

## Starburst Alloy Safety Capsules

### Instructions for Use

#### INTRODUCTION

Starburst is a high copper non-gamma II type amalgam alloy according to EN ISO 24234:2004. Capsules conform to EN ISO 13897:2004. Read full directions including: PRECAUTIONS, SIDE EFFECTS and INTERACTIONS before use.

#### INDICATIONS

The restoration of all classes of cavity in posterior teeth, when other restorative materials or restoration techniques are not indicated.

#### CONTRA-INDICATIONS

1. In deep cavities a liner should be used.
2. Not suitable where aesthetics is of prime importance.
3. In case of allergic reaction to the components of this alloy or to amalgam of similar composition.
4. No new amalgam restoration should be placed in pregnant women or in patients suffering from severe kidney dysfunction.
5. Retrograde root canal fillings.

Since small children exhibit increased sensitivity to mercury, it should be carefully evaluated in the light of current Department of Health advice whether or not to place amalgam restorations in children's teeth.

#### CAVITY PREPARATION

In order to obtain the best results, correct cavity preparation with adequate undercuts and insulated lining is essential. Starburst Alloy is zinc free. However always keep the working area dry.

#### PROPORTIONS AND PRESENTATION

Code 124 Size 1 400mg alloy and 420mg mercury per capsule  
Code 125 Size 2 600mg alloy and 630mg mercury per capsule  
Code 126 Size 3 800mg alloy and 840mg mercury per capsule  
The ratio of alloy to mercury is 1:1.05 by mass.  
The alloy powder contains 45% silver, 3% tin, 24% copper and contains spherical and lathe-cut particles.  
Capsule length is 30.5mm and maximum exterior diameter is 11.6mm.

#### MIXING

The vibration time in a Silamat is approximately 5-7 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. When mixed snap open with the breaker rod supplied and dispense into Dappen dish.

#### PACKING AND CONDENSING

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. Automatic condensing may be used if desired. Correctly mixed amalgam will form a silvery, pliable and cohesive mass without any further processing. If necessary, gently tap the capsule to dislodge any material that is trapped within the capsule.

#### CARVING TIME

Approximate carving time limit is:  
Regular set 5 minutes

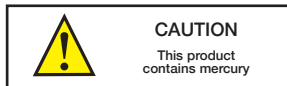
#### FINISHING AND POLISHING

The best surface is obtained by burnishing after carving. It is unnecessary to polish but if so it should be done at the earliest after 24 hours. Permanent and sufficient water cooling is necessary.

#### PRECAUTIONS

Starburst alloy possesses exceptionally high early strength. However the patient should be advised not to exert undue pressure for the first 1-2 hours. Keep cavity dry. Do not mill in contact with skin. The number of amalgam restorations for one patient should be kept to a minimum. Inhalation of mercury vapour by dental staff must be avoided by proper handling of the amalgam and the use of masks, along with adequate ventilation. Avoid contact with the skin and wear safety glasses and gloves. Mixing time and speed essentially influence the consistency of the amalgam. Restoring the cavity without adequate pulp/dentine protection, especially if deep or medium deep cavities have not been lined, may lead to irritations of the pulp. Pressing Amalgam into the sulcus gingivae during condensation of the restorative material leads to damage of the tooth retaining tissues in this area.

According to the present level of knowledge, there is no proof of risks of embryo-fœtal toxicity caused from presence / placement and / or removal of amalgam restorations. It is, however, recommended not to have an extensive amalgam therapy, placement and especially removal of amalgam restorations) during pregnancy. In some instances local reactions of the mucosa have been observed. These could be irritations or allergic reactions. In case of allergy to components of dental amalgam, the use of suitable alternatives materials must be considered.



 Refer to Safety Data Sheet.

#### 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 sulphur powder and removed. Avoid inhalation of the vapour.

#### Moisture contamination

If moisture is introduced into the amalgam before it has set, properties such as strength and corrosion resistance may be affected adversely. Whenever it is possible use a dry field. Store amalgam scrap in well sealed containers. Regulations for disposal must be observed.

#### STORAGE

P102 Keep out of reach of children. Keep in a cool place. Maximum recommended storage temperature 25°C. Replace lid immediately after use. P233 Keep container tightly closed.

#### SIDE EFFECTS

Prior to use, read health and safety datasheet and this direction for use. Avoid inhalation of mercury vapours. Exposure to mercury may cause irritation to skin, eyes, respiratory tract and mucous membrane. In individual cases, hypersensitivity reactions, allergies or electrochemically caused local reactions have been observed. Mercury may also be a skin sensitiser, pulmonary sensitiser, nephrotoxin and neurotoxin. Allergic reactions of type IV and/or electrochemical reactions (e.g. taste sensations and irritations of the mucous membrane) have been shown in research to occur infrequently. Electrochemical processes may provoke lichen planus of the oral mucosa. After the placement or removal of amalgam fillings a slight increase of the mercury concentration in the blood or the urine can be observed for a limited period of time.

#### INTERACTIONS

Amalgamation and subsequent electrochemical reaction may occur when unset silver amalgam or, in particular mercury which has been expressed during condensation, comes into contact with gold or other precious metal (restorations or dentures).

Contact between the occlusal or any lateral surface and adjacent crowns, bridges, inlays or fillings made of different alloys may lead to galvanic effects (caused by corrosion).

Electrochemical reactions due to contact of the amalgam filling with other alloys may cause local unpleasant sensations (e.g. taste). If this occurs for more than a short period of time then the amalgam filling should be replaced with a different material.

#### REMOVAL OF AMALGAM FILLINGS

**Removal of clinically acceptable amalgam restorations especially in expectant mothers should be avoided so as to minimize mercury exposure.**

Appropriate precautionary measures when removing amalgam restorations, such as using aspirators, rubber dam, water spray, keeping the surgery ventilated, disposing of amalgam residues according to official guide lines and best practice will reduce the danger due to possible exposure to mercury to the health of patients and surgery staff.

#### HEALTH AND SAFETY

The capsules contain mercury in maximum 1 gram size sealed sachets and alloy powder. Do not open until after mixing. Do not inhale vapours. In case of accidental opening do not inhale powder dust. H331 Toxic by inhalation. H373 Warning cumulative effects. P102 Keep out of the reach of children.

P233 Keep container tightly closed. S3 Keep in a cool place. P309/P311 If exposed or if you feel unwell immediately call a poison centre or doctor/physician. H410 Very toxic to aquatic life with long lasting effects. P501 Dispose of contents and container in accordance with all local, regional, national and international regulations.

**For further information request a safety data sheet.**

#### LOT NUMBERS

The lot number is shown on all containers.  
This product is specifically formulated for use in dentistry.

*Starburst is an internationally registered trademark of Davis Schottlander & Davis Limited.*