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Statement on Dental Amalgam

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For dental patients: Please visit the ADA's MouthHealthy website for information about [amalgam and silver-colored fillings](#).

Dental amalgam is considered a safe, affordable and durable material that has been used to restore the teeth of more than 100 million Americans. It contains a mixture of metals such as silver, copper and tin, in addition to mercury, which binds these components into a hard, stable and safe substance. Dental amalgam has been studied and reviewed extensively, and has established a record of safety and effectiveness.

The FDI World Dental Federation and the World Health Organization concluded in a 1997 consensus statement: "No controlled studies have been published demonstrating systemic adverse effects from amalgam restorations." Another conclusion of the report stated that, aside from rare instances of local side effects of allergic reactions, "the small amount of mercury released from amalgam restorations, especially during placement and removal, has not been shown to cause any ... adverse health effects."

In 1998, the ADA's Council on Scientific Affairsⁱⁱ published its first major review of the scientific literature on dental amalgam which concluded that "based on available scientific information, amalgam continues to be

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a safe and effective restorative material.” The Council’s report also stated, “There currently appears to be no justification for discontinuing the use of dental amalgam.”

In an articleⁱⁱⁱ published in the February 1999 issue of the Journal of the American Dental Association, researchers report finding “no significant association of Alzheimer’s Disease with the number, surface area or history of having dental amalgam restorations” and “no statistically significant differences in brain mercury levels between subjects with Alzheimer’s Disease and control subjects.”

A 2003 paper published in the New England Journal of Medicine^{iv} states, “Patients who have questions about the potential relation between mercury and degenerative diseases can be assured that the available evidence shows no connection.”

In 2004, an expert panel reviewed the peer-reviewed, scientific literature published from 1996 to December 2003 on potential adverse human health effects caused by dental amalgam and published a report. The review was conducted by the Life Sciences Research Office (LSRO) and funded by the National Institutes of Dental and Craniofacial Research, National Institutes of Health and the Centers for Devices and Radiological Health, U.S. Food and Drug Administration (FDA). The resulting report states that, “The current data are insufficient to support an association between mercury release from dental amalgam and the various complaints that have been attributed to this restoration material. These complaints are broad and nonspecific compared to the well-defined set of effects that have been documented for occupational and accidental elemental mercury exposures. Individuals with dental amalgam-attributed complaints had neither elevated urinary mercury nor increased prevalence of hypersensitivity to dental amalgam or mercury when compared with controls.” The full report is available from LSRO (www.lsro.org). A summary of the review is published in Toxicological Reviews.^v

In 2006, the Journal of the American Medical Association (JAMA) and Environmental Health Perspectives published the results of two independent clinical trials

designed to examine the effects of mercury release from amalgam on the central and peripheral nervous systems and kidney function. The authors concluded that “there were no statistically significant differences in adverse neuropsychological or renal effects observed over the 5-year period in children whose caries are restored using dental amalgam or composite materials”;^{vi,vii} and “children who received dental restorative treatment with amalgam did not, on average, have statistically significant differences in neurobehavioral assessments or in nerve conduction velocity when compared with children who received resin composite materials without amalgam. These findings, combined with the trend of higher treatment need later among those receiving composite, suggest that amalgam should remain a viable dental restorative option for children.”^{viii}

In May 2008, a Scientific Committee of the European Commission addressed safety concerns for patients, professionals and the use of alternative restorative materials.^{ix} The committee concluded that dental amalgams are effective and safe, both for patients and dental personnel and also noted that alternative materials are not without clinical limitations and toxicological hazards.

The ADA Council on Scientific Affairs prepared a [comprehensive literature review](#) (PDF) on amalgam safety that summarized the state of the evidence for amalgam safety (from January 2004 to June 2010). Based on the results of this review, the Council reaffirmed at its July 2009 meeting that the scientific evidence supports the position that amalgam is a valuable, viable and safe choice for dental patients.

On July 28, 2009, the U.S. Food and Drug Administration (FDA) issued its [final rule](#) on encapsulated dental amalgam classifying amalgam and its component parts, elemental mercury and powder alloy, as a class II medical device. Previously there was no classification for encapsulated amalgam, and dental mercury (class I) and alloy (class II) were classified separately. This new regulation places encapsulated amalgam in the same class of devices as most other restorative materials, including composite and gold fillings. At the same time, the FDA also reaffirmed the agency’s position that the

material is a safe and effective restorative option for patients.

The CSA supports ongoing research on the safety of existing dental materials and in the development of new materials, and continues to believe that amalgam is a valuable, viable and safe choice for dental patients.

References

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- ix. European Commission: Scientific Committee on Emerging and Newly Identified Health Risks. [The Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users](#) May 6, 2008. Accessed October 9, 2013.

Additional Resources

- [ADA Principles of Ethics and Code of Professional Conduct](#)
- Search [JADA](#) for amalgam-related articles
- Search the [ADA Catalog](#) for amalgam-related resources
- See the [ADA Professional Product Review](#) for amalgam separator evaluations
- [ADA Library](#)

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