

Nogama™ , Prosilver™ , Spherodon-M™ , ProCopper™ , Spherodon+™

High-Copper, Non-Gamma II Amalgam Alloys

INDICATIONS FOR USE

Intended for the use as a direct dental restorative material in the treatment of dental caries.

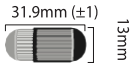
CONTRAINDICATIONS FOR USE

Dental amalgams shall not be used:

- As retrograde filling material.
- In patients with a known history of allergy to mercury, identified by a patch test.
- In patients where the kidney has been weakened as a consequence of impaired kidney function.
- For dental treatment of deciduous teeth, of children under fifteen years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.

ALLOY CONTENT:

1 spill (400mg) Yellow Cap 2 spill (600mg) Green Cap 3 spill (800mg) Dark Blue Cap



Mercury mass/capsule (mg)

| | 1 Spill | 2 Spill | 3 Spill |
|-------------------------|---------|---------|---------|
| Nogama / ProSilver | 435 | 690 | 935 |
| Nogama Slow | 435 | 690 | 935 |
| Spherodon-M / ProCopper | 400 | 600 | 800 |
| Spherodon-M Slow | 400 | 600 | 800 |
| Spherodon + | 290 | 400 | 530 |

Composition / Particle Shape (%):

| | Ag | Sn | Cu | Zn | Hg | Spherical | Lathe Cut |
|-------------------------|------|------|------|-----|----|-----------|-----------|
| Nogama / ProSilver | 69 | 20.8 | 9.5 | 0.7 | 53 | 20 | 80 |
| Nogama Slow | 67 | 22 | 10.3 | 0.7 | 53 | 20 | 80 |
| Spherodon-M / ProCopper | 45.5 | 31.5 | 23 | - | 47 | 60 | 40 |
| Spherodon-M Slow | 45.5 | 31.5 | 23 | - | 48 | 30 | 70 |
| Spherodon + | 56 | 28.8 | 15.2 | - | 40 | 100 | - |

*All percentages are by weight.

*** The alloy to mercury ratio varies depending on the size and setting time.

Triturating Time:

| Amalgamator | Speed | 1 Spill | 2 Spill | 3 Spill |
|-------------------------|---------------|---------|---------|---------|
| Silamat | | 4-5 | 5-6 | 7-8 |
| Vari-Mix II / Wig-L-Bug | H | 10-15 | 15-20 | 20-25 |
| Duomat (4000rpm) | 3200 | 5-6 | 5-6 | 7-8 |
| ProMix | High (Rabbit) | 5-7 | 7-9 | 9-12 |

SLOW SPEED AMALGAMATORS SHOULD NOT BE USED

Silmet amalgams give satisfactory results with modern high speed vibrators. Not designed to be used with planetary mixers such as Copernicus and Capmix.

Working Time (minutes)*:

| | Condense | Carving |
|-------------------------|----------|---------|
| Nogama / ProSilver | 2.5 - 4 | 4-5.5 |
| Nogama Slow | 5.5-7 | 7-8.5 |
| Spherodon-M / ProCopper | 3.5-5 | 5-7 |
| Spherodon-M Slow | 5.5-7 | 7-8.5 |
| Spherodon + | 2-3.5 | 3.5-5 |

*working time may vary, depending on triturating conditions and technique applied Polish 24 hr. after placement.

MECHANICAL PROPERTIES

Compressive Strength (24hr): > 350 MPa Dimensional Change: ≤ 0.15% Creep: ≤ 0.75%

Note: The triturated amalgam should be bright and have a plastic consistency. If the amalgam is excessively plushy and wet looking and/or sets fast, decrease trituration time or amalgamator speed. A mix that appears excessively dry indicates that trituration time or amalgamator speed should be increased. Your clinical experience in obtaining a satisfactory working consistency will be the best guide to trituration times.

INSTRUCTIONS FOR USE

- Place and secure the capsule in the mixing arms of the desired amalgamator.
- To triturate, set the desired speed and time of the amalgamator.
- After trituration, remove the capsule from the amalgamator. Before opening, capsule to release amalgamated mass from inner walls of capsule.
- Before opening, tap amalgam into the body of the capsule.
- With gloved hands, grasp the cap of the capsule with one forefinger and thumb, grasp the body of the capsule with the other forefinger and thumb, and pinch the cap while pulling apart. The cap should click apart.
- The amalgam in the body of the capsule should be tapped into an amalgam well.
- Inspect amalgam mass to ensure that the membrane from the mercury pillow pack is not mixed in with the amalgam. Remove the membrane from the amalgam if this is observed.
- Begin placement of amalgam.
- After placing the amalgam, snap the capsule body and cap back together and dispose of in accordance with all applicable regulations. Adherence to the ADA's current "Best Management Practices for Amalgam Waste (BMPs)" and "Dental Mercury Hygiene Recommendations" is strongly recommended.

Placement of amalgam

- Insertion of the amalgam should commence immediately after trituration.
- Vertical condensing should begin immediately after triturating using instrument with fat smooth surface.
- Carving of the dental amalgam may begin immediately after completion of condensation.
- Relieve marginal ridge area with an explorer before removal of matrix band.
- A final polish will enhance the restoration's qualities. Conventional finishing and polishing techniques may be used.

Special Note:

1. Spillages: "Mercury presents a health hazard if incorrectly handled. Spillages of mercury should be removed immediately according to local regulations."
2. Moisture contamination: "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."
3. Refer to American Dental Association Publication, "Recommendations in Dental Mercury Hygiene".

SHELF LIFE

The lot number & expiry date are indicated on the product. Do not use this product after its expiration date

CAUTION

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTIST.

Keep out of the reach of children. For single use only. Do not place the device in direct contact with other types of metals.

STORAGE

It is recommended that this product be stored in a well-ventilated place.

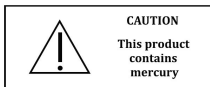
SDS available online at: www.silmetdental.com

WASTE DISPOSAL

Waste material and all primary containers that have held mercury shall be disposed of following appropriate management practice

WARNING - CONTAINS MERCURY

The capsules and the dental amalgam product made contain mercury .Mercury vapors may be harmful if inhaled



Precautions

- The use of a rubber dam may decrease the amount of mercury absorbed by a patient during the removal or placement of an amalgam.
- Use this product with adequate ventilation (vapor exposure should be kept under 0.05 mg/m³ or any lower limit set by any governmental or regulatory agency governing your use of the product).
- Dental amalgams are for single use only.
- Wear gloves when handling the capsules and dental amalgams.
- Mercury reacts with and embrittles particular metals and their alloys. Avoid unnecessary contact between mercury and those metals (and their alloys)
- Use an enclosed amalgamator when mixing the self-activating capsules.
- Properly dispose of spent capsules and any excess unused amalgam.
- Use HGX, or similar type mercury-absorbing compounds in the event of spillage of the contents of the self-activating capsules.
- If a patient experiences a localized hypersensitivity reaction to dental amalgam, the amalgam should be removed. These precautionary procedures should always be used in addition to procedures recommended by your local regulatory agency and dental association.

STATEMENTS BY GOVERNMENTAL AGENCIES REGARDING RESTRICTIONS AND RECOMMENDATIONS ON THE USE OF DENTAL AMALGAMS

REGULATORY NOTES: USA

"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.

REGULATORY NOTES: CANADA

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. Whenever 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 vapor and to prevent amalgam waste from being flushed into municipal sewage systems.
5. Dentist 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. You should 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.

ADVERSE REACTION

Effects and Hazards of Eye Contact: Irritant.

Acute Exposure: Contact may cause irritation. Mercury is corrosive and may cause corneal injury or burns.

Chronic Exposure: Mercury may be deposited in the lens of the eye, causing visual disturbances.

Effects and Hazards of Skin Contact: Irritant/Sensitizer/Neurotoxin/ Nephrotoxin. Acute Exposure: May cause redness and irritation.

Chronic Exposure: Possible sensitization, dermatitis, and swelling. Mercury may be absorbed through the skin causing urinary problems. Effects and Hazards of Inhalation: Irritant/Sensitizer/Neurotoxin.

Acute Exposure: Inhalation of mercury vapor can cause cough, fever, nausea, and vomiting.

Chronic Exposure: Inhalation of high concentrations of mercury vapor over a long period may cause mercurialism. Findings are extremely variable and include tremors, salivation, stomatitis, loosening of teeth, blue lines on gums, pain, and numbness in extremities.

Effects and Hazards of Ingestion: Neurotoxic/Nephrotoxic. Acute Exposure: May cause nausea, vomiting, kidney damage and nerve effects. Chronic Exposure: Symptoms include central nervous system (CNS) disorders.

CALIFORNIA PROP 65 WARNING

This product contains mercury, a chemical known to the State of California to cause birth defects or other reproductive harm.

Conforms to ISO 20749

LIMITED WARRANTY – LIMITATION OF SILMET'S LIABILITY

Silmet's technical advice, whether verbal or in writing, is designed to assist dentists in using Silmet's product. Such advice does not expand Silmet's limited warranty or relieve the dentist of testing Silmet's products to determine their suitability for the intended uses and procedures. The dentist assumes all risk and liability for damages arising out of the improper use of Silmet's product.

In the event of a defect in material or workmanship, Silmet's liability is limited, at Silmet's option, to replacement of the defective product or part thereof, or reimbursement of the actual cost of the defective product. In order to take advantage of this limited warranty, the defective product must be returned to Silmet. In no event shall Silmet be liable for any indirect, incidental or consequential damages.

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For instructions in additional languages, please refer to:

https://www.silmetdental.com/downloads/downloads_instruction

or scan the following code:



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