CE 0459

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Prefabricated prosthetic components of the Anthogyr® dental implant product lines: Axiom® REG; Axiom® PX; Axiom® 2.8; Anthofit® HE

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 R Sterilised by irradiation.

Not sterile.

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

Do not sterilise by autoclave.

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.

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

PG AM49 Complies with norms and standards in Russia.

GTIN : Global Trade Item Number

Indications

The prefabricated prosthetic components are intended for implant-supported prosthesis.

The healing prosthetic components are used to pre-form the gum during the healing phase. The cover screws and plugs protect the connection of the implant during the integration period. The other prosthetic components are intended to be placed directly or indirectly in the Anthogyr dental implants to ensure support for the temporary or permanent prosthetic reconstitutions such as crowns, bridges and hybrid prostheses. The prosthetic components of the Axiom® 2.8 product line are intended to ensure support for single crowns only.

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. You absolutely must follow the instructions of the surgical manual corresponding to the type of implant. These documents are available on ifu.anthogyr.com or on simple request from Anthogyr to the contact details above. The prosthetic components should be fastened 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:
- Damage of the implant, the prosthetic component or other components
- Loosening of the prosthetic component or other components
- Incorrect final restoration or dysfunction of the crown, the bridge or the hybrid prosthesis or any other final prosthetic part
- Malfunction of the patient's mastication
- Rejection of the implant
- Loosening of the implant

Temporary restorations should be positioned out of occlusion.
Do not use rotating movements to remove temporary prosthetic components in order to avoid mobilisation of the implant or loosening of other components.
Temporary cement, cement or any other material used to fix prosthetic components or other elements should be handled in accordance with the manufacturer's instructions.

Description - compatibilities

The prefabricated prosthetic components are used only for Anthogyr Axiom® REG; Axiom® PX; Axiom® 2.8; Anthofit® HE; implant restorations. Be sure to use only original Anthogyr parts with the corresponding connection for an Anthogyr implant restoration: risk of injury, damage and dysfunction of the implant, risk of damage of the components or the accessory. The prosthetic components of the various Anthogyr implant systems are not interchangeable except for the following pairs: Axiom® REG/ Axiom® PX. A wide variety of parts is available to fit your clinical situation: refer to the prosthetic overview or the implant system's user guide.

Sterilisation

Prosthetic components delivered sterile are labelled with: STERILE R . Do not use these components if the packaging was opened or damaged or if the use-by date has expired. These products should be kept in a clean, dry and cool place. The sterilisation status indicator turns red during the Anthogyr sterilisation process. It does not guarantee product sterility in itself. It should not be confused with the colour coding of the implant or prosthetic platform diameter.
It is possible to re-sterilise prosthetic components in titanium, titanium alloy, or PEEK in an autoclave with moist heat, cycle at 135°C (275°F) at 2.13 bars for at least 20 minutes.

The non-sterile prosthetic parts supplied are identified by the logo: they must be cleaned, decontaminated and sterilised according to the cleaning and sterilisation manual available on the ifu.anthogyr.com website or simply upon request from the Anthogyr website mentioned above.
Moist heat autoclave sterilisation (cycle at 135°C (275°F) at 2.13 bars for at least 20 minutes) is possible only for prosthetic components bearing the 135°C previously taken out of their original packaging and placed in an appropriate bag.
Anthogyr recommends using a class B autoclave.

Prosthetic components made of zirconia must not be sterilised in an autoclave. They must undergo dry heat sterilisation at 160 °C (320 °F) for 4 hours.

Protocol

Dimensions and type of prosthetic component: see the label. Single-use devices: do not reuse or re-sterilise. Risk of contamination and risk of deterioration of functional surfaces.

Before any tightening or impaction of a prosthetic component, make sure that the connection is free of any fluid or other substance that could compromise good hold of the prosthetic component in the implant.

Each prosthetic component should be used only with its original screw, if applicable.

Prosthetic screw components must be tightened at the recommended tightening torque indicated in the tables below, with the INCCD or Torq Control® dynamometric ratchet or manually with the OPCS100 surgical wrench.

Axiom® REG and Axiom® PX Prosthetic Components	
Type of component	Recommended tightening torque
Prosthetic components with M1.6 threading	25 N.cm
Prosthetic components with M1.4 threading	15 N.cm
Cover screw / healing screw / protective cap for MU/OPAC/ OPSC abutments	Moderate manual tightening (<10 N.cm)
Other temporary prosthetic components	Manual tightening

Anthofit® HE prosthetic components	
Type of component	Recommended tightening torque
Permanent prosthetic components with M2 threading	35 N.cm
Permanent prosthetic components with M1.4 threading	15 N.cm
Temporary prosthetic components in PEEK	15 N.cm
Other temporary prosthetic components	Manual tightening

Torque values less than the recommended values may result in loosening of the prosthetic component, which may cause deterioration of the prosthetic component and/or the implant. Torque higher than 35 N.cm can result in mobilisation or failure of the implant and/or cause deterioration of the prosthetic component and/or the implant and/or the accessory.

Impacted permanent prosthetic components of the Axiom® 2.8 product line should be inserted only when the implant is osseointegrated, using the SafeLock® instrument with the appropriate tip. Recommended number of impacts: 5.

Prosthetic components inserted permanently should not be removed: risk of damaging the implant connection.

Temporary prosthetic components in PEEK of the Axiom® 2.8 product line should be inserted by manual pressure with the OPCF100 or OPOP028 wrench, do not impact with the SafeLock® instrument. Temporary prostheses should have a system of support on adjacent teeth.

Never apply cement in the connection part of the implant.

Make sure that the implant is sufficiently stable before placing the prosthetic components.

Modifications of prefabricated prosthetic components:

To be considered only if the patient's anatomy or the clinical situation requires it.

Rework of prosthetic components may compromise the mechanical strength of the prosthetic reconstruction and thus result in implant failure. In addition, it may prevent the insertion of elements for taking impressions.

Rework of the Z Plus zirconia abutment should be limited so as to ensure at least a 3-mm cementing height and a wirecloth greater than 0.5 mm. Rework of zirconia parts should be performed with a fine-grained diamond bit at high speed and under copious irrigation.

The emergence profile should not be reworked so as to preserve the surface state at the gingiva level.

Contraindications

Allergy or hypersensitivity to the chemical components of the materials used: titanium, titanium alloy (Ti-6Al-4V ELI.), PEEK, PMMA, Zirconia 3Y-TZP, gold alloy (Ceramicor®, Pivozyl®).

The AxIN® solution is contraindicated in the molar sector :

- on AxIN® BL bases 1.5 mm thick and with a Ø4.0 and Ø5.0 mm diameter.
- on a TL implant with a 1.5 mm neck height on platform N and R.

Patient information

The patient should agree to regular medical follow-up and should see his/her doctor in the event of an unexpected change in the performance of the prosthetic reconstitution.

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 completely 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 disclaims responsibility in the event of clinical failure related to not following the surgical protocol.

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