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

ENGLISH

INSTRUCTIONS FOR USE

Indications for use: Filling material as a treatment for dental caries.
Contra-indications for use: Do not use in persons with a known mercury allergy.

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%.

The coloured plunger denotes the spill size, whilst the coloured base indicates the setting time:

			Mercury (mg)			
Spill	Plunger	Alloy (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	346	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	5.5	

INSTRUCTIONS:
1. Select the appropriate size capsule according to colour coding.
2. 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.
3. Slightly spread the amalgamator clips and carefully insert the capsule. Ensure that the capsule is securely anchored between the clips. (see figure 3).
4. 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 triturated.
5. After trituration has been completed, **carefully** remove the capsule from the clip.
6. 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).
7. 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.
8. 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. If the alloy contains zinc, such contamination may result in an excessive expansion (delayed expansion). 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 plugger, 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.

WARNING - CONTAINS MERCURY
DANGER - POISON
May be harmful if vapours are inhaled. Avoid breathing.
Keep container closed. Use with adequate ventilation.

Do not open capsules prior to trituration. Do not remove the coloured plunger from the capsule. The wearing of gloves, glasses and protective clothing is recommended for all dental procedures. **Dispose of used capsules in accordance with national regulations.**
- **Ingestion:** Mercury may cause neurotoxic effects and renal damage.
- **Inhalation:** Mercury may cause respiratory disorders including inflammation and fluid retention.
- **Eyes & Skin:** Mercury may cause irritations and allergic reactions.
- **Acute Exposure:** Mercury may cause irritations and allergic reactions including dermatitis, digestive and respiratory 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.

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.

The U.S. FDA states the following on dental amalgams: 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.

CAUTION: Federal law restricts this device to sale by or on the order of a dentist.
Keep out of the reach of children. Single use only. Do not place the device in direct contact with other types of metals.

Spillages: Mercury presents a health hazard if incorrectly handled. Spillages of mercury should be removed immediately, including from places which are difficult to access. Use a plastic syringe to draw it up. Smaller quantities can be covered by sulfur powder and removed. Avoid inhalation of the vapour.
The information provided herein is given in good faith, but no warranty expressed or implied is made. MSDS available at www.sdi.com.au or contact your regional representative.

STORAGE: It is recommended that this product be stored at temperatures below 25ºC / 77ºF in a well ventilated place.

Composition of alloys:
Permite: Ag 56%, Sn 27.9% Cu 15.4%, In 0.5%, Zn 0.2%
THIS ALLOY CONTAINS ZINC; THE AMALGAM MADE THEREFROM MAY SHOW EXCESSIVE EXPANSION IF MOISTURE IS INTRODUCED DURING MIXING OR CONDENSING.
Lojic+: Ag 60.1%, Sn 28.05%, Cu 11.8%, Pt 0.05%
GS-80: Ag 40%, Sn 31.3%, Cu 28.7%

Permite, Lojic+ and GS-80 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)

Made in Australia by SDI Limited
Bayswater, Victoria 3153
Australia 1 800 337 003
Austria 00800 022 55 734
Brazil 0800 770 1735
France 00800 022 55 734
Germany 0800 100 5759
Ireland 01 886 9577
Italy 800 780625
New Zealand 0800 734 034
Spain 00800 022 55 734
United Kingdom 00800 022 55 734
USA & Canada 1 800 228 5166
www.sdi.com.au

EC REP
SDI Dental Limited
Block 8, St Johns Court
Swords Road, Santry
Dublin 9, Ireland
Tel +353 1 886 9577

PAK41055 G

Last Revised: 07-2011

Figure 1, Abbildung 1, Figura 1, 图 1
Rycina 1

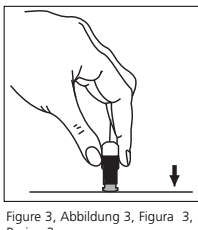


Figure 2, Abbildung 2, Figura 2, 图 2
Rycina 2

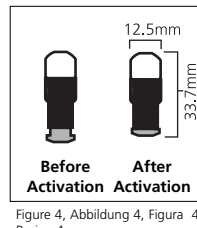


Figure 3, Abbildung 3, Figura 3, 图 3
Rycina 3

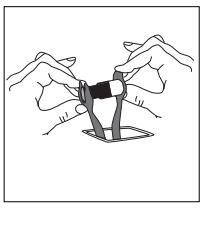
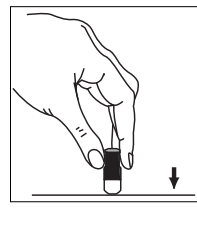


Figure 4, Abbildung 4, Figura 4, 图 4
Rycina 4



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

WICHTIG: Der ESPE Rotomix wird nicht zum Anmischen von SDI Kapseln empfohlen.Capmix, Vari-Mix II, Vari-Mix III, Silamat, Wig-L-Bug, Spirit, Executive, Torit, Duomat, Zenith, AutoMix und Rotomix sind keine geschützten Produkte der Firma SDI Ltd.

OBSERVAÇÃO: O Rotomix ESPE não é recomendado para misturar as cápsulas de amálgama da SDI. Capmix, Vari-Mix II, Vari-Mix III, Silamat, Wig-L-Bug, Spirit, Executive, Torit, Duomat, Zenith, AutoMix e Rotomix não são marcas registradas da SDI Limited.

NOTA: El ESPE Rotomix no está recomendado para mezclar las cápsulas de amalgama SDI. Capmix, Vari - Mix II, Vari - Mix III, Silamat, Wig – L – Bug, Spirit, Executive, Torit, Duomat, Zenith, Automix y Rotomix no son marcas registradas de SDI Limited.

NOTE: Le ESPE Rotomix n'est pas recommandé pour mélanger les capsules d'amalgame SDI. Capmix, Vari-Mix II, Vari-Mix III, Silamat, Wig-L-Bug, Spirit, Executive, Torit, Duomat, Zenith, AutoMix et Rotomix ne sont pas des marques déposées de SDI Limited.

NOTA: Il miscelatore Rotomix ESPE non è adatto per la miscelazione delle capsule di amalgama SDI. Capmix, Vari-Mix II, Vari-Mix III, Silamat, Wig-L-Bug, Spirit, Executive, Torit, Duomat, Zenith, AutoMix and Rotomix non sono marchi registrati da SDI Limited.

注意：不建议用ESPE Rotomix来混合SDI银汞胶囊。Capmix、Vari-Mix II/III、Silamat、Wig-L-Bug、Spirit、Executive、Torit、Duomat, Zenith、AutoMix和Rotomix不是SDI Limited公司注册的品牌。

Table 1, Tabelle 1, Tabela 1, Tabla 1,Tabella 1, Tableau 1, Tabela 1 **表1** :
Recommended amalgamator settings / Valores recomendados / Empfohlene Mischzeiten für verschiedene Mischgeräte/ Tempi di miscelazione suggeriti / Réglages recommandés de l'amalgamateur/ Tiempo recomendado de mezcla / Zalecane ustawienia mieszalnika.
推荐的银汞调拌机设置

Trituration time		permite		lojic+		qs-80	
amalgamator	**speed setting**	**1,2, 3 spill**	**5 spill**	**1,2,3 spill**	**5 spill**	**1,2,3 spill**	**5 spill**
Ultramat 2 (SDI)	Fixed	8±1	6±1	6±1	6±1	8±1	6±1
Capmix (ESPE)		8±1	7±1	8±1	7±1	8±1	7±1
Vari-Mix II (Caulk)	M2	8±2	7±2	8±2	7±2	8±2	7±2
Vari-Mix III (Caulk)	M	8±2	7±2	8±2	7±2	8±2	7±2
Silamat (Vivadent)	Fixed	7±1	6±1	6±1	6±1	8±1	7±1
Wig-L-Bug (Crescent):							
LP-60	Medium	10±2	9±2	9±2	8±2	10±2	9±2
SC-40		20±5	18±5	20±5	18±5	20±5	18±5
S2000	Low	10±2	9±2	9±2	8±2	10±2	9±2
DS80	Low	20±2	18±2	20±2	18±2	20±2	18±2
Spirit (Pelton Crane)	3500 CPM	10±2	9±2	9±2	8±2	10±2	9±2
Executive (Pelton Crane)		10±2	9±2	9±2	8±2	10±2	9±2
Torit	Fixed	12±2	10±2	11±2	10±2	12±2	10±2
Duomat (Degussa)	3800 CPM	10±2	9±2	8±2	7±2	10±2	9±2
Zenith	M	10±2	9±2	8±2	7±2	10±2	9±2
AutoMix (Kerr)	3600 CPM	10±1	9±1	9±2	8±2	10±1	9±1