CE 0459

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

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 R Sterilised by irradiation.

Not sterile.

135°C Sterilisation by autoclave, at the specified temperature.

135°C 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.

Complies with norms and standards in Russia.

GTIN : Global Trade Item Number

Indications for use

The prefabricated prosthetic components are intended for use as accessories to dental implants to support implant-supported restorations.

The prosthetic components of the Axiom 2.8 product line are intended to ensure support for single crowns only.

Description

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.

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 corre-sponding 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 mobilization 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.

Compatibilities

The prefabricated prosthetic components are used only for Anthogyr Axiom® REG; Axiom® PX; Axiom® 2.8 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.

Sterilization

Prosthetic components delivered sterile are labeled 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 sterilization status indicator turns red during the Anthogyr sterilization process. It does not guarantee product sterility in itself. It should not be confused with the color coding of the implant or prosthetic platform diameter.

The non-sterile prosthetic parts supplied are identified by the logo: NON STERILE 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.

To clean and sterilise Anthogyr components, please refer to the sterilisation manual (AXIOMR-PX_NOT_US).

Protocol

Dimensions and type of prosthetic component: see the label.

Prosthetic components, except for trial abutments, should not be reused. 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 (<10N.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 deterio -ration 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 osseoin-tegrated, 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 mechani-cal strength of the prosthetic reconstruction and thus result in implant failure. In addition, it may prevent the insertion of ele-ments for taking impressions.
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, 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 labeled 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 compo -nent, 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.
The Anthogyr systems have not been evaluated for safety and compatibility in the MR environment. The Anthogyr systems have not been tested for heating or migration in the MR environment.