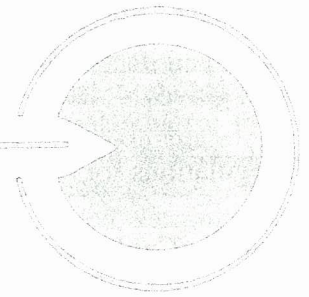


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NEWSLETTER



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AMALGAM WARNING BY MANUFACTURER!

Dentsply/Caulk, a major manufacturer of dental amalgam, has placed the following warning for its amalgam products *Dispersalloy*, *Megalloy*, and *Unison* on their internet site. The URL's for the various products are: <http://www.caulk.com/MSDSDFU/DispersDFU.html>, www.caulk.com/MSDSDFU/UnisonDFU.html, and www.caulk.com/MSDSDFU/MegalloyDFU.html.

Contraindication

The use of amalgam is contraindicated:

- In proximal or occlusal contact to dissimilar metal restorations.
- In patients with severe renal deficiency.
- In patients with known allergies to amalgam.
- For retrograde or endodontic filling.
- As a filling material for cast crown.
- In children 6 and under.
- In expectant mothers.

Side Effects/Warning:

- Prior to use, read the MSDS information and product instructions for this item.
- Exposure to mercury may cause irritation to skin, eyes, respiratory tract and mucous

membrane. In individual cases, hypersensitivity reactions, allergies, or electrochemically caused local reactions have been observed. Due to electrochemical processes, the *lichen planus* of the mucosa may develop.

- Mercury may also be a skin sensitizer, pulmonary sensitizer, nephrotoxin and neurotoxin.
- After placement or removal of amalgam restorations, there is a temporary increase of the mercury concentration in the blood and urine.
- Mercury expressed during condensation and unset amalgam may cause amalgamation or galvanic effect if in contact with other metal restorations. If symptoms persist, the amalgam should be replaced by a different material.
- Removal of clinically acceptable amalgam restorations should be avoided to minimize mercury exposure, especially in expectant mothers.

Precautions:

- The number of amalgam restorations for one patient should be kept to a minimum.
- Inhalation of mercury vapor by dental staff may be avoided by proper handling of the amalgam,

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the use of masks, along with adequate ventilation.

- Avoid contact with skin and wear safety glasses and gloves.
- Store amalgam scrap in well sealed containers. Regulations for disposal must be observed.

Dentsply/Caulk has also placed the MSDS for mercury on another page [www.caulk.com/MSDSDFU/DispersalloyMSDS.html#MERC]. Of particular importance, are some statements made in *Section VIII - Control Measures, Inhalation, Chronic*: Inhalation of mercury vapor over a long period may cause mercurialism, which is characterized by fine tremors and erethism. Tremors may affect the hands first, but may also become evident in the face, arms, and legs. Erethism may be manifested by abnormal shyness, blushing, self-consciousness, depression or despondency, resentment of criticism, irritability or excitability, headache, fatigue, and insomnia. In severe cases, hallucinations, loss of memory, and mental deterioration may occur. Concentrations as low and (*sic* "as") 0.03 mg/m³ have induced psychiatric symptoms in humans. Renal involvement may be indicated by proteinuria, albuminuria, enzymuria, and anuria. Other effects may include salivation, gingivitis, stomatitis, loosening of the teeth, blue lines on the gums, diarrhea, chronic pneumonitis and mild anemia. Repeated exposure to mercury and its compounds may result in sensitization. Intrauterine exposure may result in tremors and involuntary movements in the infants. Mercury is excreted in breast milk. Paternal reproductive effects and effects on fertility have been reported in male rats following repeated inhalation exposures.

The fact that *Dentsply/Caulk* has placed this information on the Internet, available to the public and professionals alike, has a vital impact on various aspects of the current controversy over the safety of mercury/silver amalgam dental fillings.

The American Dental Association (ADA): The ADA may now be in a difficult, if not untenable, position. The prevailing ADA position is that patient exposure to mercury from amalgam dental fillings is harmless. The ADA currently promotes this position on its Internet site (dated 1995, without consideration of current published research), at the same time and contradictory to the ADA position, a major amalgam manufacturer is exhibiting its public warning.

Of major significance is the fact that the ADA has pleaded in a Court of Law that it has no legal duty of care to protect the public from allegedly danger-

ous materials used in dentistry, as it does not design, manufacture, supply or install amalgam fillings [*see* BPNL, 11(4), July 1995].

Meanwhile, the ADA has added to its *Principles of Ethics and Code of Professional Conduct* a provision declaring it unethical for a dentist to recommend the removal of clinically serviceable amalgam fillings to eliminate exposure to mercury [Section 1-J], a provision widely utilized by state dental boards. At the same time, the ADA Code contains a provision providing an "obligation" for dentists to inform on the results of their investigations when they are useful in safeguarding or promoting the health of the public [Section 4]. This is clearly a dilemma for dentists in regard to dental amalgam; dentists are unethical if they do inform and unethical if they do not inform patients of potential adverse effects to amalgam mercury!

Government Agencies: The influence of the ADA with government agencies is a matter of record; the ADA has been represented on amalgam "committees" established by government agencies and, arguably, is instrumental in the composition and conclusions of these committees. An example is the current proposal of the Agency for Toxic Substances and Disease Registry (ATSDR) to raise their Minimal Risk Level (MRL) standard for general population chronic exposure to mercury vapor by almost fifteen fold, and declare patient exposure to dental amalgam mercury to be harmless, based primarily on the position of the ADA [*see* following article]!

The position of the Food and Drug Administration (FDA) is of particular interest, as FDA regulations specifically direct the Agency to rely on safety information on products that is provided by the manufacturer. So, if the information from the manufacturer is contrary to that from the ADA, the FDA must follow the manufacturer. The FDA currently has accepted and classified only "dental mercury (Class I)" and "amalgam alloy (Class II)", but not mixed amalgam. The FDA is now responsible for the information provided by *Dentsply/Caulk*, which contradicts a classification of Class I for dental mercury, and complicates their current consideration for classification of "dental amalgam."

Dental Boards: The *Dentsply/Caulk* public statement should have a profound effect on the attacks by dental boards on mercury-free dentists, many of whom have been brought before boards simply for providing information on potential adverse effects of amalgam mercury. The Boards have claimed that the information challenging the safety of amalgam constitutes fraud and misrepresentation. This position by the Boards is obviously now determined