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SHERAALLOY-NP

INSTRUCTIONS FOR USE

MD CE 0123

Precious metal bonding alloy based on cobalt for PFM restorations, type 2–4, cylindrical

1. Indications

Biocompatible casting alloy with minimal oxide formation for the fabrication of individual restorations based on the clinician's specifications such as crowns and bridges. Can be veneered with all suitable ceramic materials that are compatible with the CTE of the alloy. SHERAALLOY-NP is a class IIa medical device as defined by Directive 93/42/EEC and satisfies the requirements of DIN EN ISO 9693 & DIN EN ISO 22674. It is characterised as "free from nickel and beryllium". For use by qualified personnel. Wall thicknesses, bond strengths and construction are subject to their experience.

2. Instructions for the clinician

Prepare as a chamfer or rounded shoulder with 1 mm contact surface. Remove the substance occlusal and incisal 1.5–2 mm, edge radius 0.7 mm, preparation angle 6–8°. Ensure the final wall thickness is at least 0.2 mm; we recommend a wall thickness of 0.35 mm.
Before placing the dental restoration in the mouth, it must be cleaned and disinfected according to good clinical technical practice. Cementation is performed with conventional cements or glass ionomer cement with a minimum length of the preparation of 3 mm.

3. Contraindication / adverse effects

In rare, isolated cases, allergies to components of the alloy or electrochemically induced paraesthesia are possible. In case of known allergies or incompatibilities to alloy components, the alloy should not be used. In rare cases, cobalt-based alloys may cause skin irritation in susceptible persons. A patch test is recommended. Prepared tooth stumps with a length < 3 mm are not suitable for treatment.

4. Safety instructions

Metal dust and vapour are harmful to health. When grinding and blasting, use an appropriate extraction system. We also recommend using type FFP3-EN149 respiratory protection.
Carefully note the presence of other metals in the oral cavity before inserting the dental restoration. Different metals can lead to electrochemically induced paraesthesia.
It is recommended that patients are made aware of the possibility that dental alloys can affect MRI results.

5. Processing instructions

Wax-up / spruing

During wax-up ensure that the cross-section is appropriate and that the finished work will have a wall thickness of 0.35 mm.
For bridge constructions the connectors must be adequately dimensioned and, if necessary, reinforced minimally by scalloping.
The frame must be fabricated to support ceramic. Attach the sprue according to standard dental technical rules with a sufficiently sized sprue system.

Investing / preheating

Only use phosphate-bonded investment materials. Follow the instructions of the investment manufacturer.
We recommend a preheating temperature of 850°C to 900°C for 30–45 minutes.

Crucible

Only use clean ceramic (magnesium, silicon, aluminium oxide) crucibles with a separate crucible for each alloy. To prevent contamination, do not use flux or melt in a graphite crucible.

Only use new metal

With repeated melting, the essential formation of bonding oxides and a good metal-ceramic bond cannot be assured.

Induction casting / high-frequency method

Pre-melt the metal until it collapses. Insert the muffle into the casting unit and then continue melting until the molten metal starts to move. Start the casting immediately after the oxide skin tears open.

Flame casting

Melt the metal with propane/oxygen or acetylene/oxygen in the low-oxygen flame zone. The optimal casting time is when the molten metal develops a honey-like consistency and can be moved by the flame.

Deflasking

The best alloy structures are achieved if the muffle is allowed to cool down slowly to room temperature. Remove larger residues of investment material using deflasking pliers. Do not strike the cone. Then blast with aluminium oxide of 110 to 250 µm with a pressure of 3–4 bar.

Trimming

Process with tungsten carbide burs and aluminium oxide stones. To avoid contamination, the same set of grinding tools should always be used for each metal.

6. Ceramic firing

Oxidation firing is recommended and should be carried out at 960°C for 5 minutes. Before veneering, blast with 100–250 µm single-use aluminium oxide abrasive with a maximum pressure of 3–4 bar and clean thoroughly with water or a steam-jet unit. Never pickle precious metal alloys. Ceramic firing and cooling must be carried out according to the manufacturer's instructions.

7. Technical specifications

Vickers hardness HV10 (N/mm^2)	280
Density (g/cm^3)	8.3
0.2% yield strength (N/mm^2)	490
Elongation after fracture (%)	10.1
Young's modulus (N/mm^2)	210,000
Coefficient of thermal expansion (20/600°C)	$14.0 \times 10^{-6}\ K^{-1}$

8. Temperatures (°C)

Preheating temperature of muffle	850–950
Solidus	1310
Liquidus	1370
Casting temperature	1430

9. Material composition (%)

Cobalt	63
Chromium	24
Tungsten	8.1
Molybdenum	2.9
Silicon	1.1
Other elements less than 1%	Nb

10. Soldering / laser welding

Avoid soldering / laser welding. When necessary, use a flux, solder or laser welding wire that is suitable for the composition and melting range.
Never use gold or palladium solders.

11. Storage

Store in a dry place between 5°C and 50°C in the original packaging and keep away from direct sunlight. Visually inspect the label applied to the cylinders to check the product identification before use.

12. Batch tracing:

Every batch is supplied by us with a batch number (LOT). Record this number in the documentation for each patient to ensure batch tracing.
For precise batch tracing only use new metal.

13. Disposal

Dispose of contents / container in accordance with local regulations.

14. Warranty

SHERA Werkstoff-Technologie GmbH & Co. KG is certified according to DIN EN ISO 13485 and guarantees flawless quality of the products based on its thorough quality assurance system. Our usage recommendations are based on guidelines determined in our test laboratory. These values can only be guaranteed if the procedural steps as described are adhered to. The user is responsible for processing the products. No liability is assumed for faulty outcomes because SHERA has no influence on the further processing. Nevertheless, any claims for damages arising from such processing refer solely to the merchandise value of our products.
Serious incidents must be reported to SHERA Werkstoff-Technologie GmbH & Co. KG and the competent authorities

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Explanations of the symbols used:


Consult instructions for use


Do not reuse

Batch number

Article number

Medical device


Date of manufacture


Manufacturer

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