

Mediloy S-Co

Co63.9Cr24.7W5.4Mo5.0Si1.0 [%]

CE 0197

Instructions for use

Cobalt-based dental alloy for metal-ceramics, type 5

Grain size 10–45 µm

Mediloy S-Co conforms to ISO 22674 and ISO 9693-1

REF 50551 – 5 kg

Alloy characteristics

According to ISO 22674 free of nickel, cadmium, beryllium and lead

Type (according to ISO 22674)	5
Solidus, liquidus temperature °C	1390, 1425
Density g/cm ³	8.6
Modulus of elasticity GPa	228/238*
0.2% elongation limit (R _{p0.2}) MPa	1000/755*
Ductile yield (A _n) %	8/5*
Hardness (HV10)	470/425*
BEGO colour code	8 (white)
Coefficient of thermal expansion (CTE) 25–500 °C, 10 ⁻⁶ K ⁻¹	14.0/13.7*
Stress relief heat treatment 800°C/*simulated ceramic firing	
Veneering ceramic	ceramic with compatible CTE value, e.g.: VITA VMK Master
Oxide firing	not recommended, but if control firing is desired: 5 min at 900°C/ preferred under vacuum
Highest recommended firing temperature	980°C
Heating rate	recommended max. 55°C/min
Fluxes	e.g. Minoxid (REF 52530)
Soldering before firing:	Wirobond solder (REF 52622)
Soldering after firing:	–
Laser wire:	Wiwoweld (REF 50003, 50005)

Intended purpose: Mediloy S-Co is indicated for the fabrication of dental restorations, implant prosthetics and orthodontic appliances by the selective laser melting (SLM) process.

Indication: Mediloy S-Co is a cobalt-based dental alloy for the SLM process.

It is suitable for the fabrication of dental restorations (e.g. crowns, bridges, metal-ceramic crowns and bridges, partial dentures). Furthermore, it is suitable for implant prosthetics (e.g. abutments, bars, secondary bar structures, screw retained bridges) as well as orthodontic appliances (e.g. orthodontic bands, retainers, space maintainers). Mediloy S-Co is available as powder for the SLM process.

Contraindications: Brackets, tubes, archwires and attachments for orthodontic appliances. Further, unwanted biological reactions such as allergies to contents of the alloy or electrochemically based reactions may very rarely occur. In case of known incompatibilities and allergies to contents of the metallic material it should not be used.

Clinical benefit: Artificial replacement of hard tissue (teeth), to restore masticatory functionality (aesthetic and function).

Warnings: Metal dust (Mediloy S-Co) is harmful to health. Avoid dust formation! The opening of packages, filling of powders, grinding and blasting of dental restorations should be performed carefully and using an appropriate extraction system. Respiratory protection of type FFP3-EN 149, protective goggles with side protection (DIN EN 166), protective gloves (made of butyl rubber or nitrile rubber, category III, EN 374) and ESD-certified safety shoes are recommended. In the event of contact with eyes, rinse with plenty of water. In the event of skin contact, wash with water and soap. If irritation persists, seek a physician's care.

Collect any spilled amounts mechanically with a moist rag (water or isopropanol) and dispose of in accordance with local or national statutory regulations. Metal powders are combustible. Remove all sources of ignition. Suitable extinguishing media: special powders against metal fires, sand. Pay attention to safety data sheet!

Precautions: In the case of approximal or occlusal contact from Mediloy S-Co with other metals, electromechanically related reactions may occur in very rare cases. The Mediloy S-Co has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Mediloy S-Co in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Patient group: Objects made of Mediloy S-Co can be used regardless of the age of the patient. The alloy should not be used in cases of known incompatibilities or known allergies to alloy components.

Side-effects: Mediloy S-Co has no known side-effects. However, individual reactions to components of Mediloy S-Co in very rare cases cannot be excluded. In such cases, Mediloy S-Co should not be used.

Digital wax-up: Wax-up is performed using suitable CAD software under consideration of dental technology regulations. Wall thickness after finishing: min. 0.3 mm, implant prosthetics with screw channels 0.5 mm, bands 0.7 mm, arches 1.5 mm, avoid sharp edges and corners. Veneer frames to be designed in anatomically reduced form. Allow connectors to be as strong and high as possible (height: min. 3.5 mm, width: min. 2.5 mm).

Work steps in the manufacturing centre: For equipment-specific work steps and settings, the device manufacturer's specifications must be adhered to! Please follow the instructions for use and safety instructions of the equipment manufacturers!

Storage conditions: Store dry in tightly closed container.

SLM procedures: Prevent the formation of dust when opening the packaging and during transport as well as when filling the powder into the SLM system. Use an SLM system with suitable laser (e.g. Ytterbium fibre laser or Nd:YAG laser (wavelength approximately 1060–1100 nm)) with the following settings: powder layer thickness 0.03 mm, laser output 195 W, scan speed 1200 mm/s and track spacing 0.09 mm, with a laser beam diameter of 0.1 mm. The current operating instruction of the device must be observed for the individual settings.

Cleaning Production platform: Remove the production platform from the SLM-System, pour off the unused powder and clean the platform completely from powder, with help of a brush, alternatively use an suction-system.

Re-use: If unmet powder is to be reused, it must be sifted beforehand using an ultrasound sieve (63 µm) or a powder sieve (80 µm).

Stress relief heat treatment: The removable part of the production platform with the manufactured objects is inserted in a suitable oven with a temperature of 650°C. The temperature is increased to 800°C within 12 minutes, and held for 15 minutes. Next, the temperature is decreased to 550°C within 15 minutes. The platform is removed from the oven at 550°C (or below) for further processing.

Separation of the restorations from the plate: Avoid dust formation! After the stress relief heat treatment and cooling of the platform, remove the restorations using a band saw, rotary instruments or forceps, for example. Also remove the remaining supports using forceps.

No reuse of laser-sintered material: Materials (e.g. a bridge or bar) that have already been melted via SLM may not be reused for the manufacture of a new restoration (e.g. by casting).

Finishing: Use fine-toothed carbide burs.

Warning: Implant interfaces may not be finished!

Polishing: In order to simplify the rubber-polishing, blast polishing with Perlablast® micro (REF 46092, lead-free soda lime glass) is possible. Then, rubber-polish with a suitable rubber polisher, and polish using suitable pre- and post-polishing pastes. Partial denture prostheses: Glazing (Eltropol, Wirolyt polishing liquid). Next, clean thoroughly (steam blasting or boiling in distilled water).

Ceramic veneer: In the case of abutments or implant-worn, screw-retained bridges, no ceramic firings may be performed! Use veneering ceramics with a suitable CTE (ISO 9693-1), observe the instructions for use of the respective ceramics manufacturer. Before the ceramic veneering, the frame must be sandblasted (250 µm/3–4 bar with, for example, Korox 250; REF 46014). The oxide is to be sandblasted, as the case may be, if a control firing is performed (250 µm/3–4 bar with, for example, Korox 250; REF 46014). Through cleaning with a steam blaster or by boiling in distilled water is required. After this step, do not touch the surfaces again with your hands. Use arterial clamps or similar. Ensure that the frames are supported appropriately during firing.

Composite veneers: The respective manufacturers' instructions must be held when working with composite veneering materials.

Soldering: Objects with implant interfaces may not be soldered! Affix parts to be soldered (e.g. with soldering investment material Bellatherm® REF 51105), parallel-walled soldering gap: max. 0.2 mm. Use suitable BEGO flux. Following the soldering, the flux residue and metal oxides must be acid-cleaned and the surfaces should be cleaned with a steam blaster or by boiling in distilled water.

Laser welding: When possible, work with X-sutures and filler material.

Please follow the instructions for use and safety instructions of the equipment manufacturer!

Warranty: Application-related recommendations provided by us, whether given verbally, in writing or by way of practical instructions, are based on our own experience and tests and may therefore only be regarded as general guidelines. Our devices are subject to continuous development. We thus reserve the right to make modifications in construction and composition without notice.

Any serious incident that has occurred in relation to the use of Mediloy S-Co should be reported to BEGO Bremer Goldschlögerei Wilh. Herbst GmbH & Co. KG and the competent authority.

Instructions for disposal

Waste treatment procedures

Device

The assignment of a waste key number as per the European Waste Catalogue Ordinance (AVV) must be carried out in consultation with the regional waste disposal contractor. Do not dispose of with household waste.

Packaging

Packaging must be fully emptied and properly disposed of in compliance with statutory regulations. Packaging that is not fully emptied must be disposed of in coordination with the regional waste disposal contractor.

US Labeling requirements: The device labeling meets the recommendations of FDA applicable guidance documents.



Consult instructions for use



Caution



Use-by-date



Keep dry



Batch code



Non-sterile

Rx only

Only for technical personnel!



Catalogue number



Medical device



Manufacturer

BEGO Bremer Goldschlögerei Wilh. Herbst GmbH & Co. KG
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