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Simeda® 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.

Caution

Contains hazardous substances

**Indications**

Simeda® customised prostheses are designed for use in implant-supported prosthetic restorations assembled on Anthogyr dental implants or conical abutments or on other implant systems MPS (Multi Platform Solutions) and 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.

Single-use devices: do not reuse. Risk of contamination and of altering the functional surfaces.
Customised prostheses are designed for a specific patient.

Colbalt-Chrome prostheses: Contains hazardous CMR substances: Cobalt 61.1% of the chemical composition.

**Cleaning and Sterilisation**

Customised prostheses and their screws are supplied NON STERILE. They must be cleaned and sterilised according to the cleaning and sterilisation manual available at ifu.anthogyr.com (search code: INBM100S for example) or you may request this from Anthogyr at the contact details below.

**Protocol**

→ Digitalisation of implant platforms :

When an impression is taken, the digitisation will be carried out using:

- scan-adapters for laboratory scanners placed on analogs of implants or abutments.

- digital transfers for intra-oral scanning placed on implants or abutments.

If an impression on the prosthetic part is possible, the impression must be taken on the prosthetic part (without the addition of a post-impression intermediate element).

→ Customised prosthesis design:

Simeda® 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 and Additive 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: CET (25–500°C) = 10.0 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: CET (25–500°C) = 10.3 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: CET (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**

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:

For Simeda® prostheses machined on other implant systems, the tightening torques must comply with the manufacturer's recommendations and the screwing must be performed using:

| 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 |

| SCREW-RETAINED PROSTHESES ON INLINK® CONNECTION | |
|---|---|
| Type of component | Recommended tightening torque |
| Inlink® abutment on implant | 25 N.cm |
| Axiom® TL Implant | 25 N.cm |

- The manufacturer's ancillary for Simeda® prostheses without Angulated Access.

- The Anthogyr golden ball ancillary for Simeda® prostheses with Angulated Access.

⚠ For prostheses supplied with at least one angulated screw channel, use Angulated Access permanent screws for all screw channels.

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.

## Clinical benefits

- Restoration of masticatory function
- Aesthetic restoration

## Contraindications

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

Long-span zirconia bridges and inlay/onlay/Maryland/cantilever bridges are contraindicated for patients with parafunctions (e.g. bruxism). Please refer to the customised prosthesis design manual (Ref. 402MANUEL-CAD_NOT) available online at www.anthogyr.com

## Residual risks and possible side effects

The clinical outcome of dental treatment is influenced by multiple factors. The following residual risks and possible side effects are related to the use of healing components and may lead to additional dental treatment at the dental practice: additional treatment at dentist's office; bite / mastication / phonetic problems; haematoma, damage to adjacent/opposing tooth;bleeding; discomfort; toxic reaction; injuries of gingiva; local infection (including peri-implantitis, periodontitis, gingivitis, fistula) or systemic; longer recovery / healing time than expected; loss of prosthetic component; poor aesthetic outcome; possibility to swallow / inhale small parts during the procedure; recall to the dentist's office; swelling; bruising; resorption of maxillary/mandibular ridge bone.

## Safety information regarding magnetic resonance imaging (MRI):

The safety and compatibility of Anthogyr devices that remain in the patient's body have not been evaluated in the magnetic resonance (MR) environment. They have not been tested for heat build-up, migration or artefacts in MR environments. The safety of Anthogyr devices in an MR environment is unknown. Performing an MRI examination on a patient wearing such a device may result in injury.

## Materials composition

→ Sina-Z (Z1) & Sina-T (Z2), Sina-ML (Z3), and Sina XT-T (Z4)

| Elements | weight (%) |
|---|---|
| $ZrO_2 + HfO_2 + Y_2O_3$ | ≥ 98.5% |
| $Y_2O_3$ | >4.5 and ≤ 7.65 |
| $HfO_2$ | ≤ 5.0 |
| $Al_2O_3$ | ≤ 0.5 |
| Other Oxides | ≤ 1 |

→ Technical feature Titanium (Milled and additive)

| Chemical components | Mass components (%) |
|---|---|
| Aluminium | 5.5 to 6.5 |
| Vanadium | 3.5 to 4.5 |
| Total residue (Fe, O, C, N, H) | ≤ 0.66 |
| Titanium | Balance |

→ Technical feature Cobalt Chrome alloy

| Chemical components | Mass components (%) |
|---|---|
| Chrome | 28,00 ± 2,00 |
| Tungsten | 8,50 ± 1,00 |
| Silicon | 1,65 ± 0,50 |
| Nickel | ≤ 0,10 |
| Total residue (Fe, Mn, Nb, N, Be, Cd, Pb, others) | ≤2,16% |
| Cobalt | Balance |

**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.

Any product-related issues must be reported to the local Anthogyr organisation together with the product in question. In the event of a serious incident, the user must file a report with the local Anthogyr organisation and the appropriate competent authority in accordance with local regulations.

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.

**Additional information**

Additional information is available in the following documents:

Customised prosthesis design manual (Ref.402MANUEL-CAD_NOT): www.anthogyr.com

**Serenity Warranty Exclusions:**

- Failures related to a trauma or damage caused by the patient or a third party.
- Failures occurring in patients presenting contraindications affecting the success of the restoration or implants.
- Products returned non-decontaminated and/or non-sterilised.
- Use of products non compliant with the indications specified in the Anthogyr instructions or non compliant with current best practices.
- An impression for which the tolerance would make the loading of the CAD/CAM customised prosthetic part manufactured by Anthogyr impossible.
- Any reworking made to the CAD/CAM customised prosthetic part manufactured by Anthogyr.
- Anthogyr reserves the right to withdraw the Serenity® programme warranty if the design is not compliant with the defined mechanical limits.
- Cases of force majeur.