



Starburst 45 Capsules

Instructions for Use

INTRODUCTION

Starburst 45 is a high copper alloy of the High Copper Single Composition-type. It consists of micro-fine lathe-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 from Starburst 45 is free from the corrosion-prone and weak gamma-2 phase. Durable restorations with a lasting lustre can be made.

Silver (Ag): 45.0% (m/m) Alloy composition:

Tin (Sn): 30.5% (m/m) Copper (Cu): 24.0% (m/m) Zinc (Zn): 0.5% (m/m)

Starburst 45 is in full compliance with EN ISO 24234:2015.

INDICATIONS

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

CONTRA-INDICATIONS

- Use of amalgam is not recommended when a physician has deemed it unsuitable for the patient.
- Hypersensitivity (allergic reaction) to amalgam components. In such cases the use of suitable alternative materials must be considered.
- In deep cavities a liner should be used.
- Not suitable where aesthetics is of prime importance.
- Retrograde root canal fillings.









- After placement or removal of dental amalgam restorations increased mercury con centration 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.
- There are no proven adverse effects on the foetus associated with the placement or presence of dental amalgam fillings in the mother. It is sensible however, where clinically feasible, to minimise health interventions during pregnancy and avoid any unnecessary chemical exposure to the foetus. This precaution should be observed with the use of all dental materials.
- 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.

 $\textbf{Note:} \ \mathsf{For} \ \mathsf{retrograde} \ \mathsf{root} \ \mathsf{canal} \ \mathsf{fillings}, \mathsf{zinc-free} \ \mathsf{amalgam} \ \mathsf{is} \ \mathsf{recommended}.$ Storage at temperature no higher than 25°C is recommended. Dispose of cotton wool and used capsules in accordance with national regulations.

CAVITY PREPARATION

In order to obtain the best results, correct cavity preparation with adequate undercuts and insulated lining is essential. Always keep the working area dry.

PROPORTIONS AND PRESENTATION

400mg alloy and 420mg mercury per capsule Size 1 600mg alloy and 630mg mercury per capsule Size 2 800mg alloy and 840mg mercury per capsule

The ratio of alloy to mercury is 1:1.1 by mass. Capsule length is 32mm and maximum exterior diameter is 14mm.

The vibration time in a Silamat is approximately 7-8 seconds depending on the machine concerned. The amalgamation speed should be the standard machine setting. Other amalgamators may be suitable and should be used according to the instructions of the machine manufacturer. Insert the safety capsule into the amalgamator and vibrate as above.

Note: For safety reasons it is best, after taking out the mixed amalgam and before cleaning or disposal, to re-close the empty capsule.

The pre-dosed capsules are self-activating: contact between alloy and mercury occurs automatically when the capsule is subjected to the action of the mixing machine. When mixed dispense into Dappen dish.

PACKING, CONDENSING AND CARVING

Pack the amalgam immediately after mixing using multiple mixes for large restorations. Expel the mercury after packing each portion. Use small faced pluggers to pack into angles and undercuts followed by successively larger pluggers as the filling is built up. Express as much mercury as possible from each layer during packing. Over pack well above the margin, carve to occlusion, trim margins and remove cervical overhangs.

Approximate time limit for packing is 3 minutes. The filling can be polished approximately 8-10 minutes after mixina.

FINISHING AND POLISHING

The best surface is obtained by burnishing after carving. It is unnecessary to polish. "THIS ALLOY CONTAINS ZINC; THE AMALGAM MADE THEREFROM MAY SHOW EXCESSIVE EXPANSION IF MOISTURE IS INTRODUCED DURING MIXING OR COMPACTING³

HEALTH AND SAFETY

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.

- Treat mercury and amalgam with care. Be MERCURY-AWARE.
- Ideally a high-energy mixer should be equipped with a protective cap to cover the capsule whilst mixing.
- Small droplets of spilled mercury can be collected with the aid of a 'mercury-collecting forceps' or a small amount of freshly mixed amalgam that will easily absorb liquid mercury. NEVER use a vacuum cleaner!
- 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. 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.

Warnings: H330 Fatal if inhaled. H360D May damage the unborn child. H372 Causes damage to organs through prolonged or repeated exposure. H410 Very toxic to aquatic life with long-lasting effects.

Precautions: P101 If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children. P103 Read label before use. P260 Do not breathe dust/fumes/gas/mist/vapours/spray. P284 (In case of inadequate ventilation) wear respiratory protection. P310 Immediately call a POISON CENTER/doctor. P320 Specific treatment is urgent (see on this label). P405 Store locked up. P501 Dispose of contents/container in accordance with local regulation.

Technical advice, whether verbal, in writing or by way of trials, is given in good faith but without warranty, and this also applies where proprietary rights of third parties are involved. It does not release you from the obligation to test the products supplied by us as to their suitability for the intended processes and uses. The application, use and processing of the products are beyond our control and, therefore, entirely your own responsibility. Should, in spite of this liability be established for any damage, it will be limited to the value of the goods delivered by us and used by you. We will, of course, provide consistent quality of our products within the scope of our Conditions of Sale.



LOT NUMBERS

The Lot number is are shown on all containers.

STORAGE

Store in a cool dry place away from direct sunlight at a temperature of less than 25°C.

This product is specifically formulated for use in dentistry.

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