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Edition : A

REF. 063PROTH-ITMA_NOT_EN



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.



Sterilised by irradiation.



Not sterile.



Sterilisation by autoclave without packaging, at the specified temperature.



Do not sterilise by autoclave.



Catalogue reference.



Batch number.



Do not use if the package is damaged.



Store in a dry place.



Store away from light.



Manufacturer.



Manufacturing date.



La 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.



Tightening torque

GTIN : Global Trade Item Number

Indications

The sealing and healing screws protect the connection of the Axiom® TL REG/PX implant during the bone and tissue healing process. inLink® abutments are intended to be placed in the Axiom® BL REG/PX dental implants, these abutments include an inLink® connection

and Axiom® TL REG/PX lock are designed to support the prosthetic elements with inLink® connections.

The Multi-Unit TL abutments are designed to be placed in Axiom® TL REG/PX dental implants. They enable the support of multiple-unit restorations utilising the components of the Multi-Unit range.

The lock allows the connection of a multiple or complete Simeda prosthetic restoration to an Axiom® TL REG/PX implant or an inLink® abutment.

M1.6 screws helps to connect to a single temporary abutment or a single Simeda prosthetic restoration to an Axiom® TL REG/PX implant

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 and the prosthetics Axiom® Multi Level®. 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 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. Materials used to fix prosthetic components should be handled in accordance with the manufacturer's instructions.

Description - compatibilities

inLink® abutments are used on Axiom® BL REG/PX implants.

The other premanufactured prosthetic parts are used exclusively on the Axiom® TL REG/PX implants.

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.

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.

It is possible to re-sterilise prosthetic components in titanium, titanium alloy 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 previously taken out of their original packaging and placed in an appropriate bag.

Anthogyr recommends using a class B autoclave.

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 of a prosthetic component, make sure that the connection is free of any fluid or other substance that could compromise good hold of the pros-

thetic component in the implant.

Each prosthetic component should be used only with its original screw or lock, 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.

PROSTHETIC COMPONENTS	
Type of component	Recommended tightening torque
inLink® abutment, Multi-Unit TL abutments temporary abutment, definitive lock and screw	25 N.cm
Other temporary prosthetic components	Moderate manual tightening (<10 N.cm)

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 values higher than the recommended 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.

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.

Contraindications

Allergy or hypersensitivity to the chemical components of the materials used: titanium, titanium alloy (Ti-6Al-4V ELI.)

 The Multi-Unit TL abutments must not be used if there is an axial divergence greater than 40° between the 2 implants, due to the risk of impossible insertion of the prosthesis.

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.