

Instructions For Use

Cavex Non Gamma-2

CE 0197

Product description

Cavex Non Gamma-2 is a dispersed phase amalgam alloy: a mixture of lathe-cut particles and microfine eutectic spherical particles. The handling characteristics are comparable to a conventional amalgam: sufficient condensation pressure should be applied.

Composition

The overall chemical composition of Cavex Non Gamma-2 is as follows:

silver	: app. 69.2 %
tin	: app. 18.6 %
copper	: app. 11.9 %
zinc	: app. 0.3 %

The recommended mixing ratio is: 10 parts of alloy to 10.7 parts of mercury.

Indication for use

Dental Amalgam is used for restorative purposes, stress-bearing fillings in posterior teeth (Class I and II)

Contra-indications & Warnings

Contra-indications:

- 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 the 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 effects 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.

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Handling:

Directions for use

Mixing:

Cavex Non Gamma-2 is available as pre-dosed capsules. It should be noted, that 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 Non Gamma-2 is: 10 parts alloy / 11 parts mercury by weight.

Cavex Non Gamma-2 in all cases 5 – 7 seconds in High-energy mixer (such as Silamat)

- I-spill (alloy/mercury 400/435 mg)
- II-spill (alloy/mercury 600/653 mg)
- III-spill (alloy/mercury 800/865 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 automatically when the capsule is subjected to the action of the mixing machine. Length: 32mm, max. exterior diameter: 14mm.
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.

Labelling:

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

<p>MERCURY DANGER</p> <ul style="list-style-type: none">• 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.	
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Intended Patient(s)

Dental amalgam is used for restorations in posterior teeth. It can be used for any patient suffering from defective dental elements due to caries. Dental amalgams are not recommended to be used on 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).

Intended User(s)

Cavex Amalgams will only be used by dental professionals (dentist).

Clinical benefits

Cavex Non Gamma-2 is a modern dispersed phase high-copper alloy. The copper content is substantially higher than that of conventional alloys. The composition chosen means, that this product belong to the group of non gamma-2 alloys. This indicates, that the mechanically weak and corrosion prone gamma-2 phase will not be present. This is why they excel in a high mechanical strength, low creep and high corrosion resistance.

Claims

- High silver content
- Durable – long term restorations
- Easy to process
- Short curing time

Product characteristics and specifications

Cavex Non Gamma-2 is in full compliance with EN ISO 24234:2021 "Dental Amalgam".

Characteristic	EN 24234	Cavex Non Gamma-2	
Working time	--	3	min.
Setting time	--	8	min.
Compressive strength			MPa
- 2h.	>100	160	
- 24h.	>350	>400	
Dimensional change	-0,10 +0,15	+0,1	%
Creep	Max 2,0	0,6	%
Foreign materials	Must comply	Must comply	
Corrosion resistance	>80	82	%

Accessories used in combination:

The self-activating capsules are mixed in Amalgamator mixing devices. The amplitude, frequency and mixing time will influence the behaviour and quality of the amalgam restoration. Therefore, information on mixing in different mixing devices is essential information provided by the manufacturer of amalgam.

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Combination products:

Combination with resin bond is sometimes used in order to minimize microleakage and increase the tensile bond strength to the tooth structure. For correct application the instruction of the manufacturer should be followed.

Special advice

According to EU Medical Device Regulation users/ patients are obliged to report serious incidents with a medical device to the manufacturer and to the competent authority of the country, the incident occurred.

Storage advice

Do not store at temperatures higher than 25°C (77°F). Do not use this material beyond its expiry date. Avoid direct exposure to sunlight. Close containers firmly after use and keep out of reach of children.

Disposal information

Dispose of in accordance with local regulations. Do not dispose of contents or partially emptied packaging in household waste or allow them to enter the sewage system.

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Made in The Netherlands

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Version: ZL709.16

Date: 03-06-2024