

Dispersalloy®

Dispersed Phase Alloy

Self-Activating Capsules

DENTSPLY
CAULK

DIRECTIONS FOR USE – ENGLISH

For dental use only.

USA: Rx only.

1. PRODUCT DESCRIPTION

Dispersalloy® Dispersed Phase Alloy is a dispersed phase admix amalgam, containing lathe-cut particles and silver/copper eutectic spheres.



Contains 50% mercury by weight.

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.

1.1 Delivery forms

Dispersalloy® Alloy is available in:

- Pre-dosed, encapsulated Self-Activating Capsules
- 1 spill, 2 spill and 3 spill weights, in Fast Set or Regular Set

1.2 Composition

Alloy Powder	Weight %
Silver	69.5%
Tin	17.7%
Copper	11.8%
Zinc	1.0%

Pre-dosed capsules (nominal)

	1-spill	2-spill	3-spill
Alloy	400 mg	600 mg	800 mg
Mercury	400 mg	600 mg	800 mg

Performance data

Compressive Strength (24hrs)	>300MPa
Dimensional Change during hardening (%)	-1% - +2%
Working Time (min)	Fast Set 2'30" - 3'30" Regular Set 3'30" - 4'30"

1.3 Indication for use

Dispersalloy® Alloy is designed for use in stress bearing restorations (Class I and II), when other restorative materials or restoration techniques are not indicated.

1.4 Contraindication

The use of amalgam is contraindicated in patients with known allergies to mercury or any of the components.

1.5 Compatible adhesives

Dispersalloy® Alloy is compatible with DENTSPLY adhesives and adhesive liners designed for use with dental amalgam materials. For details, see complete directions for use of the selected adhesive system. The use of other dentin and enamel adhesive systems is at the discretion and sole responsibility of the dental practitioner.

2. GENERAL SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other chapters of these directions for use.



Safety alert symbol

This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings

1. (The following statement is required by the state of California). This product contains mercury, which is known by the state of California to cause birth defects or other reproductive harm. Prior to use, read the Safety Data Sheet (SDS) information and product instructions for this item.
2. Alloy amalgam capsule products contain mercury, which can cause skin sensitization or other allergic reaction. Proper care should be taken to prevent exposure to mercury.
Avoid skin contact with this product by wearing protective safety glasses, clothing and gloves. If contact with skin occurs immediately wipe off and flush with generous amounts of water, then wash well with soap and water after contact. If skin rash, irritation, sensitization or other allergic reaction occurs, discontinue use and seek medical attention immediately.
Avoid eye contact as product may be irritating to eyes. Before using this product wear protective glasses as well as covering the patient's eyes to protect from excess. The use of an enclosed amalgamator is recommended. In case of accidental contact with eyes, rinse eyes immediately with plenty of water and seek medical attention.
Avoid ingestion of this product. Do not swallow or take internally. Whenever possible, the use of protective barriers such as rubber dam isolation and protective mask during placement and removal is recommended. If accidental swallowing occurs, drink lots of water. If nausea or illness develop, seek medical attention immediately. Contact regional Poison Control Center immediately.
Avoid inhalation as this product may be harmful if vapors are inhaled. Use with adequate ventilation. Whenever possible, the use of protective barriers such as rubber dam isolation, high-volume evacuation and protective mask during placement and removal is recommended. Give oxygen or artificial respiration if necessary.
3. Do not open capsule prior to trituration. Do not remove or handle mixing pestle or plastic wafer containing mercury.
4. Capsules are for single use only. Do not attempt to clean and/or reuse capsules.
5. This alloy contains Zinc; amalgam made therefrom may show excessive expansion if moisture is introduced during mixing and condensing.

2.2 Precautions

1. This product is intended to be used only as specifically outlined in the Directions for Use. Any use of this product inconsistent with the Directions for Use is at the discretion and sole responsibility of the practitioner.
2. Wear suitable protective eyewear, clothing, mask and gloves. Protective eyewear, and whenever possible, barrier techniques such as rubber dam is recommended for patients. (See Warnings)
3. Devices marked "single use" on the labeling are intended for single use only. Discard after use. Do not reuse.
4. Regulations for disposal must be observed. Adherence to the American Dental Association's current "Best Management Practices For Amalgam Waste (BMPs)" and "Dental Mercury Hygiene Recommendations" is strongly recommended. Among these practices:
 - Salvage and store non-contact amalgam scrap in well-sealed containers and recycle.
 - Salvage and store contact amalgam pieces from restorations, traps and filters in well-sealed containers and recycle.
 - Do not dispose of amalgam scrap, waste or extracted teeth in regulated infectious waste containers that will be incinerated, or in regular garbage.
 - Recycle used disposable amalgam capsules and plastic wafer (which contained mercury before mixing).
5. In the event of mercury spillage, clean up with commercially available mercury absorbing compounds.

6. Dispersalloy® Alloy contains zinc. If moisture is introduced into the amalgam before it has set, properties such as strength and corrosion resistance may be affected adversely. If the alloy contains zinc, such contamination may result in an excessive expansion (delayed expansion). Whenever it is possible, use a dry field.
7. Manufacturer's variation in amalgamators and differences in local electrical current may necessitate adjusting trituration time to obtain an optimal mix.
8. Insufficient data exist to support the use of amalgamators not listed in the chart below. Use of amalgamators other than those listed may result in less than optimally triturated amalgam. The operator must investigate non-listed equipment compatibility and/or consult amalgamator manufacturer for recommendations.
9. Do not attempt to place improperly triturated amalgam, or amalgam that has exceeded working time (dry, crumbly). Improperly handled amalgam alloy may have reduced physical properties and increased risk of mechanical failure.
10. Do not place dental amalgam in direct contact with other types of metals to reduce risk of corrosion and galvanic reaction.

2.3 Storage conditions

Dispersalloy® Alloy in Self-Activating Capsules should be stored in a well ventilated place at temperature not to exceed 25°C/77°F. Do not allow exposure to moisture or excessive humidity. Do not use after expiration date.

2.4 Adverse reactions

1. Product may irritate skin, eyes. Skin contact: irritation or possible allergic response. Reddish rashes may be seen on the skin. Eye contact: irritation and possible corneal damage. (See Warnings and Precautions)
2. Inhalation of vapors may cause varying degrees of damage to the affected tissue and also increased susceptibility to respiratory illness. (See Warnings and Precautions)
3. Product may cause neurotoxic, nephrotoxic or other serious health effects if inhaled or ingested. (See Warnings)

3. STEP-BY-STEP INSTRUCTIONS

1. **Treatment of the preparation:** Clean freshly instrumented enamel and dentin with water spray and then air dry. The use of pulpal protection, bases and/or cavity liners is at the discretion of the operator, as dictated by the clinical presentation. If desired, Dispersalloy® Alloy may be placed over an adhesive liner or adhesively bonded by following the instructions contained in the compatible Adhesive System (available separately).
2. **Trituration:** Simply place Dispersalloy® Self-Activating Capsules in the amalgamator. These capsules are activated by the amalgamator – they do not require manual activation. Trituration speed and time is an important factor in preparing the amalgam, in order to achieve proper amalgam mix consistency. The chart that follows provides guidelines in determining amalgamator trituration time and speed setting for Dispersalloy® Self-Activating Capsules:

Approximate Trituration Time Range (in seconds) RS = Regular Set / FS = Fast Set

		1 Spill		2 Spill		3 Spill	
Amalgamator	Speed Setting	RS	FS	RS	FS	RS	FS
Caulk ProMix	Turtle (3700 cpm)	11-17	11-17	11-17	11-17	10-14	10-14
Caulk Vari-Mix II M	M2 (3900 cpm)	11-17	11-17	11-17	11-17	10-14	10-14
Caulk Vari-Mix III	M (3900 cpm)	11-17	11-17	11-17	11-17	10-14	10-14
Wig-L-Bug MSD	3800 cpm	12-15	12-15	12-15	12-15	10-14	10-14
Wig-L-Bug LPD	3800 cpm	12-15	12-15	12-15	12-15	10-14	10-14
Kerr AutoMix*	4000 cpm	11-17	11-17	11-17	11-17	10-14	10-14
ADEC Model 6440*	#7 (4200 cpm)	11-15	11-15	11-15	11-15	10-13	10-14
Pelton & Crane Spirit Model SM*	4000 cpm	9-13	10-14	10-15	11-15	10-15	11-15
Zenith Stirspeed Model TP-103*	Fixed 3950 cpm	11-14	10-13	11-14	10-14	10-12	9-12
Zenith Stirspeed Model Z-1A	H (4100 cpm)	10-14	10-14	10-14	10-14	10-13	10-13
Vivadent Silamat Plus*	Fast 4700 cpm	6-8	6-8	6-8	6-8	6-8	6-8
SDI Ultramat 2*	4400 cpm	9-12	9-12	9-12	9-12	7-10	7-10
ESPE CapMix*	Fixed 4400 cpm	6-7	6-7	6-7	6-7	6-7	6-7
Torit Capmaster*	4200 cpm	13-16	13-16	13-16	13-16	11-15	11-15
ESPE Rotamix*	Not recommended for use with Dispersalloy® Alloy						
Torit Single Speed Model TRA-18-1* Not recommended for use with Dispersalloy® Alloy							

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- 2.1 The triturated amalgam should be bright and have a plastic consistency. If the amalgam is excessively splashy and wet looking, INCREASE trituration time or amalgamator speed. Amalgam that appears excessively dry indicates trituration time or amalgamator speed should be DECREASED.
- 2.2 Suggestions for obtaining optimum mix: When performing adjustments, it is recommended to adjust trituration time in 2 second increments, until optimum mix is obtained. Greater adjustments may indicate amalgamator incompatibility or compromised functionality.

Decrease trituration time:	Increase trituration time:
- To lengthen working time	- To shorten working time
- If mix is too hot	- If mix is too wet
- If mix is too dry	
- 2.3 Properly triturated Dispersalloy® Alloy does not require mulling to produce a smooth plasticity; however you may mull for 1-2 seconds after removing pestle to collect amalgam into a single mass.

3. Condensation

- 3.1 No tool is needed to open the Self-Activating Capsule. Just grasp both ends of the capsule, twist, and pull apart. Turn the opened capsule upside down to drop the amalgam mass into the work area. Dispersalloy® Alloy is now ready for immediate placement and condensation. A gentle tap may be required to free amalgam from the capsule. Do not attempt to manually express mercury from the triturated mass prior to placement.
- 3.2 A plastic wafer and/or plastic mixing pestle may be seen. These have no further function and should be properly recycled.
- 3.3 Condense immediately after mix is completed. Use a clean amalgam carrier to transfer increments to the cavity. Pack each increment into angles and undercuts with small-faced plugger and sufficient pressure to insure good adaptation. Build the restoration with additional portions, until the cavity is slightly overfilled. Remove any mercury-rich amalgam from the surface that may develop during condensation.
4. **Carving/Burnishing:** Carving can begin immediately after condensation. A sharp carver will give best results. The anatomy should be carved proceeding from the proximal margins towards the center of the restoration. Before the matrix band is removed, the marginal ridge should be supported by a condenser. After removal of the matrix band, gingival margins may be smoothed with a curved explorer. Burnishing setting amalgam is recommended to improve surface smoothness.
5. **Polishing:** The quality of the Dispersalloy® Alloy restoration will be enhanced by polishing. The amalgam should be allowed to set 24 to 48 hours before polishing. See selected polishing instrument manufacturer's directions for use.

4. HYGIENE



Cross-contamination

- Do not reuse single use products. Dispose in accordance with local regulations.
- Properly dispose of the used and/or contaminated capsules, components and amalgam scrap in accordance with local regulations

5. LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiry date. ISO standard is used: "YYYY/MM"
2. The following numbers should be quoted in all correspondence:
 - Reorder number
 - Lot number on package
 - Expiration date on package

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