

Managing the Regulatory Environment

ADA's Guidelines for Practice Success™ (GPS™)

ADA Tip Sheet on Lasers

There are currently more than 20 approved indications for the use of dental lasers in the United States. Some may be suitable for use in multiple situations, others might be more limited in scope and usage recommendations. The ADA's [Statement on Lasers in Dentistry](#), which was developed by the Council on Scientific Affairs, provides basic information about the use of lasers in the dental office.

You should also be aware that the Food and Drug Administration (FDA), a division of the Department of Health and Human Services (HHS), requires dental laser manufacturers to seek and obtain clearance for each laser product and each specific indication for use. The FDA website includes more information on [510\(k\) Clearances](#) and has a [Frequently Asked Questions About Medical Devices](#) resource available on its website.

- Within dentistry, dental lasers that have obtained 510(k) clearance may be labeled, promoted and advertised by their manufacturers only for the specific indications for use for which each device has been cleared for marketing.
 - ✓ Not every laser is cleared for every conceivable use and FDA marketing clearances apply to certain products and are specific to the manufacturer and product.
 - ✓ For any specific laser device, the specific indications for use, as marketing clearances, can be found in the professional information section of the operator's manual for the device.
 - ✓ Dentists should read and understand the specific indications for use for each device.
 - Dentists may choose to use lasers, or other products or devices, for "off label" purposes, meaning that the product or device is being used in a manner not specified in the FDA's approved packaging label, as allowed by the scope of the dentist's license to practice.
 - When considering the off label use of any item, especially dental lasers, dentists are encouraged to carefully consider and evaluate the individual patient's needs as they relate to available scientific evidence and the benefits and risks of any off label use.
 - ✓ Dentists can search the FDA's [510\(k\) Premarket Notification](#) database of medical devices for information.
 - Individual manufacturers can also provide specific and up-to-date information about cleared indications for use for any laser.

- Dentists should be appropriately trained on the use of dental laser devices and use the devices within their licensed scope of practice and according to their training and experience.
 - ✓ Basic tips regarding the use of lasers include:
 - use protective eyewear and keep in mind that different lasers require different eyewear
 - keep the instruction manual near the laser machine
 - have warning signs posted at every entry into the operatory when the laser is in use and have the appropriate security policies in place
 - laser security policies vary by state
 - consult your state's Department of Public Health for information on radiation security and a copy of the state's written radiation plan
 - they can also advise you regarding any state requirements regarding registering the equipment
 - have the equipment calibrated by a radiological hygiene specialist according to the schedule recommended by the manufacturer
 - ✓ Consider whether there's merit in appointing a member of the team to serve as the practice's laser safety officer; while not required, it may provide some peace of mind for you and your team.
 - ✓ Specific training is available from manufacturers and through independent providers of continuing education (CE), including professional organizations and academic institutions.

- It's a good rule of thumb to make certain that CE presenters disclose any possible conflicts of interest at the beginning of any presentation.
- Additional guidance on the safe use of dental lasers use is available through the American National Standards Institute's (ANSI) [Standard Z136.1](#) Safe Use of Lasers and [Standard Z136.3](#) Safe Use of Lasers in Health Care Facilities.
- See the American Dental Association's (ADA) [Statement on Lasers in Dentistry](#) for more information.

Additional information is available in the ADA's 2012 white paper titled [Dental Radiographic Examinations: Recommendations for Patient Selection and Limiting Radiographic Exposure](#).

Resources: ADA [Statement on Lasers in Dentistry](#)
 FDA [510\(k\) Clearances](#)
 FDA [Frequently Asked Questions About Medical Devices](#)
 FDA [510\(k\) Premarket Notification](#)
 ANSI [Standard Z136.1](#) Safe Use of Lasers
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