



pre-dosed amalgam capsules permite, lojic+ & gs-80

ENGLISH

INSTRUCTIONS FOR USE

Permite : The non-gamma 2 admix alloy unsurpassed by any other with its high strength, high polishability and superior handling qualities. The alloy to mercury ratio varies between 1/0.86 and 1/0.96 depending on the size and setting time, i.e. 46.2% to 49.5% by weight mercury. The compressive strength of Permite at 24 hours is 500 MPa, and the dimensional change during hardening is +0.04%.

Lojic+ : The platinum modified, high silver, non-gamma 2 spherical amalgam. Lojic+ has exceptional early strength, smooth handling and excellent polishability. The alloy to mercury ratio varies between 1/0.73 and 1/0.78 depending on the size and setting time, i.e. 42.2% to 43.8% by weight mercury. The compressive strength of Lojic+ at 24 hours is 520 MPa, and the dimensional change during hardening is -0.04%.

GS-80 : The technically advanced, non-gamma 2 admix amalgam at an affordable price. GS-80's high strength ensures longevity and patient satisfaction. The alloy to mercury ratio varies between 1/0.85 and 1/0.94 depending on the size and setting time, i.e. 45.9% to 48.5% by weight mercury. The compressive strength of GS-80 at 24 hours is 510 MPa, and the dimensional change during hardening is +0.02%.

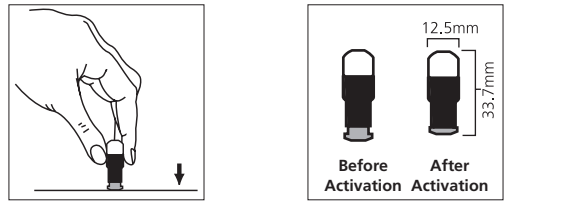
COMPOSITION OF ALLOYS:
Permite: Ag 56%, Sn 27.9%, Cu 15.4%, In 0.5%, Zn 0.2% (Contains zinc in an alloyed form, not free zinc)
Lojic+: Ag 60.1%, Sn 28.05%, Cu 11.8%, Pt 0.05% (zinc free)
GS-80: Ag 40%, Sn 31.3%, Cu 28.7% (zinc free)

INDICATIONS
 • For the restoration of carious teeth.

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.

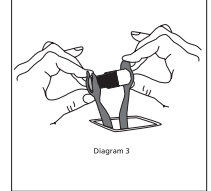
PLACEMENT PROCEDURE
 1. Isolate tooth.
 2. Prepare cavity using standard technique for amalgam restoration. Note: In cases where pulp protection is necessary, use a calcium hydroxide liner or glass ionomer cement.
 3. Activate a capsule on a bench or hard surface until plunger is fully flushed with the body of the capsule.

Figure 1, Abbildung 1, Figura 1, Rycina 1 Figure 2, Abbildung 2, Figura 2, Rycina 2



4. Place activated capsule in a high speed multi-use triturator..

Figure 3, Abbildung 3, Figura 3, Rycina 3



5. Triturate capsule as per recommended in Table 1 below.

Table 1. Mechanical Amalgamation Mixing Time Requirement.

Amalgamator	Speed	PERMITE		LOJIC+		GS-80	
		1, 2 & 3 spill	5 spill	1, 2 & 3 spill	5 spill	1, 2 & 3 spill	5 spill
Ultramat 2 (SDI Ltd.)	Fixed (4600 rpm)	8 ± 1 sec	6 ± 1 sec	6 ± 1 sec	6 ± 1 sec	8 ± 1 sec	6 ± 1 sec
		1, 2 & 3 spill	5 spill	1, 2 & 3 spill	5 spill	1, 2 & 3 spill	5 spill
Ultramat 2 (SDI Ltd.)	Fixed (450 rpm)	8 ± 1 sec	6 ± 1 sec	6 ± 1 sec	6 ± 1 sec	8 ± 1 sec	6 ± 1 sec
		1, 2 & 3 spill	5 spill	1, 2 & 3 spill	5 spill	1, 2 & 3 spill	5 spill

Note:
 1. Insufficient data exists to support the use of triturators not listed in Table 1. Use of triturators other than those listed may result in less than optimally triturated amalgam.
 2. It is recommended for operators to consult triturator manufacturer for recommendations.
 3. Trituration speed and time is an important factor in preparing the amalgam to a proper consistent mix.
 4. A dry, crumbly mix is often a sign of under trituration. Trituration time can be increased by 1-5 seconds to achieve a wetter/plastic mix. If resulting amalgam mix is still unacceptable, the triturator may need to be looked at by a service technician.

Table 2. Working times and Capsule Identification Table.

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)	Slow (cream)	ECT (green)
• Permite						
1	pink	400	344	364	380	372
2	purple	600	522	552	576	564
3	yellow	800	696	736	768	752
5	dark green	1200	-	1128	-	-
Working time:						
Condensing time (minutes)			2.5	3.5	4.5	5
Carving time (minutes)			5.5	5.5	5.5	7
• Lojic+						
1	orange	400	292	304	308	
2	cream	600	438	456	462	
3	brown	800	584	608	616	
5	cerise	1200	-	936	-	-
Working time:						
Condensing time (minutes)			2.5	3	4	
Carving time (minutes)			4.5	6	6	
• GS-80						
1	grey	400	340	360	376	
2	light green	600	510	540	564	
3	burgundy	800	680	720	752	
5	gold	1200	-	1116	-	-
Working time:						
Condensing time (minutes)			3.5	4.5	5.5	
Carving time (minutes)			5.5	5.5	8.5	

6. Carefully remove the triturated capsule from the triturator and gently tap the base on a bench or hard surface once.
 7. Open the capsule by removing the base from the body to access the prepared amalgam.
 Note: Freshly mixed amalgam should have a bright look and a plastic consistency.
 8. Immediately insert amalgam into prepared cavity using a clean amalgam carrier employing standard amalgam condensation technique.
 Note:
 i. "If moisture is introduced into the dental amalgam before it has set, properties such as strength and corrosion resistance can be affected adversely. If the alloy contains zinc, such contamination can result in excessive expansion (delayed expansion). Use a dry field, whenever it is possible."
 ii. Permite contains zinc in an alloyed form and not free zinc. It's the free zinc which is very sensitive to moisture.
 9. Remove any mercury rich amalgam from the surface that may develop during condensation.
 10. Trimming and carving can begin after condensation using a sharp carver.
 11. Light burnishing can be carried out after 24 hours to improve surface smoothness. Avoid over heating by ensuring adequate water cooling and low speed.

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.

For spills on impervious surfaces (e.g. vinyl, concrete, lino, tiles etc)
 1. Contain the area of the spill and thoroughly examine the area to detect all visible droplets of mercury. Droplets of mercury can travel some distance, so a large area around the spill point should be checked.
 2. Pick-up droplets using pasteur pipette, eye-dropper, suction bottle, or strips of adhesive tape, avoiding skin contact.
 3. Sprinkle sulphur powder, calcium polyphosphide with excess sulphur, zinc dust or proprietary products like Mercurisorb, HgX on contaminated area, using at least twice as much powder as volume of spill. Mix well if possible. Allow time for mercuric sulphide, etc to form, which can take from half an hour to 24 hours. Sweep up the powder, avoiding generating dust. If using a vacuum cleaner, use only special dedicated vacuum cleaners fitted with charcoal filters.

WASTE DISPOSAL:
 1. 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.
 2. 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. 15 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.

The information provided herein is given in good faith, but no warranty expressed or implied is made:

Permite, Lojic + and GS-80 capsules conform to ISO 24234 and ANSI/ADA Standard No. 1.

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