CE 0459

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

Attention:The accompanying instructions must be consulted; Danger.

Do not reuse.

Not sterile.

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

REF Catalogue reference.

LOT Batch number.

Do not use if the packaging is damaged.

Manufacturer.

Date of manufacture

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

Complies with norms and standards in Russia.

25 N.cm Tightening torque

GTIN : Global Trade Item Number

Description

Titanium base for customised prosthetic restoration on Anthogyr Axiom® REG/PX implants.

M1.6 Black OPTS160 screw to firmly secure the customised prosthetic restoration to the implant.

Indications

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

Single-tooth sealed restorations and single -tooth restorations that are screw-retained on Anthogyr Axiom® REG/PX implants.

Contraindications

Allergy to a constituent material of the titanium bases: Ti6Al4V-ELI titanium.

Warnings and Precautions

Only clinicians trained in dental implants should install these components.
Single-use devices: do not reuse or re-sterilise. Risk of contamination and risk of deterioration of functional surfaces.
Prosthetic components must be attached to prevent their accidental inhalation or swallowing during intraoral use.
The titanium bases should not be modified (neither on the gingival nor on the coronal section). EVERY MODIFICATION RISKS WEAKENING THE MECHANICAL STRENGTH OF THE COMPONENT. Only sanding of the coronal section is permitted using corundum (Al_2O_3) with a particle size of 50 µm to 125 µm and at a pressure of 2 to 4 bars IN CASES WHERE SANDING IS REQUIRED BY THE MANUFACTURER OF THE CEMENTATION MATERIAL.
The M1.6 Black OPTS160 screw may only be used in order to firmly secure the prosthetic restoration to the implant in the mouth.
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
- Impairment of patient mastication
- Rejection of the implant

Sterilization

The titanium base provided together with its final screw is supplied non-sterile and should be cleaned and sterilized in accordance with the procedures in place for working with dental prostheses prior to placement inside the patient's mouth. CONSULT THE RECOMMENDATIONS OF THE MANUFACTURERS OF THE RESTORATION MATERIALS (COPING AND CEMENT) REGARDING COMPATIBILITY WITH THE METHODS OF STERILIZATION.

Instructions for use

➔ Fabricate the suprastructure using CAD/CAM machining or using the press technique. CONSULT THE RECOMMENDATIONS OF THE MANUFACTURERS OF THE RESTORATION MATERIALS REGARDING THE MINIMUM THICKNESS OF THE SUPRASTRUCTURE. WHERE ZIRCONIA IS MACHINED, THE THICKNESS OF THE WALLS OF THE SUPRASTRUCTURE SHOULD BE GREATER THAN OR EQUAL TO 0.4 mm. Where the suprastructure is fabricated by machining, the corresponding CAD library can be downloaded at www.anthogyr.com.
➔ Assemble the titanium base with the suprastructure in order to create the prosthetic restoration. CONSULT THE RECOMMENDATIONS OF THE MANUFACTURERS OF THE CEMENTATION MATERIALS REGARDING THE CEMENTATION PROTOCOL. In order to cement the ZIRCONIA suprastructure, Anthogyr recommends the use of the following cements: MULTILINK AUTOMIX from IVOCLAR VIVADENT or PANAVIA™ F2.0 from KURARAY DENTAL.
➔ Clean and sterilize the prosthetic restoration as well as the M1.6 Black OPTS160 screw.
➔ Screw the prosthetic restoration onto the implant using the M1.6 Black OPTS160 screw with 25 N.cm, for example with the aid of an INCCD or TORQ CONTROL® dynamometrical instrument.

Safety, Responsability

The proper use and handling of this product are entirely the responsibility of the user; they are performed without any supervision on our part.

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

Anthogyr systems have not been evaluated for safety and compatibility in the MR environment. Anthogyr systems have not been tested for heating or migration in the MR environment.

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