

Instructions For Use

Manufactured by:
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Warning: CONTAINS MERCURY, may be harmful if vapor is inhaled.

Intended Use: Dental Amalgam Alloy for posterior restoration.

Caution: Federal law restricts this device to sale by or on the order of a dentist.

Contraindications:

- Do not use in patients with renal deficiency.
- Do not use in persons with a known mercury allergy.
- Whenever possible, amalgam fillings should not be replaced in or removed from teeth of pregnant women.

Precautions:

- Single use only.
- Do not place device in direct contact with other types of metals.
- Use with adequate ventilation.
- Store in a dry, cool, well-ventilated place.
- Use of gloves when handling the device.
- When possible, non-mercury filling material should be considered for treating primary teeth in children.

Keep Out of Reach of Children

WARNING: Contains Mercury. Can cause birth defects or other reproductive harm.
www.P65Warnings.ca.gov

Alloy Powder Physical Characteristics:

Ingredients: Silver, Tin, Copper

Approximate Alloy Content:

Silver 56%, Tin 29%, Copper 15%

Appearance: Silver colored powder

Specific Gravity: 9gm/cc

Melting Point: 1500° C

Physical Properties:

Compressive strength: @ 1 hour 167.26 MPa

Compressive strength: @ 24 hours 358.4 MPa

Maximum Creep: .397%

Dimensional Change: .048% during hardening

Particle Size Distribution: 325 mesh, spherical (u) and shape

Working Time(s): 11/2 -3 minutes

(Eames Test Method)

Mercury Physical Characteristics:

Appearance: Silver colored liquid

Specific Gravity: 13.6 gm/cc

Melting Point: Liquid at room temperature

Boiling Point: 120° C

Mercury complies o: ISO 24234:2015

CAS Number: 7439-97-6 DOT Number: UN3506

OSHA PEL: 0.01 mg/m³ ACGIH TLV: 0.025 mg/m³

NIOSH: 0.05 mg/m³

Precautions for Safe Handling:

- Prior to working with mercury, you should be trained in its proper handling and storage.
- Avoid breathing dust and contact with skin.
- Spill should be cleaned up immediately. Kits specific for cleanup for mercury are available.
- It is necessary to dispose of mercury as hazardous waste.
- Mercury is a CORROSIVE CHEMICAL.

Fire Hazard:

- Poisonous gas produced in fire.
- Use dry chemicals appropriate for extinguishing metal fires. Do not use water.
- Mercury must be stored to avoid contact with chlorine dioxide, nitric acid, nitrates, ethylene oxide, chlorine and methylazide. Violent reactions will occur when exposed to these chemicals.
- This silver alloy must be stored to avoid contact with acetylene, ammonia, hydrogen peroxide or ethyleneimine since a violent reaction will occur.
- Silver powder alloy can be a combustible solid.
- Store at temperature no higher than 25° C.

Health Hazard Data:

Acute Health Effects: The following acute (short-term) health effects may occur immediately or shortly after exposure to mercury.

Routes of entry: Inhalation

- Mercury can affect breathing.

OSHA legal limit for 8-hour exposure is 0.01 mg/m³

- Exposure to high levels of mercury vapor (1.2mg/m³) can irritate the lungs causing cough, chest tightness, shortness of breath and fever. This usually begins one to four hours after exposure and can go on to fluid in the lungs (pulmonary edema) and death.

Skin — If skin contacts silver dust or small particles enter small cuts, tattooing may occur. Wash thoroughly to prevent staining.

Eyes — Flush immediately with a large quantity of water. Seek medical attention.

Acute Exposure:

May cause sensitization dermatitis and possible visual disturbances.

Information for Use

Dental amalgam has been demonstrated to be an effective restorative material that has benefits in terms of strength, marginal integrity, suitability for large occlusal surfaces, and durability. Dental amalgam also releases low levels of mercury vapor, a chemical that at high exposure levels is well-documented to cause neurological and renal adverse health effects. Mercury vapor concentrations are highest immediately after placement and removal of dental amalgam but decline thereafter.

Clinical studies have not established a causal link between dental amalgam and adverse health effects in adults and children age six and older. In addition, two clinical trials in children aged six and older did not find neurological or renal injury associated with amalgam use.

The developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor. Very limited to no clinical information is available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed.

The Agency for Toxic Substances and Disease Registry's (ATSDR) and the Environmental Protection Agency (EPA) have established levels of exposure for mercury vapor that are intended to be highly protective against adverse health effects, including for sensitive subpopulations such as pregnant women and their developing fetuses, breastfed infants, and children under age six. Exceeding these levels does not necessarily mean that any adverse effects will occur.

FDA has found that scientific studies using the most reliable methods have shown that dental amalgam exposes adults to amounts of elemental mercury vapor below or approximately equivalent to the protective levels of exposure identified by ATSDR and EPA. Based on these findings and the clinical data, FDA has concluded that exposures to mercury vapor from dental amalgam do not put individuals age six and older at risk for mercury-associated adverse health effects.

Continued

Taking into account factors such as the number and size of teeth and respiratory volumes and rates, FDA estimates that the estimated daily dose of mercury in children under age six with dental amalgams is lower than the estimated daily adult dose. The exposures to children would therefore be lower than the protective levels of exposure identified by ATSDR and EPA.

In addition, the estimated concentration of mercury in breast milk attributable to dental amalgam is an order of magnitude below the EPA protective reference dose for oral exposure to inorganic mercury. FDA has concluded that the existing data support a finding that infants are not at risk for adverse health effects from the breast milk of women exposed to mercury vapors from dental amalgam.

Chronic Health Effects:

The following chronic (long-term) health effects can occur at some time after exposure to mercury and can last for months or years:

- Repeated low exposure or a very high single exposure can cause mercury poisoning. Symptoms include tremors (shaking), trouble remembering and concentration, gum problems, increased salivation, loss of appetite, and changes in mood and personality.
- Repeated vapor exposure (usually more than five years) can cause clouding of the eye lens.
- Mercury may cause a skin allergy. If allergy develops, very low future exposures can cause skin irritations.
- Exposure can cause kidney damage.
- Mercury may lower sex drive.

Hazard Communication Standard Pictogram

<http://www.osha.gov/Publications/OSHA3491QuickCardPictogram.pdf>

TRITURATION CHART

| | | Time Range in Seconds | | |
|--------------------------------|---------------|----------------------------------|----------------------------------|----------------------------------|
| Spherical Settings Amalgamator | Speed Setting | 400 MG. Alloy 300 MG. Mercury | 600 MG. Alloy 445 MG. Mercury | 800 MG. Alloy 600 MG. Mercury |
| Disp. Settings Amalgamator | Speed Setting | 400 MG. Alloy 400 MG. Mercury | 600 MG. Alloy 600 MG. Mercury | 800 MG. Alloy 800 MG. Mercury |
| Darby | M | 8 ± 2 | 10 ± 2 | 12 ± 2 |
| Vari-Mix II | M-2 | 8 ± 2 | 10 ± 2 | 12 ± 2 |
| Wig-L-Bug LP60 | Med. | 8 ± 2 | 10 ± 2 | 12 ± 2 |
| Wig-L-Bug Model 80 | Med. | 8 ± 2 | 10 ± 2 | 12 ± 2 |
| Silamat | — | 5 ± 2 | 6 ± 2 | 7 ± 2 |
| Zenith | — | 6 ± 2 | 8 ± 2 | 10 ± 2 |

Trituration:

This capsule system is recommended for use only in high energy amalgamator (4200 rpm).

Variations in machines and voltage may require you to adjust trituration time slightly to your needs. If the capsule does not activate at recommended setting, increase speed or the time until activation occurs. As a general rule, increased trituration makes the mix brighter, wetter and faster set.

Less trituration gives the mix more body and slows the setting speed. Mix should have a shiny appearance and be pliable.

Properly Recycle All Amalgam Waste.

