


Simeda® and Connect+® customised prostheses

Explanation of symbols and pictograms on the labels and packaging

 Read the precautions for use

 Do not reuse

 Non-sterile

 Manufacturer

 Identifying No.

Indications

Simeda® customised prostheses are designed for use in implant-supported prosthetic restorations assembled on Anthogyr dental implants or conical abutments or in tooth-supported prosthetic restorations (placed directly on natural teeth) in a specific patient.

Connect+® customised prostheses are designed for use in implant-supported prosthetic restorations assembled on dental implants or conical abutments on other MPS (Multi Platform Solutions) implant platforms or in tooth-supported prosthetic restorations (placed directly on natural teeth) in a specific patient.

Warnings and precautions for use

These components are intended to be used solely by dental practitioners and implantologists specially trained in oral and dental medicine or implant dentistry.

Sterilisation

The customised prostheses and their final screws are delivered non-sterile and must be cleaned and sterilised according to the current procedures adopted in implant dentistry.

Protocol

Customised prostheses are designed for a specific patient and must not be reused, as functional surfaces may be altered.

→ Digitalisation of implant platforms :

With standard impression taking, digitalisation will be performed with Scan-Adapters set on the master model with implant analogues or conical abutments. For multiple screw-retained prostheses, the impression must be taken with the platforms planned to be used (without adding conical abutments after the impression).

→ Customised prosthesis design :

Simeda® and Connect+® customised prostheses are designed digitally with Open Source CAD software (exocad®, 3Shape® or Dental Wings®).

Adjusting prosthetic components may compromise the mechanical strength of the prosthetic restoration and result in damage to the assembly as well as implant shock. ANY ADJUSTMENT CARRIES A RISK OF MECHANICALLY WEAKENING THE ASSEMBLY. The emergence profile must not be adjusted in order to preserve the condition of the surface at the gingival level.

Adjusting customised prostheses should be contemplated only if required by the patient's anatomy or the clinical situation. The following paragraphs describe the conditions that must be met for the warranty to be valid.

- Zirconia :

The adjustment of customised zirconia prostheses must be limited to a minimum height of 4 mm and 0.5 mm minimum wall thickness to ensure the mechanical hold of the prosthesis. The adjustments of zirconia elements must be performed with a fine grained diamond coated tip, at high speed and under abundant irrigation.

- Titanium :

The adjustment of customised titanium prostheses must be limited to a minimum height of 4 mm and 0.5 mm minimum wall thickness to ensure the mechanical hold of the prosthesis. The adjustment of titanium elements must be performed with specific titanium tools.

- Cobalt-Chrome :

The adjustment of customised cobalt-chrome prostheses must be limited to a minimum height of 4 mm and 0.5 mm minimum wall thickness to ensure the mechanical hold of the prosthesis. The adjustment of cobalt-chrome elements must be performed with specific cobalt-chrome tools.

→ Ceramisation of customised prostheses :

- On zirconia

Verify the compatibility of your products with the thermal expansion coefficient of zirconia: TEC (25–500°C) = 10.5 µm/mK.

For more details, please see the recommendations of your ceramic powder supplier.

- On titanium :

Verify the compatibility of your products with the thermal expansion coefficient of titanium: TEC (25–500°C) = 10 µm/mK.

For more details, please see the recommendations of your ceramic powder supplier.

- On cobalt-chrome :

Verify the compatibility of your products with the thermal expansion coefficient of cobalt-chrome: TEC (25–500°C) = 14.2 µm/mK.

For more details, please see the recommendations of your ceramic powder supplier and the RECOMMENDATIONS FOR THE PREPARATION OF COBALT-CHROME FRAMES PRIOR TO CERAMISATION.

- For titanium or CoCr prostheses, you can sand-blast lightly inside the connections to remove the oxidation layer (sand-blasting with aluminium oxide 50 µm, up to 2 bars).

→ Tightening the screws of customised implant prostheses :

The screw supplied by Anthogyr is specially reserved for clinical use and not laboratory use.

Before tightening any customised implant prostheses, ensure the connection is dry and free from any substance that may compromise the good hold of the element in the implant.

- On the master model, we recommend you use laboratory screws :

Do not exceed a tightening torque of 10 Ncm, as surfaces may deteriorate before placement in the mouth.

- When placing in the mouth, we recommend you use the screws supplied (failing that, use those supplied by the implant manufacturer).

If needed, the screws supplied are compatible with the tools and tightening torques of the implant system brand.

For the permanent tightening of the Simeda® prostheses, the following tightening torques should be applied:

MULTIPLE SCREW-RETAINED PROSTHESES ON ANTHOGYR MULTI-UNIT ABUTMENTS	
Type of component	Recommended tightening torque
Axiom® BL Multi-Unit abutment	15 N.cm
Anthofit / Ossfit conical abutment	15 N.cm

SINGLE SCREW-RETAINED PROSTHESES ON ANTHOGYR IMPLANTS	
Type of component	Recommended tightening torque
Axiom® BL and Axiom® TL implant	25 N.cm
Anthofit / Ossfit implant	35 N.cm

For Connect+® prostheses machined on other implant systems, follow the recommendations of the implant or conical abutment manufacturer.

Tightening at a torque lower than the recommended values may result in loosening of the customised prosthesis and deterioration of the prosthetic component and/or implant. Excessive tightening may result in mobilisation or implant shock and/or deterioration of the customised prostheses and/or implant and/or ancillary.

Customised prostheses installed permanently must not be removed: there is a risk of damaging the implant connection. Protect the implant connection at each step.

Ensure sufficient implant stability before assembling the customised prostheses.

Contraindications

Allergy or hypersensitivity to chemical components in the materials used: titanium, titanium alloy (Ti-6Al-4V ELI), cobalt-chrome, zirconia 3Y-TZP.

Patient information

Patients must accept regular medical follow-up and consult their doctor in case of an unexpected change in the performance of the customised prosthesis.

Patients must be informed of the need to ensure regular oral hygiene.

Safety, responsibility

The correct use and handling of customised prostheses are entirely the user's responsibility. Each customised prosthesis is identified with a reference number on the delivery note and on the traceability label: users are responsible for ensuring the traceability of customised prostheses used for each patient.

Waste resulting from the intervention (packaging, part extracted, etc.) must be handled as medical waste under the responsibility of the implant establishment.

Anthogyr thanks you for your trust and will be happy to supply you with additional information.