but are not limited to:**
 - consultancies (paid or unpaid)
 - ownership of companies, stock options, stock ownership, equity
 - current or pending ownership of patents, patent licensing agreements, royalties, copyrights
 - financial interest (honoraria for lectureships or other teaching activities, stipends)
 - special customer preferences (material donations, clinical materials, special discounts, special gifts)
 - governance (corporate responsibility, corporate allegiances such as service on governing boards)
 - research contracts, grants, or other support for investigation
 - paid expert testimony
 - by virtue of present or past employment of immediate family or relatives.

2. **ALD requires disclosure of dual commitments.** In determining the significance and extent of a dual commitment, ALD considers the following:
 - scope of the commitment or relationship
 - frequency and timing – whether past, recent, occasional, or long-standing
 - number – a single, exclusive relationship vs. multiple, competing relationships.
 - Have received financial compensation (eg: salary, retainer, or other stock shares/options, free or discounted equipment/supplies/services
 - Have a modest relationship [less than \$10,000] or a significant relationship [greater than \$10,000] or indicate NONE.
 - If you have no relationships, we expect you will indicate NONE.

3. If a dual commitment is related to material contained in the submission, it must be disclosed to the readers and audience, regardless of scope, frequency, timing, or number.

4. Failure to disclose may be determined to be a violation of ALD's Principles of Ethics and Code of Professional Conduct. Penalties for failure to disclose will be considered at the discretion of the ALD.

**Disclosure of Unlabeled and/or Investigational Product Usage
or Noncompliance with Manufacturer's Directions for Use
Academy of Laser Dentistry**

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 technique and device parameter settings (e.g., laser wavelength, delivery system, emission mode, fluence, power, energy, pulse rate, pulse duration, 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.

Continuing Dental Education – AGREEMENT Page 1 of 2

STANDARD V. COMMERCIAL OR PROMOTIONAL CONFLICT OF INTEREST (for Lasers or products used in Workshops) (CDE Standard V – Commercial Support – Products/Technology)

In 1997 the U.S. Food and Drug Administration (FDA) issued a policy statement entitled “Guidance for Industry:

Industry Supported Scientific and Educational Activities.” This policy states that activities designed to market or

promote the products of a commercial company (staffed exhibits, live presentations, advertisements, sales activities) are subject to FDA regulation under the labeling and advertising provisions of the Federal Food, Drug and Cosmetic Act.

Activities that are independent of commercial influence and non-promotional are not subject to FDA regulation. In this context, the ADA CERP standards and criteria are designed to ensure separation of promotional activities from continuing dental education (CDE) activities in the following ways: 1) CDE providers must demonstrate that all educational activities offered are independent of commercial influence, either direct or indirect, and 2) CDE providers must ensure that all financial relationships between the provider and commercial entities, as well as all financial relationships between course planners and faculty and commercial entities are fully disclosed to participants.

Standard V Regarding Uses of Lasers in Continuing Dental Education Activities

ADA CERP Standard V as it may pertain to uses of equipment is outlined in Standard V 7-10:

The primary goal for laser workshops is to provide clinical activities that promote improvements in oral healthcare and not a specific drug, device, service or technique of a commercial entity. In providing lasers for use during workshops sponsored by the Academy of Laser Dentistry, ALD does not receive financial support from any laser company for the use of lasers during workshops. This agreement outlines the responsibilities of the ALD and _____ COMPANY NAME in providing commercial support in the form of lasers for use during continuing education workshops.

- A Standard V.8) Commercial exhibits or advertisements must not influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CDE activities.
- B Standard V.9) ALD will disclose to participants any monetary or other special interest the speaker/instructor may have with any company whose products are discussed in its CDE activities. Disclosure must be made in publicity materials and at the beginning of the educational activity.
- C Standard V.10) Both ALD and the laser provider must ensure that a balanced view of all therapeutic options is presented in CDE activities. Whenever possible, generic names must be used to contribute to the impartiality of the program presented.
- D Standard V.1, 2, 3) The use of lasers during a workshop is for educational purposes. Product promotion material or product-specific advertisements of any type is prohibited in or during CDE activities. No selling of any kind is permitted during the CDE activity.

Continuing Dental Education RULES Page 2 of 2

STANDARD V. COMMERCIAL OR PROMOTIONAL CONFLICT OF INTEREST (for Lasers or products used in Workshops) (CDE Standard V – Commercial Support – Products/Technology)

ALD'S POLICY RULES ON ACCEPTING COMMERCIAL SUPPORT FOR ANY CDE WORKSHOP RELATED ACTIVITIES (NOVEMBER 2017)

During continuing dental educational activities where hands-on workshops are designed, it is ALD's policy to invite laser equipment support from ALD's corporate members. ALD strives to provide scientifically relevant, clinically valid, balanced views of laser technology while maintaining our unbiased view toward any specific laser manufacturer. ALD does not own any laser equipment. When hands on activities require equipment supplied by corporate members, the following rules apply:

- 1) To obtain a balanced continuing educational event, all ALD corporate member laser manufacturers are invited and encouraged to participate by providing laser equipment for Continuing Dental Education activities. The intent is to have as many different laser devices represented from different laser wavelengths so that attendees are exposed to a balanced view of laser devices and the clinical scientific rationale for safe patient care.
- 2) Manufacturers are encouraged to provide several laser devices, at least one clinical key opinion leader familiar with the device/technology, and laser safety eyewear for up to 6 people for each device provided.
- 3) Manufacturers provide any related financial expense such as shipping costs and key opinion leader support, if necessary, following appropriate conflict of interest disclosure policies.
- 4) Absolutely no selling may occur during any ALD hands-on workshop CDE events.
- 5) All commercially available products will have the same fair exposure and no additional publicity is allowed during the educational workshop.
- 6) In exchange for laser workshop support, the lead faculty for the workshop, will introduce the company briefly in the same manner for all corporate participation.
- 7) Full faculty/speaker disclosures are always required for ALD CE events and must be announced during the CDE event.
- 8) ALD's course publicity will focus on the scientific and clinical rationale of the program and not on the commercial participation.
- 9) Strict adherence to ADA CERP Policy on Publicity and AGD PACE is required.

List products for use in workshop(s):