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Mediloy® RPD

Co66.2Cr28.2Mo5.5N [%]

CE 0197

Instructions for use
Cobalt-based dental alloy, type 5
Grain size 10-45 µm
Mediloy® RPD satisfies ISO 22674
REF 50532 – 5 kg

Alloy characteristics

Acc. to ISO 22674 free of nickel, cadmium, beryllium and lead		
Type (according to ISO 22674)		5*
Solidus, liquidus temperature	°C	1380, 1420
Density	g/cm³	8.5*
Modulus of elasticity	GPa	235*
0.2% elongation limit ($R_{p\,0.2}$)	MPa	800*
Tensile strength (R_m)	MPa	1300*
Ductile yield (A_5)	%	13*
Hardness (HV10)		395*
BEGO shade code		8 (white)
Veneering ceramic	cannot be veneered with ceramics	
Flux	e.g. Minoxyd (REF 52530)	
Solder:	Cobalt-chrome solder (REF 52520)	
Laser wire:	Wiroweld (REF 50003, 50005)	

*Stress relief heat treatment 800°C

Intended purpose: Mediloy® RPD is intended for the fabrication of patient-customized dental surgical guides and dental restorations such as partial dentures by the selective laser melting (SLM) process.

Indication: Mediloy® RPD is intended to treat the condition of missing hard tissue (teeth).

Contraindications: Brackets, tubes, archwires and attachments for orthodontic appliances.

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

Further, unwanted biological reactions such as allergies to contents of the alloy or electrochemically based reactions may very rarely occure. In case of known incompatibilities and allergies to contents of the metallic material it should not be used.

Warnings: Metal dust 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-EN149, 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 with other metals, electrochemically-related numbness may occur in very rare cases. Frames fabricated from Mediloy® RPD may disrupt the analysis of MRI exams and should be separated before such examinations.

Adverse effects: Mediloy® RPD has no known adverse effects. However, individual reactions to components of Mediloy® RPD in very rare cases cannot be excluded. In such cases, Mediloy® RPD should not be used.

Digital wax-up: Wax-up is performed using suitable CAD software under consideration of dental technology regulations. In order to achieve the clinically required stability, the base should possess, as part of the design process, a minimum thickness of 0.6 mm, and 0.5 mm after finishing.

Please note: Since the stability of an upper jaw base consists of a combination of shape, expansion and material thickness, 0.5 mm should be considered as the minimum. The design basics for the partial denture technique must be adhered to.

Standard bases possess base thicknesses of approx. 0.75 – 0.85 mm, smaller bands or skeletonised frames 1.0 – 1.2 mm.

Lower jaw brackets should possess a thickness of approx. 1.8 – 2.0 mm × 4.0 – 4.2 mm.

The parameters must be selected and set accordingly in the design software!

At critical object locations, e.g. at the transition of a minor connector to a clasp, the wall thickness should be set to approx. 1.2 – 1.5 mm × 1.8 – 2.0 mm.

Clasp design: The design of the clasps is based on their position and function, on the expansion of the restoration and on the specifications of the practitioner.

In the clasp shoulder area, the transition from minor connector to clasp is to be rounded off. In this area, clasps ideally possess a thickness of approx. 1.5 mm × 2.0 mm and taper off toward the clasp tip to 1.2 mm - 1.5 mm. The clasp tip is to be rounded off.

At critical object locations, e.g. at the transition of a minor connector to a clasp, the wall thickness should be set to approx. 1.2 – 1.5 mm × 1.8 – 2.0 mm.

The shapes of the clasp profiles and the parameters must be selected and set accordingly in the design software!

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 the tightly closed original container.

SLM procedures: Prevent the formation of dust when opening the packaging and during transportation as well as when filling the powder into the SLM system. Suitable SLM system EOSINT M 270/280 (wavelength 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.

If unmelted 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 fabricated objects is inserted in a suitable oven with a temperature of 800°C. As soon as the oven has once again reached 800°C after insertion of the production platform, the temperature must be maintained for 45 min. The platform is removed from the oven at 800°C for further processing. After the stress relief heat treatment, allow platform to cool to lukewarm with air, on a protected and well-labelled location. Do not chill in water!

Separation of the restorations from the platform: 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 supports from the object with forceps or smooth down using a dental grinding stones.

No reuse of laser-sintered material: Materials (e.g. partial denture frames) that have already been melted via SLM may not be reused for fabrication of a new restoration (e.g. by casting). Mediloy® RPD may not be processed through casting.

Finishing: Use fine-toothed carbide burs.

Polishing: In order to facilitate the rubber-polishing, it is possible to blast polish with Perlablast® micro (REF 46092, lead-free soda lime glass), and electrolytic glazing if needed (Eltropol, Wirolyt polishing liquid). Then, rubber-polish with a suitable rubber polisher, and polish using suitable pre- and post-polishing pastes. Finally, clean thoroughly (e.g. clean in an ultrasonic bath or steam blast).

Acrylic saddle: In order to fabricate the acrylic parts, the relevant instructions of the acrylics manufacturer must be observed. The retention areas for acrylic saddles are not polished, instructions for preparation can be found in the instructions for use of the respective acrylics manufacturer.

Assembly of surgical guide: Press the metal surgical drill guide sleeve(s) into the corresponding hole(s) of the surgical guide. Ensure to use only compatible and validated metal sleeves.

Soldering: 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. After soldering, flux residue and metal oxides must be removed and the surfaces are to be cleaned through steam blasting.

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

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

Cleaning/disinfection: The restorations are produced non-sterile and must be disassembled into their individual parts, cleaned, disinfected and sterilized before being inserted into the patient's mouth.

Disinfection: When selecting the disinfectant, make sure that it is suitable for cleaning and disinfecting dental restorations and that it is compatible with the materials of the restorations to be cleaned and disinfected. The instructions from manufacturer of the disinfectant must be observed.

Optional: Sterilization. Only the metallic components may be sterilized; any plastic parts/plastic veneers are not suitable for steam sterilization!

Steam sterilization: Temperature 134°C, hold time 5 min, drying time 20 min. Allow to dry and cool sufficiently before using the dental components on the patient. The device manufacturer's instructions must be observed. Check the cleanliness by visual inspection. If the prosthetic components are not clean, the cleaning process must be repeated in its entirety. In addition, residual moisture must no longer be visible; otherwise the drying process must be repeated.

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 products are subject to continuous development. Therefore we reserve the right to make modifications in design and composition.

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

If any severe incidents should occur in relation to the use of Mediloy® RPD, please notify BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG and the responsible authorities.

Instructions for disposal/Waste treatment procedures: The assignation 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.

Consult instructions for use

Caution

Use-by-date

Keep dry

LOT
Batch code

NON STERILE
Non-sterile

Rx only
Only for technical personnel!

REF
Catalogue number

Contains hazardous substance

MD
Medical device

UFI: Q6SW-30GV-T006-81DV

CMR: Co

Manufacturer

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BEGO

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