

INDICATIONS FOR USE:

- Filling material as a treatment for dental caries.

CONTRA-INDICATIONS

- Do not use in persons with a known mercury or metallic allergy
- Do not use in children under 15 years, or pregnant or breastfeeding women, unless deemed strictly necessary by the dental practitioner on the grounds of specific medical needs of the patient.

Ultracaps + is a low creep non-gamma 2 dental amalgam. Ultracaps + contains pre-measured quantities of dental alloy and mercury for the preparation of dental amalgam. The alloy to mercury ratio varies between 1/0.84 and 1/0.89 depending on the size and setting time. i.e. 45.6% to 46.8% by weight mercury. The compressive strength of Ultracaps + at 24 hours is 500 MPa, and the dimensional change during hardening is +0.04%.

Ultracaps + capsules have a green body and the coloured plunger denotes the spill size, whilst the coloured base indicates the setting time:

Spill	Plunger	Alloy (mg)	Mercury (mg)	
			Fast (blue)	Regular (grey)
1	green	400	336	352
2	blue	600	504	528
3	red	800	-	704
5	brown	1200	-	1068

Working time:

Condensing time (minutes)	4.5	5.5
Carving time (minutes)	8.0	8.0

INSTRUCTIONS:

- Select the appropriate size capsule according to colour coding.
- With the capsule inverted, SLOWLY press the plunger end of the capsule against a flat surface (see figure 1) until the flange of the plunger is flush with the capsule body (see figure 2). THIS IS MOST IMPORTANT. Initially, resistance will be felt, then suddenly released as the plunger pierces a diaphragm allowing the mercury to enter the mixing chamber.
- Slightly spread the amalgamator clips and carefully insert the capsule. Ensure that the capsule is securely anchored between the clips. (see figure 3).
- Select the appropriate mixing time from the suggested mixing times (see table 1). A range of mixing times is given to accommodate mixing variations that can occur due to machine type, age and line voltage. Correctly triturated amalgam will form into a bright homogeneous plastic mass. A hot, shiny, sticky mass indicates over trituration whilst a dull, dry or powdery mass is under trituration.
- After trituration has been completed, **carefully** remove the capsule from the clip.
- Tap the base end of the capsule sharply on the bench to ensure that the mixed amalgam is located in the base of the capsule (see figure 4).
- Separate the base from the body and remove the prepared amalgam from the capsule. If the small separating diaphragm has come away from the capsule wall during activation and mixing, it will separate cleanly from the amalgam.
- CONDENSATION:**
Moisture contamination: If moisture has introduced into the amalgam before it has set, properties such as strength and corrosion resistance may be affected adversely. Whenever it is possible, use a dry field. Insertion of the amalgam should commence immediately after trituration. It is not necessary to express mercury prior to insertion. Traditional condensation techniques are recommended. Pack angles and undercuts with a small-faced plunger, using sufficient pressure to ensure good adaptation. Build the restoration with additional portions until cavity is slightly over filled. Remove any mercury rich amalgam from the surface, that may develop during condensation.

9. FINISHING:

Trimming and carving can be commenced immediately condensation has been completed. Light burnishing can be used to advantage and if the restoration is polished, this procedure should be carried out after 24 hours. Avoid overheating by ensuring adequate water cooling and low speed polishing.

WARNINGS**CONTAINS MERCURY**

- Harmful if vapours are inhaled.
- Avoid breathing vapours.
- Harmful if swallowed.
- Use with adequate ventilation
- Single-use only
- For professional use only
- CAUTION:** Federal law restricts this device to sale by or on the order of a dentist.
- Keep out of reach of children
- Do not open capsules prior to trituration
- Do not remove the coloured plunger from the capsule.
- Effect of mercury on metals: Mercury reacts with and embrittles particular metals and their alloys. Avoid unnecessary contact between mercury and those metals (and their alloys).
- The wearing of gloves, glasses and protective clothing is recommended for all dental procedures
- Do not eat, drink or smoke when using this product
- Follow good safety clinical practices when performing amalgam restorations.
- Always keep unused product in original, labelled container and store in temperatures below 25°C / 77°F in a cool, well-ventilated area.
- Existing studies indicate that some people with amalgam restorations may be sensitive to prolonged close encounter with sources of electromagnetic radiation, ie mobile phone. In patients hypersensitive to amalgam, existing amalgam restorations should be replaced with an alternative material.
- Some patients may experience a metallic taste post restoration especially when placed in close contact with other metal restorations due to galvanic effect. If this persists, consider replacing with an alternative material.
- Dispose of used capsules in accordance to national regulations. Refer to Waste Disposal section below.

PROCEDURE FOR HANDLING MERCURY SPILLAGE:

- Mercury presents a health hazard if handled incorrectly.
- Mercury is toxic by vapour inhalation and the effect is cumulative.
- Spillages of mercury should be removed immediately, including from places which are difficult to access.
- Avoid contact with any spillage.
- Use a plastic syringe to draw it up.
- Smaller quantities can be covered by sulphur powder and removed.
- Individual small droplets can be picked up by tin (i.e. Sn) foil and removed.
- Avoid inhalation of mercury vapour.
- During and after a clean-up thoroughly ventilate the area where the spill has occurred.
- Lower the room temperature if possible.
- Never use a day to day use vacuum cleaner, mop or broom to clean a mercury spill. Once contaminated with mercury, these items must be disposed of as contaminated waste in accordance to local regulations.
- If using a spill-clean up kit, carefully follow the direction provided in the kit.

WASTE DISPOSAL:

- Waste material and all primary containers that have held mercury shall be disposed of following appropriate management practice and in accordance with national regulations, and that all amalgam waste products, including spillage, amalgam residues, particles, fillings, and teeth, or anything contaminated by dental amalgam, is handled and collected by an authorised waste management establishment.
- Amalgam waste shall never be released, either directly or indirectly, into the environment.

GOVERNMENTAL AGENCIES STATEMENT & WARNING ON THE USE OF DENTAL AMALGAMS:

The health authorities of various countries including Germany, France, the United Kingdom, Norway and Austria have made statements regarding the safety of dental amalgam in certain individuals such as pregnant and nursing women and persons with impaired kidney function. Check with the authorities in your country that govern the practice of dentistry and dental materials to determine what recommendations or restrictions apply to the use of dental amalgams.

California Prop 65 Warning: This product can expose you to mercury, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Health Canada Warning: (1) Non-mercury filling materials should be considered for restoring the primary teeth of children where the mechanical properties of the material are suitable. (2) Wherever possible, amalgam fillings should not be placed in or removed from the teeth of pregnant women. (3) Amalgam should not be placed in patients with impaired kidney function. (4) In placing and removing amalgam fillings, dentists should use techniques and equipment to minimize the exposure of the patient and the dentist to mercury vapour and to prevent amalgam waste from being flushed into municipal sewage systems. (5) Dentists should advise individuals who may have allergic hypersensitivity to mercury to avoid the use of amalgam. In patients who have developed hypersensitivity to amalgam, existing amalgam restorations should be replaced with another material where this is recommended by a physician.

Statement from the US FDA:

"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.

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."

FIRST AID

- For health hazard data and full first aid directions, refer to Safety Data Sheet (SDS), available at www.sdi.com.au or contact your regional representative.

Inhalation: If affected move individual to fresh air. Seek medical attention.

Skin Contact: Immediately remove all contaminated clothing, including footwear.

Flush skin and hair with running water, and soap if available. Thoroughly clean clothing, shoes and leather goods before reuse or dispose of safely.

Eye Contact: Immediately hold eyelids apart and flush continuously with running water for at least 15 minutes. Ensure complete irrigation by keeping eyelids apart and occasionally lifting upper and lower eyelids. Seek medical attention.

Ingestion: Seek IMMEDIATE medical attention. Call an ambulance or doctor at once. Rinse mouth with water. Drink large quantities of water, if conscious.

STORAGE

Store at temperatures below 25°C / 77°F in a well-ventilated place.

Composition of alloy:

ultracaps +: Ag 50%, Sn 30%, Cu 20%

ultracaps + capsules conform to ISO 24234 and ANSI/ADA Specification No. 1.

AMERICAN DENTAL ASSOCIATION MECHANICAL AMALGAMATION REQUIREMENT

AMALGAMATOR	SDI ULTRAMAT 2
Cycles per second	75
Time of Mixing (Seconds)	8
Plastic Capsules	(2 spill regular setting time)

Figure 1

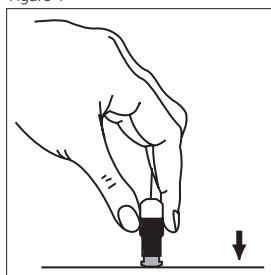


Figure 2

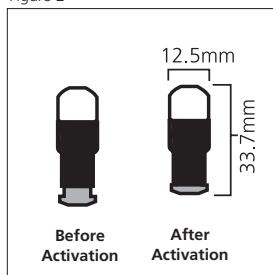


Figure 3

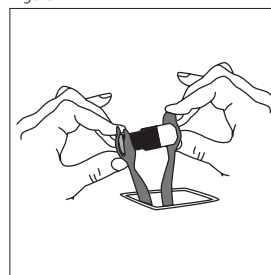


Figure 4

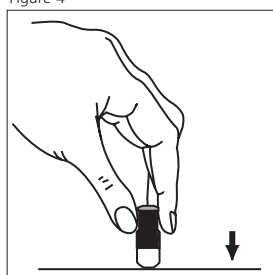


Table 1:

Recommended amalgamator settings

Ultracaps + trituration recommendations for 1, 2, 3 & 5 spill:

AMALGAMATOR	SPEED SETTING	1,2 & 3 spill TIME(sec)	5 spill TIME(sec)
SDI Ultramat	Single speed	8 +/-1	6 +/-1
Capmaster (SS white)	Single speed	12 +/-2	10+/-1
Vari-Mix II (Caulk)	M2	9 +/-1	7+/-1
Vari-Mix III (Caulk)	M	9 +/-1	7+/-1
Silamat (Vivadent)	Single speed	8 +/-1	6+/-1

Wig-L-Bug (Crescent)			
LP-60	Medium	12 +/-2	10+/-1
SC-40	Medium	22 +/-5	20+/-1
MSD	3800 cpm	9 +/-1	7+/-1
Ventura Mix		9 +/-2	7+/-1
Ventura VT (IV)		14 +/-2	12+/-1
Capmix (Espe)		8 +/-1	6+/-1
Duomat (Degussa)	4500 cpm	9 +/-1	7+/-1

NOTE: The ESPE Rotomix is not recommended for mixing SDI amalgam capsules. Capmaster, Vari-Mix II, Vari-Mix III, Silamat, Wig-L-Bug, Ventura Mix, Ventura VT, Capmix, Duomat, and Rotomix are not the registered trademarks of SDI Limited.

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