

## Questions About Miscellaneous Topics

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### DECS Product Evaluation Process (12/11) **Updated**

**Question:** I've been thinking about becoming a product evaluator for DECS. Will it take up a lot of my time? Is there a bunch of paperwork I'll have to fill out? Will being an evaluator cost me or my clinic any money? How exactly is the program run?

**Answer:** Actually, the process of being a clinical evaluator of new products is relatively simple. Before we get into the actual clinical-user part of the evaluation, I'd like to give you a brief overview of how DECS evaluates products. If DECS decides to evaluate a new product, whether it is a new dental material or a piece of equipment, we obtain it from the manufacturer and perform appropriate laboratory tests to see if it meets appropriate military and/or international standards for performance. The product is then mailed to interested clinicians who are currently on our evaluator list. Along with the product they receive questionnaires and a cover letter describing the evaluation process. It is important to note that we evaluate only commercially available products: not prototypes or experimental products. Also, the clinical-user evaluations are evaluations of the handling characteristics of the dental material or piece of equipment. They are not clinical trials, so you will not be recalling patients and re-evaluating the quality or performance of a material. We are primarily interested in whether you liked or disliked the way the product handled and its various features.



After using the product for a period of from 3 to 6 months, each evaluator completes a questionnaire and returns the questionnaire to DECS. We like to have a minimum of two clinicians use the product at each facility. Our unspoken policy here is "the more evaluators, the merrier;" that way we get as broad a range of opinions as possible. If the item being evaluated is a piece of equipment, it does need to be returned to DECS or the manufacturer. If the item is a material or other type of consumable, it does not. DECS then takes the results of the laboratory and clinical-user evaluations and generates a final report for our Web site and the manufacturer.

Many of our evaluators have told us they really enjoy being involved in the process. It gives them a chance to use state-of-the-art materials and equipment at no cost to their clinics. They also have said they like having a chance to give their opinions about the new products they are trying. If being an evaluator sounds interesting to you or if you want additional information, please contact the DECS via [e-mail](#).

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**Patients on Bisphosphonate Medications** (8/06) **Updated** (4/09)

**Question:** I've read some articles describing complications following dental treatment in patients who were taking bisphosphonate medications. Does DECS have any information on this and do you know where I can find recommendations for treating and/or managing a patient taking bisphosphonate medication?

**Answer:** Bisphosphonate medications are used to prevent or treat osteoporosis or as part of cancer treatment. Oral bisphosphonates are commonly used to treat bone loss associated with osteopenia or osteoporosis, while intravenous (IV) bisphosphonates may be administered to cancer patients to reduce bone pain, hypercalcemia of malignancy, and skeletal complications. In 2003, reports of osteonecrosis of the jaw associated with the use of bisphosphonates began to appear in the literature. Most of the reported cases of bisphosphonate-associated osteonecrosis of the jaw (BON) have been diagnosed after dental procedures such as tooth extraction. Patients being treated with bisphosphonate medications have experienced delayed hard- and soft-tissue healing following extractions and spontaneous soft-tissue breakdown leading to intraoral bone exposure. The appearance of oral lesions associated with bisphosphonates resemble those of radiation-induced osteonecrosis. The osteonecrosis is often progressive and does not respond to conventional treatment (e.g., debridement, antibiotics, hyperbaric oxygen therapy). BON has also been reported to develop spontaneously in patients taking these drugs, but is not common. In 2006, cases of BON were reported in patients taking oral bisphosphonate medications to treat osteoporosis. The exact mechanism that leads to the induction of BON is unknown, however local and systemic risk factors have been identified. There is no uniform treatment protocol to yield consistent resolution and healing of BON. While much is still unknown about this process, based on the information currently available, the risk for developing BON is much higher for cancer patients on IV bisphosphonate therapy than for patients on oral bisphosphonate therapy. As a result, the recommendations for dental management of these patients differ.



The American Academy of Oral Medicine published a position paper on managing the care of patients with osteonecrosis of the jaw, and the American Dental Association (ADA) Council on Scientific Affairs has developed a set of recommendations for the dental management of patients on oral bisphosphonate therapy. The recommendations focus on conservative surgical procedures, proper sterile technique, appropriate use of oral disinfectants, and the principles of effective antibiotic therapy. The most current ADA update was published in the Journal of the American Dental Association in December 2008. The ADA cautions that because there is currently no data from clinical trials evaluating dental management of patients on oral bisphosphonate therapy, these recommendations are based on expert opinion only and serve as a resource for dentists to supplement their professional judgment, data obtained from dental and medical literature, and information from the patient's treating physician. These documents and other information are available and updated periodically on the ADA Web site: [www.ada.org/2594.aspx](http://www.ada.org/2594.aspx). Prevention of BON is the best approach to managing this potential complication. The risk for developing BON appears to be very low, however dental professionals should be aware of it and communicate with the patient and the patient's physician when managing patients undergoing bisphosphonate therapy.

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### Submitting Continuing Education Presentations (4/05) **Updated** (1/11)

**Question:** I recently developed and presented a CE lecture at my base and would like to share it with others. Does DECS have specific criteria for submitting and posting CE presentations?

**Answer:** DECS is always willing to consider posting an outstanding continuing education presentation on our Web site. We have specific criteria, however, which must be followed. The presentation needs to have a professional appearance with minimal editing required and needs to be in PowerPoint format. In addition, the slides should be readily understandable and as self-explanatory as possible. Please keep in mind that presentations consisting of only text slides can lose an audience quickly. Therefore, inclusion of non-copyrighted photographs and pictures is highly desirable. The presentation should be of sufficient relevance and depth and include a 10-question test to be able to award one hour of continuing education credit. Once posted, United States government health-care professionals worldwide will be able to view your presentation and earn CE credit. This is a great opportunity for the submitter to share some knowledge with the profession and gain some well-deserved recognition.



If you are considering sharing your presentation with us, please contact [DECS](#) for specific guidance on how to submit your PowerPoint presentation and test. After submitting your materials to DECS, the Technical Evaluation Committee will review them and notify you if your presentation is acceptable. If accepted, please note you will be responsible for keeping the information in your presentation up-to-date and reviewing it at least once every three years.

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### Custom Bur Blocks (Originally published in Jan 1996)

**Question:** I seem to be ordering the same burs and diamonds repeatedly for the same departments. Is there a way to order these items so I don't have to order each bur individually?

**Answer:** Yes. Brasseler USA will supply your clinic and laboratory with any combination of burs and diamonds you select in sterilizable aluminum bur blocks. The specific combination of burs is chosen once and then given an order number by Brasseler for purchase on a Blanket Purchase Agreement. The key to this service is getting the providers in the different sections to agree on a standardized set up, i.e. general dentistry, prosthodontics, etc. The bur block is laser etched with the clinic name and individual item numbers and is supplied with a cover. There is no surcharge for this service. When reordering, a new bur block is supplied with the burs. Individual replacement burs can be ordered for the most frequently used burs if you do not want to reorder the entire set. This will still reduce the amount of paperwork involved in ordering burs. The blocks can be ordered in plain aluminum or in one of seven colors. A total minimum order of ten kits for plain aluminum blocks or fifty kits for colored blocks is required for laser etching. This minimum requirement may be eliminated if Brasseler obtains in-house laser etching capability. A number of military bases and universities are using this service, including Lackland AFB, Kelly AFB, Brooks AFB, Bolling AFB, Edwards AFB, Ft. Gordon, Ft. Jackson, and the University of Oklahoma. Contact Brasseler USA at (800) 841-4522 for more information. Other manufacturers that offer this type of service are: American Diamond Instruments (800) 537-7474, Boyd Dental Services (800) 443-5491 (with or without a bur block), NTI Rotary Instruments (800) 355-5063, and S.S. White (800) 535-2877.

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### Water Filters and Fluoride Water Levels (Originally published in May 1999)

**Question:** The Brita water filter system advertises that it filters out lead and chlorine. Should I be concerned about it removing fluoride?

**Answer:** The Brita and other similar water filtration systems utilize activated charcoal. Mary O'Connell, a marketing spokesperson for Brita has said that slight amounts of fluoride (0.6% to 2%) are removed from the first two gallons of water filtered through the unit. After that, the fluoride-binding capacity of the charcoal is saturated. This should not really be a concern, because the manufacturer's recommendations state that the first two gallons should be discarded due to potential unbound particles of activated charcoal from the filter. Further questions concerning Brita products can be directed to the company at (800) 242-7482 or [www.brita.com](http://www.brita.com). Other information about water filters is provided by NSF International, a third-party certification agency, at (800) 673-6275, (734) 769-8010, or [www.nsf.org](http://www.nsf.org)

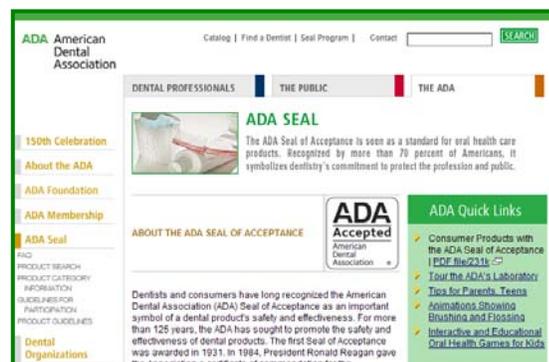
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## American Dental Association (ADA) Seal of Acceptance **Updated** (9/09)

**Question:** I've noticed that in your product evaluations you sometimes report that a product is ADA Accepted. If a product is not ADA Accepted, how can DECS rate it as "Acceptable", "Excellent", or "Outstanding"?

**Answer:** At first glance it would appear that this is a serious disconnect, however, the quick answer is that the ADA Seal of Acceptance Program is totally voluntary. A product may be perfectly acceptable yet not have been submitted to the ADA for evaluation.

The ADA has sought to ensure the safety and effectiveness of dental products for more than 125 years. For example, in 1866 an ADA committee prepared a statement concerning toothpaste. In 1930, the ADA established guidelines for the testing and advertising of dental products. The first Seal of Acceptance was awarded in 1931.



In 2005, the ADA decided to phase out the Seal of Acceptance program for professional dental products (products used by dentists) and focus instead on a product evaluation newsletter featuring different professional products in each issue. The phase-out of the Seal on professional products was completed in 2007.

The ADA continues to award the Seal of Acceptance for products sold to consumers. Currently, more than 100 companies participate in the ADA Seal program and about 300 dental products sold to consumers carry the ADA Seal of Acceptance including toothpaste, dental floss, manual and electric toothbrushes and mouth rinse.

### Not every dental product qualifies for the Seal; to qualify the company must:

- Submit ingredient lists and other pertinent product information for review and approval.
- Supply objective data from clinical and/or laboratory studies that support the product's safety, effectiveness and promotional claims.
- Conduct clinical trials as needed in strict compliance with ADA guidelines and procedures.
- Provide evidence that manufacturing and laboratory facilities are properly supervised and adequate to assure purity and uniformity of the product, and that the product is manufactured in compliance with Good Manufacturing Practices.
- Submit all product packaging and labeling for review and approval by the ADA, and comply with the ADA's standards for accuracy and truthfulness in advertising.

The ADA uses more than 100 consultants, including members of the ADA's Council on Scientific Affairs and ADA staff scientists to review the product submissions. In some instances, the ADA may conduct or

ask the company to conduct additional testing. Only after the product has demonstrated its safety and effectiveness will the ADA Council on Scientific Affairs award the Seal.

In summary, just because a product doesn't have the ADA Seal of Acceptance, one cannot assume that it is unsafe or that it is inferior to other products that have the Seal. The ADA Seal of Acceptance is designed to help consumers make informed decisions about safe and effective consumer products. To review a list of consumer products with the ADA Seal of Acceptance, [click here](#). For information about the ADA Professional Product Review (products used by dentists) [click here](#).

**References:**

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**Dental Units on Federal Contract** (Originally published in Sept 2000)

**Question:** I just returned from a dental meeting and noticed how many different companies make dental units. Why is it that there are only three manufacturers of dental units on the federal contract? Having so few seems to really limit our choices.

**Answer:** The federal contracts for dental/medical equipment are awarded by the [Defense Supply Center in Philadelphia](#) (DSCP). DSCP requires a dental manufacturer's equipment to meet certain specifications in order to successfully handle unique situations that may present in military environments. For instance, dental equipment must function successfully in overseas areas where the electrical power is of a different voltage than in the US. Also, equipment may be required to withstand conditions that are more rigorous than those usually encountered in the typical civilian dental practice. For example, dental units that are aboard Navy ships must be stable and secure so they are able to withstand forces experienced by a ship at sea.

The DSCP has several ways that it uses to insure that the dental units available to the military meet the specific needs of the services. First, DSCP has written a Medical Procurement Item Description (MPID) that lists specific requirements that dental units must meet. These include design features, electrical safety requirements, and construction specifications. Second, the DSCP has the right to inspect the manufacturer's facility. Also, DSCP requires the manufacturer to supply all service documentation and to maintain service records for up to three years. Finally, DSCP requires the manufacturer to guarantee that it will have surge capability (i.e., that it will be able to provide a large number of dental units on demand).

As you can see, a manufacturer must exhibit good quality control and be able to document it for the company to be able to submit items for inclusion on the dental unit federal contract. It is important to note, however, that just because a particular dental manufacturer is not on the contract does not imply that his dental units are of poor quality. Often, manufacturers are not on the contract because they can not meet surge demands or they may have decided that the process involved in submitting their units for possible inclusion on the contract is too involved administratively or financially.

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**The Meaning of the CE Mark on Products** (Originally published in Jan 2001)

**Question:** I noticed that many of the composite resins and bonding agents we use in our clinic have a marking on their box that looks like a "CE." What does it mean?

**Answer:** Since January 1996, the CE Mark (which stands for Conformance Europeene) has been required on certain goods sold into the European market. The mark was established by the European Commission as an indication that the product conforms to legal requirements of European Union health, environmental, or safety directives. Many of the directives mandate a certain level of quality. You can think of the mark as a kind of passport that permits



manufacturers to freely circulate their products throughout the European marketplace. The basic purpose of establishing the mark was to eliminate barriers to trade in Europe that arose because of the many restrictions put into effect by the various countries. A myriad of products can bear the CE mark, from children's toys to computers. Although CE Mark applies only to products covered by certain kinds of directives or regulations, it covers nearly 50% of the goods exported to Europe from the United States.

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### Antibiotic Prophylaxis for Patients with Joint Replacements **Updated** (9/09)

**Question:** Has there been an update to the recommendations for antibiotic prophylaxis for dental patients with prosthetic joints?

**Answer:** In 1997, an expert consultant panel consisting of dentists, orthopaedic surgeons and infectious disease specialists led by the American Dental Association (ADA) and the American Academy of Orthopaedic Surgeons (AAOS) convened to publish their first Advisory Statement on Antibiotic Prophylaxis for Dental Patients with Prosthetic Joints. In 2003, the panel reconvened and published the first periodic update of the 1997 statement. The 2003 statement included some modifications of the classification of patients at potential risk and of the incidence stratification of bacteremic dental procedures, but no changes in terms of suggested antibiotics and antibiotic regimens.<sup>1</sup>

The 2003 Total Joint Advisory Statement issued by the ADA and AAOS was recently retired by AAOS consistent with their process requiring review of statements every five years. In 2009, the American Academy of Orthopedic Surgeons (AAOS) updated the guidelines for patients who have a total joint replacement. The 2009 AAOS statement consolidates their prophylaxis recommendations for dental and medical procedures. Unlike with previous updates, the ADA was not asked to provide input for the 2009 statement and the new statement does not appear to be based on new scientific evidence. Furthermore, a rationale justifying the change was not clear.<sup>2</sup>

The ADA has posted information about the update on their [Web site](#).<sup>3</sup> The 2009 AAOS Information Statement differs from the 2003 AAOS/ADA Advisory Statement on the following topics:

- The AAOS now states that, "Given the potential adverse outcomes and cost of treating an infected joint replacement, the AAOS recommends that clinicians consider antibiotic prophylaxis for all total joint replacement patients prior to any invasive procedure that may cause bacteremia."<sup>3</sup>

This is in contrast to the 2003 advisory statement which only recommended antibiotic prophylaxis for all patients within the first two years after replacement surgery; after two years, the recommendation for prophylaxis was limited to patients who had comorbidities that might place them at increased risk for hematogenous total joint infection (i.e., immunocompromised patients).<sup>3</sup>

- The new statement does not identify specific dental procedures that may potentially cause a bacteremia. In the 2003 statement, the following procedures were identified as having a higher incidence of bacteremia: dental extractions; periodontal procedures, including surgery, subgingival placement of antibiotic fibers/strips, scaling and root planing, probing, recall maintenance; dental implant placement and replantation of avulsed teeth; endodontic (root canal) instrumentation or surgery only beyond the apex; initial placement of orthodontic bands but not brackets;

intra-articular and intraosseous local anesthetic injections; prophylactic cleaning of teeth or implants where bleeding is anticipated.<sup>3</sup>

- The AAOS does not include a recommendation for an antibiotic regimen for patients who are allergic to penicillin in the new statement. In the 2003 statement, clindamycin (600 mg one hour before the procedure) was the recommended antibiotic.<sup>3</sup>

There was no change regarding antibiotic prophylaxis for dental patients with pins, plates, or screws not within a synovial joint; the AAOS does not recommend antibiotic prophylaxis for these patients.<sup>4</sup> The complete 2009 AAOS Information Statement can be accessed by visiting:

<http://www.aaos.org/about/papers/advistmt/1033.asp>.

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