HENRY SCHEIN®

AMALGAM NON GAMMA 2

INSTRUCTIONS FOR USE

GEBRAUCHSINFORMATION

Item codes:

900-2128 1 spill
900-2129 2 spill
900-2130 3 spill

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Gebrauchsinformation

Indikation
Okklusionsbelastete posteriore Restaurationen (Klasse I und II), wenn andere Materialien oder Versorgungen nicht indiziert sind

Gegenanzeigen
Nicht bei Patienten mit starker Nierenschädigung oder bekannter Allergie gegen einen der Bestandteile anwenden. Amalgam ist ungeeignet für retrograde oder endodontische Füllungen, sowie als Stumpfaufbaumaterial und Füllungsmaterial für Gußkronen.

Nebenwirkungen
In Einzelfällen wurden Überempfindlichkeitsreaktionen (Allergien) und/oder elektrochemische Reaktionen (z.B. Geschmackssensationen und Irritationen der Schleimhaut) beschrieben. Nach dem Legen oder Entfernen von Amalgamfüllungen kommt es kurzfristig zu einem geringen Anstieg der Quecksilberkonzentration im Blut oder Urin. Entsprechend dem gegenwärtigen Stand der Wissenschaft ist dieser Anstieg nicht mit gesundheitsschädlichen Wirkungen verbunden.

Wechselwirkungen
Bei approximalem oder antagonistischem Kontakt zu Kronen, Brücken, Inlays oder Füllungen aus anderen Legierungen können galvanische Effekte auftreten. In den meisten Fällen sind diese nur von kurzer Dauer. Sollte der Effekt anhalten, ist der Ersatz der Amalgamfüllung durch ein anderes Material zu erwägen.

Anwendung
In die (z.B. mit Kofferdam) trockengelegte Kavität (ein geeigneter Pulpenschutz ist erforderlich) wird das noch plastische Amalgam portionsweise eingebracht und kondensiert. Die Kondensation im Bereich approximaler Kavitätenteile erfordert die Anwendung eines geeigneten Matrizensystems.
Die Kavität wird zunächst etwas überfüllt, dann wird der Quecksilberreiche Überschuß abgetragen und die Füllung konturiert.

Okklusionsprüfung
Eine Okklusionsprüfung wird mit Artikulationsstreifen (Blaupapier, Okklusationsfolie, etc.) durchgeführt.

Politur
Die endgültige Politur erfolgt in der Regel frühestens nach einem Tag. Hierbei ist auf eine ständige und ausreichende Spraykühlung zu achten.

Haltbarkeit
Die Haltbarkeit des ungemischten Materials beträgt 5 Jahre. Das Produkt nach Ablauf des Verfallsdatums nicht mehr verwenden.

Hinweise
Nach dem Füllen mit Amalgam ohne geeigneten Pulpa-Dentinschutz insbesondere bei fehlender Unterfüllung in tiefen oder mittleren Kavitäten können Irritationen der Pulpa auftreten. Das Hineinpressen von Amalgam bei der Kondensation mehrflächiger Füllungen in den Sulcus Gingivae führt zur Erkrankung/Zerstörung des Zahnhalteapparates in diesem Bereich. Nach derzeitigem wissenschaftlichen Erkenntnisstand gibt es keine Beweise für embryo-fetaltoxische Risiken durch das Vorhandensein/Legen und/oder Entfernen von Amalgamfüllungen. Es wird jedoch empfohlen, keine umfangreiche Amalgamtherapie (Legen und insbesondere Entfernen von Amalgamfüllungen) während der Schwangerschaft durchzuführen. Im Fall einer Allergie gegen Bestandteile von Amalgam muß eine geeignete Alternative in Betracht gezogen werden.
Beim Umgang, Legen oder Entfernen von Amalgam sollte unnötiger Kontakt mit Quecksilber-Dampf vermieden werden. Das Legen und Entfernen von Amalgamfüllungen mit geeignetem Wasserspray und Absaugen durchführen.
Die entsprechenden Lagerungs- und Entsorgungsvorschriften für Amalgamabfälle sind zu beachten.

Instructions for use

Indications
Stress bearing restorations in posterior teeth (Class I and II) if other restorative materials or restoration techniques are not indicated

Contraindications
Do not use on patients with severe renal deficiency or known allergies to any of the ingredients.
Amalgam is unsuitable for retrograde or endodontic restorations, as a core build-up material and as a restorative material for cast crowns.

Side effects
In individual cases, hypersensitive reactions (allergies), or electrochemically caused local reactions (taste sensations and irritation of the mucosa) have been observed. After placement or removal of dental amalgam restorations increased mercury concentration in blood or urine has been observed. According to available scientific knowledge this increase has not been associated with any adverse health effects.

Interactions with other materials
If there is contact (approximal or antagonistic) to crowns, bridges, inlays or restorations of other alloys galvanic effects can occur. In most cases they will be of short lasting duration. If the effect persists the user should consider replacement of the dental amalgam restoration with another material.

Dosage
The amount of amalgam to be mixed depends on the size of the cavity.

Application
Small portions of the amalgam are packed into the dry (e.g. with rubber dam) cavity while still in a pliable condition (an appropriate pulp protection is necessary) and condensed. The condensation in approximal cavity areas requires the use of an appropriate matrix system.
The cavity is overfilled, the mercury-rich surplus material is removed and the restoration is shaped.

Occlusial examination
Articulating paper is used to examine the occlusion.

Polishing
As a rule final polishing is done after one day. Permanent and sufficient cooling with water spray is necessary.

Shelf life
The shelf life of the unmixed material is 5 years. Do not use after expiry date.

Notes
Filling the cavity without a suitable pulp/dentin protection may irritate the pulp. This applies especially to deep or medium deep cavities, which have not been lined. 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 for risks of embryo-fetal toxicity caused from presence/application and/or removal of amalgam restorations. It is recommended not to have an extensive amalgam-therapy (placement and especially removal of amalgam restorations) during pregnancy. In the 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 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 for AMALGAMS: Proposal for amalgams distributed according to the regulations of the Medical Device directive (CE marked product), Draft April 1999

Indications for use

Amalgam should only be used in stress bearing restorations in posterior teeth (Class 1 and 2) if other restorative materials or restoration techniques are not indicated.

Contraindications

Do not use on patients with severe renal deficiency or known allergies to any of the ingredients.
Amalgam is unsuitable of retrograde or endodontic fillings, as a core build-up material and as a filling material for cast crowns.

Precautions

Because of the possible harmful effects of exposure to mercury, the use of amalgam in young children and expectant mothers is not recommended. The removal of clinically acceptable amalgam restorations should also be avoided to minimise mercury exposure. For preventative health reasons the number of amalgam restorations for one patient should be kept to a minimum since every amalgam restoration contributes to the mercury load.
Inhalation of mercury vapour by dental staff may be avoided by proper handling of the amalgam. After processing, amalgam residues should be stored under water in well-sealed containers. Good practice ventilation is important.

Side Effects

In individual cases, hypersensitive reactions (allergies), or electrochemically caused local reactions (taste sensations and irritation of the mucosa) have been observed.
After the placement or removal of amalgam restorations, there is a temporary increase of the mercury concentration in the blood and urine.
Due to electrochemical processes, the lichen planus of the mucosa may develop.
Mercury expressed during condensation and unset amalgam may cause amalgamation and galvanic effects if in contact with other metal restorations. If symptoms persist, the amalgam filling should be replaced with a different material.

Taken from: "Dental Amalgam", A Report from an Ad-Hoc Working Group, October 1998

9. Information supplied by the Manufacturer
9.1 Requirements in the Medical Devices Directive and in the relevant standards
According to the Medical Devices Directive each device must be accompanied by the information needed to use it safely, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use and can be linked to the general essential requirement of the Directive at Annex 1, paragraph 1.2 that the solutions adopted by the manufacturer (in the design and construction of the devices) must conform to safety principles amongst which is a need to `inform users of the residual risks due to any shortcomings of the protection measures adopted´.
As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself or on the packaging for each unit, or both, or where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class 1 or IIa if they can be used safely without any such instructions. Dental filling materials currently fall under class IIa, however we return to this later.
Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbol and colours must be described in the documentation supplied with the device.
In line with the essential requirements at Annex 1 of the MDD are the European standards EN 980 (graphical symbols for use in the labelling of medical devices) and prEN 1041 (information supplied by the manufacturer with medical devices).

The label shall bear the following minimum information, which is derived from the Directive, and further developed in prEN1041 and specified for dentistry in EN 1641:
a. the name or registered trade mark and address of the manufacturer. In the case of imported restorative materials the name and the authorised representative of the manufacturer in the community or the importer;
b. a description of the contents, including name, quantity, form (for example powder, liquid, paste) shade where appropriate, and the principal chemical constituents in order to identify the type of material;
c. the batch code, preceded by the word `LOT´ or the symbol LOT related to the records of raw materials, manufacture and packaging;
d. where appropriate, the expiry date expressed in accordance with the relevant standard;
e. if the device is intended for clinical investigations, the words `exclusively for clinical investigations´;
f. any special storage and/or handling conditions;
g. any warnings and/or precautions to take.

9.1.1 Information to the patient and the user

The group considered that the information supplied by the manufacturer about dental amalgam should be made in the context of considerations concerning information supplied on all materials substituting lost tooth substance. As the dental professional is responsible for providing the patient with the relevant information, he or she must have sufficient information from the manufacturer to be able to discuss the choice of material and choose the optimum material for the individual patient to each occasion of treatment. For example there must be information about the inclusion of substances that may cause an allergic reaction.
Besides the information supplied by the manufacturer the material of choice should be based upon the knowledge expertise and experience of the dental professional and the information given on health status by the patient (or their carer). Treatment decisions should be made with the informed consent of the patient.
Therefore, in this context and irrespective of the classification within the MDD, our group considered that all dental restorative materials should be accompanied by instructions for use.

9.2 Additional information

Formal and technical details will to some extent be particular for each material. In the context of biocompatibility and safety some information is general for all dental amalgam products. To encourage uniformity he group suggested that the following is reflected in the instruction leaflet:
- In the course of risk management comprehensive information of the components of the filling material is highly desirable. As an example we would point out that a list of elements present in the alloy in concentrations greater than 0.1% m/m has to be marked on the container to conform with standard EN 21559.
- 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 the case of allergy to components of dental amalgam the use of suitable alternative materials must be considered.
- 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 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 fetus associated with the placement o 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 of the fetus. This precaution should be observed with the use of all dental materials.
- 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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