



INSTRUCTIONS FOR USE

Cavex Avalloy is a high copper alloy of the HighCopperSingleComposition-type. It consists of micro-fine lath-cut particles with a relatively high copper and low silver content. The handling characteristics are comparable to a conventional amalgam: sufficient condensation pressure should be applied.

The amalgam made of **Cavex Avalloy** is free from the corrosion-prone and weak gamma-2 phase. Durable restorations with a lasting lustre can be made.

Alloy composition:	Silver (Ag)	: 45.0% (m/m)
	Tin (Sn)	: 30.5% (m/m)
	Copper (Cu)	: 24.0% (m/m)
	Zinc (Zn)	: 0.5% (m/m)

Cavex Avalloy is in full compliance with the latest version of the ISO24234 and ADA No. 1 specifications. The mercury contained in the pre-dosed capsules is in full compliance with ISO24234.

Indication
Stress-bearing fillings in posterior teeth (Class I and II).

Contraindications
• Use of amalgam is not recommended when a physician has deemed it unsuitable for the patient.

- Use of amalgam is not recommended for the treatment of deciduous teeth, children under 15 years and pregnant or breastfeeding women, except when strictly deemed necessary by the practitioner on the ground of specific medical needs of the patient (from 1 July 2018).
- Hypersensitivity (allergic reaction) to amalgam components.

In such cases the use of suitable alternative materials must be considered.

Warnings
• After placement or removal of dental amalgam restorations increased mercury concentration in blood and urine has been observed. According to available scientific knowledge this increase has not been associated with any adverse health effects.

- If placed in close contact with other metal restorations, galvanic effects may occur. In most cases they will be of short lasting duration. If the effect persists, the user should consider replacement of the dental amalgam filling with another material.
- In individual cases, local mucosal reactions (lichenoid) have been observed. Such local reactions may be of an irritative (mechanical, chemical, electrochemical) or allergic nature. In case of allergy to components of dental amalgam the use of suitable alternative materials must be considered.

- Unnecessary exposure to mercury vapour or dental amalgam particles during handling, placement or removal of dental amalgam should be avoided. Placement and removal of dental amalgam fillings should be performed with appropriate water spray and vacuum suction.
- Instructions and regulations for storage and disposal of dental amalgam waste must be observed.

Directions for use
Mixing
Cavex Avalloy is available as pre-dosed capsules. It should be noted, that the working- and hardening time would be somewhat different, dependent on the type of mixer used: a high energy mixer gives a faster hardening. The mixed amalgam should be a plastic, coherent mass with a shiny surface.

Mixing ratio for Cavex Avalloy IS: 10 parts alloy / 10.3 parts mercury by weight

Cavex Avalloy in all cases 7 - 8 seconds in High-energy mixer (such as Silamat)
- 1-spiil alloy/mercury 400/420 mg)
- 11-spiil alloy/mercury 600/630 mg)
- 111-spiil alloy/mercury 800/840 mg)

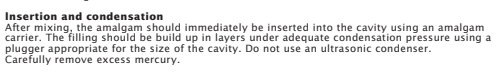
Note:
1. For safety reasons it is best to reclose the empty capsule after taking out the mixed amalgam, before cleaning or disposal.
2. The pre-dosed capsules (Type 1) are self-activating; contact between alloy and mercury occurs immediately after the capsule is subjected to the action of the mixing machine. Length: 32 mm, max. exterior diameter: 14 mm.
3. Storage at temperatures no higher than 25°C is recommended.
4. Dispose of cotton wool and used capsules in accordance with national regulations.

Insertion and condensation
After mixing, the amalgam should immediately be inserted into the cavity using an amalgam carrier. The filling should be build up in layers under adequate condensation pressure using a plugger appropriate for the size of the cavity. Do not use an ultrasonic condenser. Carefully remove excess mercury.

Finishing and polishing
Approx. 8-10 minutes after mixing, the filling can be finished. Polishing should be done in a subsequent session.

"THIS ALLOY CONTAINS ZINC; THE AMALGAM MADE THEREFROM MAY SHOW EXCESSIVE EXPANSION IF MOISTURE IS INTRODUCED DURING MIXING OR COMPACTING"

Labelling
This information is in compliance with ISO24234 and also with European legislation.



MERCURY DANGER
• May impair fertility or cause harm to an unborn child.
• Lethal if inhaled.
• Causes damage to organs in case of long-term or repeated exposure.
• Highly toxic to aquatic organisms, may cause long-term adverse effects.

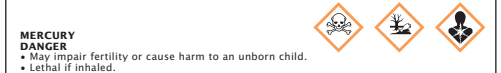
Recommendations for safety precautions
Dental clinical personnel, when using silver amalgam, should exercise proper procedures to avoid personal contact with mercury. Precautions should be taken to avoid exposure to mercury vapour in the dental environment. Waste amalgam should be collected for disposal in a manner, which will protect both those who handle the waste and the environment.

1. Treat mercury and amalgam with care. BE MERCURY-AWARE.
2. Ideally a high-energy mixer should be equipped with a protective cap to cover the capsule whilst mixing.
3. Small droplets of spilled mercury can be collected with the aid of a mercury-collecting device or a small amount of freshly mixed amalgam that will easily absorb liquid mercury. NEVER use a vacuum cleaner!
4. Placement and removal of amalgam fillings must be done under water-cooling and with effective vacuum suction. The use of eye protection and mouth mask is advisable.
5. The wastewater drain of the spittoon should be equipped with an amalgam separator. **Local regulations on type and installation of such a separator and handling/recycling of the amalgam waste should be taken into consideration.**
6. Excess mixed amalgam should be kept in a container, designed for the purpose, or at least in a closed container filled with photographic fixer.

Finition et polissage
L'obturation peut être finie environ 8 à 10 minutes après le mélange. Il est recommandé d'effectuer le polissage lors d'une séance ultérieure.

"CET ALLIAGE CONTIENT DU ZINC. L'AMALGAME PEUT DONC MONTRER UNE EXPANSION EXCESSIVE SI DE L'HUMIDITE EST INTRODUITE PENDANT LE MELANGE OU LA COMPACTATION"

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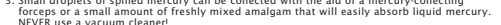
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MODE D'EMPLOI

Cavex Avalloy es un aleación de alto contenido en cobre de tipo HighCopperSingleComposition. Se compone de partículas en copeaux microfinos así como de un contenido relativamente alto de cobre y bajo platino. Las características de uso son comparables a las de una amalgama convencional: debe realizarse la suficiente presión de condensación.

L'amalgame réalisé avec du **Cavex Avalloy** est libre de toute phase gamma-2, phase faible et sujette à la corrosion. Il est possible de réaliser une obturation solide avec un lustre durable.

Composition de l'alliage:	Argent (Ag)	: 45.0% (m/m)
	Étain (Sn)	: 30.5% (m/m)
	Cuivre (Cu)	: 24.0% (m/m)
	Zinc (Zn)	: 0.5% (m/m)

Cavex Avalloy est en totale conformité avec les dernières versions des normes ISO 24234 et ADA n°1. Le mercure contenu dans les capsules pré-dosées est en totale conformité avec la norme ISO 24234.

Indication
Obturations soumises à des charges occlusales importantes dans les dents postérieures (Classe I et II).

Contre-indications
• L'usage de l'amalgame n'est pas recommandé lorsqu'un médecin l'a jugé inadapté pour le patient.

- L'utilisation d'amalgames est déconseillée pour le traitement des dents de lait, des enfants de moins de 15 ans et des femmes enceintes ou allaitantes, sauf le dentiste le juge strictement nécessaire en raison de besoins médicaux spécifiques du patient (à partir du 1er juillet 2018).
- Hypersensibilité (réaction allergique) aux composants de l'amalgame.

Dans des tels cas, il faut éviter l'usage de matériaux alternatifs adaptés à la situation.

Précautions
• Il faut observer après placement ou enlèvement de restaurations en amalgame une augmentation de la concentration en mercure dans le sang et les urines. Au vu des connaissances scientifiques disponibles à l'heure actuelle, cette augmentation n'est pas en corrélation avec un effet néfaste quelconque pour la santé.

- Si on place l'amalgame en contact étroit avec d'autres restaurations métalliques, il peut se produire un effet galvanique. Dans la plupart des cas, cet effet sera de courte durée. Si le patient se plaint, le praticien devrait considérer le remplacement de la restauration en amalgame par un autre matériau.

Dans certains cas individuels, des réactions muqueuses locales (lichenoides) ont été observées. De telles réactions locales peuvent être de nature irritative (mécanique, chimique, électrochimique) ou allergique. Dans le cas d'allergie à un des composants de l'amalgame, il faut éviter l'usage de matériaux alternatifs adaptés à la situation.

- Il faut éviter toute exposition inutile aux vapeurs de mercure ou particules d'amalgame dentaire se produisant pendant la manipulation, le placement ou l'enlèvement d'amalgame. Le placement et l'enlèvement de restaurations en amalgame devrait être effectué avec un spray et une aspiration à haute vitesse appropriés.
- Il faut observer les instructions et les règlements concernant le stockage et l'élimination des déchets d'amalgame.

Mode d'emploi
Mélange
Cavex Avalloy est disponible sous forme de capsules prédosées. Il convient de noter que les temps d'utilisation et de prise peuvent varier en fonction du type de vibreur utilisé: un vibreur à haute énergie assure une prise plus rapide. L'amalgame mélangé doit être une masse plastique, cohérente à surface brillante.

Les proportions de mélange pour Cavex Avalloy sont les suivantes : 10 parts d'alliage / 10.3 parts de mercure en poids

Cavex Avalloy dans tous les cas 7 à 8 secondes dans un mézclador à haute énergie (tels que Silamat)
- 1-spiil (aléacion/mercurio 400/420 mg)
- 11-spiil (aléacion/mercurio 600/630 mg)
- 111-spiil (aléacion/mercurio 800/840 mg)

Note:
1. Pour des raisons de sécurité, il est préférable de refermer la capsule après en avoir extrait l'amalgame mélangé, avant de la nettoyer ou de la jeter.
2. Les capsules pré-dosées (Type 1) sont auto-activées: le contact entre l'alliage et le mercure s'effectue automatiquement lorsque la capsule est soumise à l'action du mélangeur. Longueur: 32 mm, diamètre extérieur maximal: 14 mm.
3. Il est recommandé de ne pas stocker l'amalgame à des températures supérieures à 25°C.
4. Jeter les tissus de coton et les capsules usagées en accord avec les règlements nationaux.
5. Sur le marché français, seules sont disponibles les capsules pré-dosées.

Insertion et condensation
Après mélange, l'amalgame doit directement être inséré dans la cavité à l'aide d'un porte-amalgame. L'obturation doit être faite en plusieurs couches successives, sous pression de condensation suffisante et en utilisant un fouloir de taille appropriée à la cavité. Ne pas utiliser de condensateur à ultras-sons. Enlever soigneusement l'excès de mercure.

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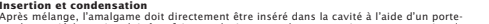
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2. Ideally a high-energy mixer should be equipped with a protective cap to cover the capsule whilst mixing.
3. Small droplets of spilled mercury can be collected with the aid of a mercury-collect

