INSTRUCTIONS FOR USE:

CHROME COBALT PROSTHETIC COMPONENTS

PRODUCT DESCRIPTION AND INDICATIONS

Advan CoCr28Mo castable abutments allow overcasting for unit, multiple, and total dental implant rehabilitations. The package contains the castable abutment, the castable plastic cannula and its retention screw. The abutments are manufactured using CoCr28Mo conforming to ASTM F1537 as the material for the connection base; the castable plastic cannula is made of Polyoxymethylene (POM); and the retention screw is made of Ti6Al4V ELI alloyed Titanium (Grade 23) conforming to ASTM F136.

CoCr28Mo alloy is composed by non-magnetic cobalt, implantable, enriched with Chromium and Molybdenum, and it exhibits excellent corrosion resistance and good fatigue strength. The grade provided has a maximum nickel content of 0.02%.

Refer to the surgical guidelines for implants and prosthetic components.

INTENDED USE

CrCo28Mo prosthetic components are intended for laboratory use in the phases of waxing and casting of infrastructure of prostheses screwed or cemented on dental and zygomatic implants.

TECHNICAL DATA

Composition:

Base: CoCr28Mo – ASTM F1537

	Co	Cr	Mo	C	Si	Mn	Fe	Ni
%by weight	65,9	27,8	5,1	0,1	0,4	0,5	0,1	0,02

Castable cannula: Polyoxymethylene (POM) Abutment screw: Ti6Al4V ELI grade 23 - ASTM F136

CoCr28Mo abutment density:

- 8,28 g/cm3

CoCr28Mo abutment fusion value range:

- 1075 – 1150 °C (1967 – 2102 °F)

CoCr28Mo abutment thermal expansion coefficient:

- 14,2 µm / K (600 °C)

Base weight (castable sleeve excluded):

- 0,3 grams

CONTRAINDICATIONS

In very rare cases, allergies or sensitivities related to the CoCr28Mo alloy cannot be ruled out. Do not use in cases of possible hypersensitivity to one or more metals contained in the CoCr28Mo alloy. Allergies or hypersensitivity to chemical components of the following materials used: Titanium alloyed Ti6Al4V ELI (Grade 23), Polyoxymethylene (POM).

POTENTIAL COMPLICATIONS

Potential complications include all the activities in which the body is exposed to severe physical strain that should be avoided immediately after the insertion of CoCr28Mo prosthetic components on dental implants. It is recommended that the physician or other authorized personnel informs the patient regarding the precautions and potential complications, as below reported, which may occur as a consequence of the surgical procedure for implanting the components. It is also recommended to invite the patient to promptly contact the physician in case of any loss of performance of the implant or of the prosthetic components.

Potential side effects and temporary symptoms: pain, swelling, phonetic difficulties, gingival inflammation.

More persistent symptoms: (1) chronic pain associated with implant and its prothesis, (2) swallowing, (3) permanent paraesthesia, (4) dysesthesia, (5) localized or systemic infection, (6) oroantral or oronasal fistulas, (7) jaw, bone oral denture fracture, (8) aesthetic problem, (9) nerve injury, (10) exfoliation, and (11) hyperplasia.

WARNINGS/CAUTIONS

Contains hazardous substances classified as CMR (substances that are carcinogenic, mutagenic or toxic to reproduction):

Co = 65.9 %

Advan CoCr28Mo abutments are part of an overall concept and should be used only with the original implants and surgical instruments, following the instructions and recommendations in the relevant surgical manual.

Patients may ingest or aspirate the component, make sure the screwdriver and screw are properly connected to avoid aspiration or ingestion. Perform implant prosthetics only with secondary components and Advan parts compatible with the implant being used. Failure to follow the procedures described in these instructions may result in any or all the following complications:

- Aspiration of a component;
- ingestion of a component;
- follow-up treatment.

Advan CoCr28Mo prosthetic components are single-use devices. Place the prosthetic artifact on an occluded implant only when the dental implant is fully osseointegrated. Store products containing plastic components (POM) away from direct sunlight. The melting point of the above alloys is such that the base is preserved from dimensional alteration upon overcasting of the castable part.

COMPATIBILITY INFORMATION

Advan dental and zygomatic implants and prosthetic lines are available in numerous configurations. Abbreviations on the label attached to each product make it easy to identify the compatibility of a particular subcomponent with the implant being restored. The name of the implant and prosthetic component contain an identifier for the connection, summarized in the following table.

Connection	Indication of compatibility
Fixture GTB	GTB restorative component
Fixture ONE CONICAL	ONE CONICAL restorative component
Fixture ONE INTERNAL	ONE INTERNAL restorative component
Fixture ZYGOMA	ZYGOMA restorative component
GFA	GFA restorative component
MUA	MUA restorative component

CLEANING AND STERILIZATIONI

CoCr28Mo prosthetic components are sold non-sterile. Before inserting the restoration into the patient's oral cavity, the product must be disassembled into its various parts, cleaned and sterilized. Advan recommends the following cleaning and sterilization procedure of the non-sterile prosthetic components before use:

1. Place the components in an appropriate solution of high-quality decontamination medium (ENZYMAX®, 0.8% v/v with demineralized water), at 35°C contained in a suitable support (i.e., becker), the components must be totally covered by the solution. Allow 10 minutes before removing.
2. Carefully rinse the prosthetic components under clean running or distilled water to remove any trace of detergent (i.e., enzymatic).
   WARNING: Use sterile water unless the drinking water is low contamination (meeting the following requirements Pharmacopoeia European monograph 0169: max 10 microorganisms/ml, max 0.25 endotoxins/ml).
3. Place the prosthetic components in a solution as in point 1 inside a suitable support (i.e., becker) and then put the support in an ultrasonic washing machine for 10 minutes at 35°C.
   NOTE: the prosthetic components must be opportunely positioned to avoid collisions between container itself; appropriate supports are recommended (i.e. becker);
4. Carefully rinse the tools under clean running or distilled water to remove any trace of detergent (i.e., enzymatic).
   WARNING: Use sterile water unless the drinking water is low contamination (meeting the following requirements Pharmacopoeia European monograph 0169: max 10 microorganisms/ml, max 0.25 endotoxins/ml).
5. Immediately after manual cleaning, or not more than 30 minutes place the prosthetic components in an appropriate solution of high-quality disinfection medium (PROSEPT® Burs, ready-to-use solution), contained in a suitable support (i.e., becker), the prosthetic components must be totally covered by the solution. Put the support in an ultrasonic washing machine for 1 minute at 20°C before removing.
   WARNING: The use of automatic cleaning and disinfection equipment is not recommended as it could compromise the integrity of the prosthetic components due to possible collisions that could occur during the automatic washing and disinfection phases (the same level of control that can be achieved manually cannot be guaranteed during these phases).
6. The best means of drying is compressed air. Its action allows water to be physically removed from surfaces. The presence of moisture on the surface of prosthetic components can promote bacterial growth and compromise the sterilization process. Drying prosthetic components is of utmost importance before storage and sterilization, as moisture accumulation on products is harmful and can cause oxidation. It is recommended to dry each component thoroughly by means of compressed air (range 1.5 - 2 bar) using only filtered air (oil-free and with low contamination of microorganisms and particles, meeting the following Pharmacopoeia European max. 0.1mg/m³ oil). Manual drying must provide a sufficient surface area, an air gun, cloths and absorbent paper material with low particle release. Alternatively, cloths that do not release filaments or dust must be used. During the drying phase, the cleanliness of the prosthetic components must be verified and checked.
7. Place the prosthetic components into a sterilization pouch, which fulfil the following requirements: EN ISO 11607 (e.g., medical grade paper); suitable for steam sterilization.
8. The use of an autoclave for steam sterilization of the prosthetic components is recommend, which fulfil the following requirements: EN ISO 17665.
   Carefully observe the instructions and recommendations of steam sterilizer manufacturer. Follow the instructions for maintenance and calibration of the autoclave. It has been validated, in accordance with EN ISO 17665, that one sterilization cycle (using the parameters given in the table) produced sterility of the surgical kit; this condition has been certified by an accredited laboratory.

	Vacuum fractionation
Sterilization time	4 minutes
Sterilization temperature	134°C

Minimum pressure	2 bar
Drying time	20 minutes

The heating time and vacuum fractionation (at least three steps) can vary between 25 and 30 minutes, depending on autoclave conditions. The maximum sterilization temperature is 138°C. The actual drying time required depends on parameters for which the operator is solely responsible (e.g., configuration and loading density, state of the sterilizer) and must therefore be determined by the operator. In any case, the drying time should not be less than 20 minutes.
WARNING: Do not autoclave this product in its original packaging.

9. If not already present on the sterilization pouch, it is recommended to place a chemical indicator inside the autoclave during the process to confirm sterilization effectiveness.
10. When removing the prosthetic components from the sterile package, follow the aseptic principles. The sterile packaging must not be opened until immediately before the use of the prosthetic components. Prosthetic components with damaged sterile packaging should not be used. We recommend keeping a replacement component handy.
WARNING: Use the devices immediately after sterilization. Do not store sterilized devices.
NOTE: Users must ensure that the sterilizer and all sterilization accessories (sterilization sheets, envelopes, sterilization trays, biological and chemical indicators) are correctly calibrated and approved for the intended sterilization cycle. The user must consult the recommendations for sterilization of the manufacturer of the restoration material. If there are visible signs of humidity (damp spots on the sterile package, stagnant water in the load) at the end of the sterilization cycle, repackage and resterilize using a longer drying time.
NOTE: To avoid voltage cracks in the temporary copings made of PMMA for cementable abutments, do not use the following: alcohol, UV radiation, sterilization by irradiation (gamma ray sterilization), immersion in liquid for over an hour or temperatures above 60°C.

SURGICAL PROCEDURE

The CoCr28Mo castable abutment is made with an overcast alloy base and a castable plastic cannula that does not release residue during the lost-wax casting process. The plastic cannula can be shortened before wax modelling if necessary. The minimum wall thickness of 0.4 mm must be observed. The connection geometry and platform to the implant must be completely free of plastic, wax and grease the absence of these leaks in this area.

Only phosphate-alloyed compounds (without gypsum) recommended for the fusion of metal alloys can be used for coating.

When choosing the cast-on alloy it is advisable to accurately assess the melting temperature with respect to that of the component to be over-ducted, which must be about 80-100 °C higher to avoid being deformed but to allow a good union between the two alloys.

Refer to the cast-on alloy for indications on oven preheating and metal CTE.

After melting, allow the cylinder to cool slowly to room temperature to prevent tensions from forming between the two alloys.

The coating and oxide can be removed by sandblasting (a maximum pressure of 2 bar is recommended to avoid alteration and damage to the implant-column connection area; before the sandblasting it is preferable to mask the connection with wax, later to be removed by steam).

Finishing and polishing are recommended to be done by sandblasting with glass spheres to avoid damage and alteration of the CoCr28Mo base.

In the need to perform ceramic layering, it is recommended to use bonding first.

STORAGE

Store the prosthetic components in a dry environment, out of direct sunlight and at room temperature. Follow the envelope manufacturer's instructions regarding storage conditions and expiration date of sterilized products.

GENERAL HANDLING, CARE AND MAINTENANCE OF THE SURGICAL INSTRUMENTS

WARNING: The clinical success of the surgical procedure of Advan CoCr28Mo castable abutment placement requires the use of instruments in perfect condition.

Care and maintenance of instruments are critical to successful treatment. Sterilized instruments not only protect patients and staff from infection and cross-infection, but are also essential to the total treatment outcome.

Due to the small size of the components, care should be taken to ensure that the components are not swallowed or aspirated by the patient. A rubber dam is recommended to prevent inhalation of loose parts.

Please read the instructions on technical sheet for surgical kit use and maintenance.

FURTHER INFORMATIONS

For more information on the use of Advan products, contact Advan customer service.

DISPOSAL

Disposal must be handled in an environmentally sustainable manner, in accordance with local regulations. Hazardous waste from contaminated devices or sharps must be disposed of in appropriate containers that meet specific technical requirements.

NOTES

Physician who use the Advan product are required to have adequate technical knowledge and training, in order to ensure its safe use. The Advan product must be used in accordance with the manufacturer's instructions for use. The physician is responsible for using the device in accordance with these instructions for use and for determining the suitability of the device for the patient's individual situation. The Advan product is part of a complete program and should be used only in conjunction with its original components and instruments distributed directly by Advan and all national Advan dealers. Use of third-party products not distributed by Advan voids any warranty or other obligation, implied or express, of Advan.

VALIDITY

These operating instructions supersede all previous versions.

AVAILABILITY

Some ADVAN Implant System items may not be available in all countries.

SYMBOLS

The following table describes the symbols that can be identified on the packaging and on the device label. Refer to the packaging label for symbols applicable to the product.

Symbols glossary

Symbol	Description
	Manufacturer
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number
STERILE R	Sterilized using irradiation

Symbol	Description
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight
	Keep dry
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Caution
N	Multi packaging (the number reported in the symbol refers to the number of units in the packaging)
MD	Medical device
	Single sterile barrier system with protective packaging inside
	Single sterile barrier system with protective packaging outside
	Distributor

Symbol	Description
UDI	Unique device identifier
R	Not locking prosthetic component
NR	Octagon locking prosthetic component
NR	Hexagon locking prosthetic component
CE 0123	Advan products covered by the CE mark fulfill the requirements of the Directive 93/42/CEE concerning medical devices and falls within Classes IIa, IIb
CE	Advan products covered by the CE mark without the identification number fulfill the requirements of the EU Regulation 2017/745 (MDR) concerning medical devices and falls within Class I

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