

# INSTRUCTIONS FOR USE

## Sure-Cap® – Ultrasonically-Welded Capsules

**MSDS available online at: [www.ivoclarvivadent.us](http://www.ivoclarvivadent.us)**

Valiant amalgam alloy is palladium enriched for high early strengths and superior handling characteristics. The Sure-Cap delivery system emphasizes simplicity and safety in the dental office. The four Valiant brands are described below:

### VALIANT®

*Palladium-enriched amalgam alloy in SURE-CAP*

Each Ivoclar Vivadent SURE-CAP capsule contains premeasured quantities of VALIANT alloy and mercury in a nominal alloy to mercury ratio of 1: .77.

Spill Size	Alloy/Mercury Ratio	Alloy mass	Mercury mass
"1" Capsule	1: .77	400 mg.*	308 mg.*
"2" Capsule	1: .77	600 mg.*	461 mg.*
"3" Capsule	1: .77	800 mg.*	612 mg.*

### VALIANT® SNAP-SET

*Palladium-enriched amalgam alloy in SURE-CAP*

Each Ivoclar Vivadent SNAP-SET capsule contains premeasured quantities of VALIANT Snap-Set alloy and mercury in a nominal alloy to mercury ratio of 1: .79.

Spill Size	Alloy/Mercury Ratio	Alloy mass	Mercury mass
"1" Capsule	1: .79	400 mg.*	320 mg.*
"2" Capsule	1: .79	600 mg.*	478 mg.*
"3" Capsule	1: .79	800 mg.*	637 mg.*

### VALIANT® Ph.D®

*Palladium-enriched phase-dispersed amalgam alloy in SURE-CAP*

Each Ivoclar Vivadent SURE-CAP capsule contains premeasured quantities of VALIANT Ph.D amalgam alloy and mercury in a nominal alloy to mercury ratio of 1: .92.

Spill Size	Alloy/Mercury Ratio	Alloy mass	Mercury mass
"1" Capsule	1: .92	400 mg.*	368 mg.*
"2" Capsule	1: .92	600 mg.*	550 mg.*
"3" Capsule	1: .92	800 mg.*	731 mg.*

### VALIANT® Ph.D® -XT

*Palladium-enriched phase-dispersed amalgam alloy. Extended worktime in SURE-CAP*

Each VALIANT Ph.D-XT SURE-CAP capsule contains premeasured quantities of VALIANT Ph.D-XT alloy and mercury in a nominal alloy to mercury ratio of 1: .94.

Spill Size	Alloy/Mercury Ratio	Alloy mass	Mercury mass
"2" Capsule	1: .94	600 mg.*	562 mg.*
"3" Capsule	1: .94	800 mg.*	746 mg.*

\*Approximate measurements

### VALIANT® Ph.D® -EXT

*Palladium-enriched phase-dispersed amalgam alloy. Extra-Extended worktime in SURE-CAP*

Each VALIANT Ph.D-EXT SURE-CAP capsule contains premeasured quantities of VALIANT Ph.D-EXT alloy and mercury in a nominal alloy to mercury ratio of 1: .97.

Spill Size	Alloy/Mercury Ratio	Alloy mass	Mercury mass
"2" Capsule	1: .97	580 mg.*	563 mg.*

\*Approximate measurements

#### INDICATION

- All posterior amalgam restorations
- Core build-up under PFM restorations

Capsule dimensions: length: 31.5 mm diameter: 11.4 mm max.

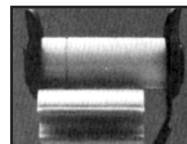


Figure 1



Figure 2

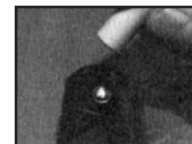


Figure 3

#### TRITURATION

Sure-CAP capsules require no activation. Insert capsule (top first) into amalgamator arms (Fig. 1) until completely seated.

#### APPROXIMATE TRITURATION TIME

(High speed amalgamators are recommended)

Amalgamator	Mixing Speed Information Hz (cycles/seconds)	Approximate Mixing Times(Seconds) #1 Spill	#2 Spill	#3 Spill
Silamat® S6	75	6-8	7-9	8-10

#### SLOW SPEED AMALGAMATORS SHOULD NOT BE USED.

**IMPORTANT:** Due to the variation of amalgamators (even from the same manufacturer), the mercury pillow in SURE-CAP may not rupture consistently on some models. If such a problem occurs, the trituration speed should be increased. If this is not possible, trituration time should be increased. Clinical experience with your amalgamator remains the best guide to trituration.

- 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.
- 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.
- New amalgam fillings should not be placed in contact with existing metal devices in the mouth such as braces.
- Dentists should provide their patients with sufficient information to make an informed choice regarding the material used to fill their teeth, including information on the risks and benefits of the material and suitable alternatives.
- Dentists should acknowledge the patient's right to decline treatment with any dental material.

#### REGULATORY NOTES: CANADA (FRENCH)

Les mesures suivantes sont énoncées conformément aux dispositions de l'article 21 du Règlement sur les instruments médicaux, en vue de réduire les risques associés à la manipulation et à l'utilisation de cet instrument :

- Chez les enfants, des matériaux d'obturation sans mercure offrant des propriétés mécaniques appropriées devraient être envisagés pour la restauration des dents primaires.
- Dans la mesure du possible, il faudrait éviter de mettre en place ou de retirer des restaurations à l'amalgame chez les femmes enceintes.
- L'amalgame ne devrait pas être utilisé chez les patients atteints d'insuffisance rénale.
- Durant la mise en place et le retrait d'obturations à l'amalgame, les dentistes devraient utiliser des techniques et de l'équipement qui permettent de réduire au minimum l'exposition du patient et du dentiste aux vapeurs de mercure et d'éviter que les déchets d'amalgame ne soient éliminés dans les réseaux d'égout municipaux.
- Les dentistes devraient conseiller aux personnes susceptibles de présenter une hypersensibilité au mercure d'éviter l'utilisation d'amalgame. Chez les patients devenus hypersensibles, les restaurations à l'amalgame existantes devraient être remplacées par un autre matériau lorsque le médecin le recommande.
- Les nouvelles obturations à l'amalgame ne devraient pas entrer en contact avec les appareils buccaux métalliques comme les arcs dentaires.
- Les dentistes devraient fournir à leurs patients suffisamment d'information pour qu'ils puissent faire des choix éclairés sur les matériaux d'obturation utilisés, y compris sur les risques et les avantages des différents matériaux et sur les produits de remplacement appropriés.
- Les dentistes devraient reconnaître aux patients le droit de refuser un traitement avec quelque matériau dentaire.



U.S. Patent No. 4,374,085 & 4,664,629 on Alloy;  
No. 4,306,651 on Capsule

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For optimum results it may be necessary from time to time to have amalgamator speeds recalibrated. Consult your dealer service department for details.

After trituration cycle, remove capsule from amalgamator arms. Firmly grasp capsule by bottom half and hold vertically. Insert opening rod into the indentation in the capsule top with delay. Apply quick leverage in any direction, and capsule will open with an audible "snap" (Fig. 2).

Turn opened capsule upside down to drop amalgam mass into work area (Fig. 3). Valiant amalgam is now ready for immediate placement and condensing. A gentle tap may be required to free amalgam from SURE-CAP capsule. A plastic wafer which contained the mercury before mixing may occasionally be seen. It has no further function and should be discarded.

The triturated amalgam should be bright and have a plastic consistency. If the amalgam is excessively plashy and wet looking and/or sets fast, decrease trituration time or amalgamator speed. A mix that appears dry or grainy indicates that trituration time or amalgamator speed should be increased.

#### CONDENSATION

Immediately condense amalgam after placement of each increment – any delay might sacrifice essential properties of the restoration. To obtain more working time, decrease the trituration time slightly. An overpack of amalgam (1 millimeter) is recommended on occlusal surfaces so that carving will remove the excess portion which contains the highest percentage of mercury, thus leaving a denser material for the exposed surface. Proper adaptation may be obtained by using lower condensation pressures than with conventional amalgams. The most efficient condensing instrument has a smooth surface.

#### CARVING, FINISHING AND POLISHING

A smooth curve may be obtained using conventional instruments. The major portion of finishing is accomplished during the carving procedure. Wait 24 hours before polishing.

#### ATTENTION:

##### 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 vapor.

##### 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.

**CAUTION:** U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED DENTIST.

#### PRECAUTIONS:

- EMPLOY PROPER MERCURY HYGIENE – Refer to American Dental Association Publication, "Recommendations in Dental Mercury Hygiene."
- Slow speed amalgamators are not recommended.
- Prior to use, read the material safety data sheet.
- Use in a well ventilated area.
- Avoid contact with the skin.
- Wear safety glasses and gloves.
- Do not place the device in direct contact with other types of metals.
- Use with adequate ventilation.
- Single-use only.

#### STORAGE:

- Store in a cool, well ventilated place.
- Do not store at temperatures higher than 25°C.



#### WARNING

Device Contains Mercury:  
Toxic by inhalation  
Danger of cumulative effects  
Corrosive to metals



Waste material and all primary containers that hold mercury shall be disposed of as hazardous waste. Refer to safety data sheets. Dispose of used capsules in accordance with national regulations.



ISO 1560: 1985

#### WARNING: THIS PRODUCT CONTAINS MERCURY

- Exposure to Mercury may cause irritation to skin, eyes, respiratory tract and mucous membranes.
- Mercury may also be a skin sensitizer, nephrotoxin, neurotoxin and pulmonary sensitizer.
- This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

#### REGULATORY NOTES: USA

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.

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.

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

Pursuant to Section 21 of the Canadian Medical Devices Regulations, to reduce the risks associated with the handling and use of this device, please be advised of the following:

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.