

CE 0459

Anthogyr
2 237, Av. André Lasquin
74700 Sallanches - France
Phone : +33(0)4 50 58 02 37
Fax : +33(0)4 50 93 78 60
www.anthogyr.com
Email : sales@anthogyr.com
Edition : 2016-11
REF. 063COCR_NOT_EN

Cast CoCr Multi-Unit coping (Ø4.0 and Ø4.8)

CE 0459 Medical device complying with European Directive 93/42/EEC.

⚠ Attention: The accompanying instructions must be consulted;
Danger.

📖 See the precautions for use.

⌛ Do not reuse.

STERILE Irradiated by irradiation.

⚠ Not sterile.

135°C Sterilisation by autoclave without packaging, at the specified temperature.

🕒 Use-by date.

REF Catalogue reference.

LOT Batch number.

🚫 Do not use if the package is damaged.

☂ Store in a dry place

☀ Store away from light.

🏭 Manufacturer.

📅 Manufacturing date.

R_X ONLY Federal (U.S.) law restricts this device to sale by or on the order of an authorised dentist.

PC AN49 Complies with norms and standards in Russia.

Indications

The cast CoCr Multi-Unit copings are intended for implant-supported prosthetic restoration on Anthogyr Multi-Unit (Ø4.0 and Ø4.8) abutments in order to ensure support for permanent prosthetic reconstructions using the casting technique. They are used and prepared in a dental laboratory.

Description

Melting range of the CoCr used for the machined ring: 1390°C-1415°C

Density: 8.28g.cm³

Composition: CoCr28Mo

Cobalt (Co)	58.86-69%
Chrome (Cr)	26-30%
Carbon (C)	0.14%
Molybdenum (Mo)	5-7 %
Nickel (Ni)	1%
Iron (Fe)	0.75%
Nitrogen (N)	0.25%

Warnings and precautions

⚠ Only clinicians who have had in-depth training in dental implantology should insert these components. The following instructions are not sufficient by themselves for risk-free implementation of Anthogyr implant systems. It is essential that you follow the instructions provided by the surgical guide "Axiom® REG and Axiom® PX user guide". This document is supplied with every kit and is available at ifu.anthogyr.com or on request from Anthogyr using the contact details provided above. The prosthetic components should be secured firmly to avoid inhalation or swallowing during intra-oral use.

If the procedures described in these instructions for use are not followed, one or more of the following complications may result:

- Incorrect final restoration or failure of the prosthesis or any other prosthetic part to function correctly
- Impairment of patient mastication
- Poor adhesion and cracks in the ceramic
- Poor adhesion of the casting alloy to the CoCr ring

Compatibilities

The cast CoCr copings are used exclusively for restorations on Multi-Unit Ø4.0 and Ø4.8 mm abutments that are compatible with Axiom® REG and Axiom® PX implants. Be sure to only use Multi-Unit parts that are compatible with original Anthogyr Multi-Unit Ø4.0 mm and Ø4.8 mm abutments with a Multi-Unit Ø4.0 or Ø4.8 mm connection: risk of injury, damage, and failure of the Multi-Unit abutment, the implant or the accessory to function correctly.

⚠ Attention: A CoCr casting alloy must always be used that has a lower melting point than that of the CoCr used for the machined ring. Other alloys do not facilitate optimum adhesion. In order to obtain a result appropriate to the reconstruction, a CoCr casting alloy must be used that is compatible with the casting process. The CoCr casting alloys used must comply with the ASTM F1537, ASTM F799, ISO 5832-12 and ISO 5832-4 standards.

Sterilisation

The cast CoCr copings are supplied non sterile. It is essential that they are cleaned, decontaminated and sterilised in accordance with the procedures applicable for prosthetic dental work prior to performing insertion on the patient.

Protocol

The cast CoCr copings may not be re-used. Risk of deterioration of functional surfaces. Before any tightening of the component, make sure that the connection is free of any fluid or other substance that could compromise secure attachment of the prosthetic component.

• Fabrication of the prosthesis in the laboratory

1. Screw the CoCr copings (ref. no. MUC400 for the Multi-Unit Ø4.8 mm abutment or ref. no. MUNC400 for the Multi-Unit Ø4.0 mm abutment) to the Multi-Unit abutment analogues (ref. no. MUA100 for the Multi-Unit Ø4.8 mm abutment or ref. no. MUNA100 for the Multi-Unit Ø4.0 mm abutment) on the master model using the Multi-Unit M1.4 titanium fixation screws (ref. no. MU141) or the long laboratory screws (ref. no. MUT102). Use a hexagonal wrench to place the screws, moderate manual tightening < 15N.cm.

2. Adjust the casting section (PMMA) of the cast CoCr copings in such a way that a homothetic framework (or casting bar) is recreated or fabricated, or add casting resin in order to link each coping. Use the Multi-Unit M1.4 titanium fixation screws or the long Multi-Unit laboratory screws in order to maintain the screw holes while adding the resin. The initial placement of the screw should be maintained without metal contamination.

The resin and casting should be thicker

than 0.7 mm prior to casting and can be trimmed to a thickness of up to 0.5 mm after casting. **The resin should be applied across the entire surface of the ring, including the base of the ring, so that the latter is entirely overmoulded**, otherwise there is a risk of a gap between the 2 types of CoCr. The application of ceramic on a surface that has not been covered by a casting alloy may lead to poor adhesion and cracks in the ceramic

3. Perform casting in accordance with the recommendations of the manufacturers of the materials.

4. During the finishing and polishing steps, be sure to protect the interface that comes into contact with the abutment using the protection analogues for the Multi-Unit Ø4.8 mm abutment (ref. no. MUA200) or for the Multi-Unit Ø4.0 mm abutment (ref. no. MUNA200). Using corrosive materials during the finishing steps is not recommended

Carry out ceramisation of the prosthesis.

Recommended furnace temperature for firing: approx. 850°C for a period of 1 hour; a higher temperature may cause oxidation of the machined ring, resulting in poor attachment of the cast.

• Verification of the cast structure

In order to verify seating, place the cast structure on the master model with the Multi-Unit M1.4 titanium fixation screw (ref. no. MU141) using moderate manual tightening of <15N.cm.

• Attachment of the prosthetic restoration to the Multi-Unit abutment

The prosthetic restoration fabricated using the coping cast in CoCr should be tightened with 15N.cm, for example using an INCCD or TORQ CONTROL dynamometrical instrument

Modifications of prefabricated prosthetic components

Only the section comprised of PMMA may be reworked. The section comprised of CoCr does not require reworking in order to be used.

Contraindication

Allergy or hypersensitivity to the chemical components of the materials used: see component table above.

Patient information

The patient should agree to regular medical follow-up and should consult his/her doctor in the event of an unexpected change in the performance of the prosthetic reconstruction. The patient's attention should be drawn to the necessity of regular oral hygiene.

Safety, responsibility

This product should be used only with Anthogyr components and instruments. The user is entirely responsible for the proper use and handling of this product. Each component is labelled with a catalogue reference and a batch number: the user must ensure traceability of the components used for each patient. The facility performing the insertion is responsible for handling waste resulting from the procedure (packaging, extracted component, etc.) as medical waste. Anthogyr does not assume any responsibility in the event of clinical failure associated with non-observance of the surgical protocol.

Anthogyr thanks you for your trust and is available to provide you with any additional information.