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Axiom® temporary components

Instructions for use

	Temporary abutments				Temporary copings				Prosthetic screws
	Axiom® BL	Axiom® TL	inLink®	Axiom® 2.8	Axiom® BL AxIN®	Axiom® TL AxIN®	Multi-Unit (straight access)	Multi-Unit (angulated access)	Axiom® BL Axiom® TL
									
Ø prosthetic platform (mm)	3.4/4.0/5.0/6.0	4.0 (N)/ 4.8 (R)	4.0 (N)/ 4.8 (R)	2.8	4.0/5.0	4.0/4.8	4.0 (N)/ 4.8 (R)	4.0 (N)/ 4.8 (R)	-
Gingival height (mm)	0.75/1.5/2.5/3.5/4.5	-	-	1.0/2.5/4.0/5.5	-	-	-	-	-
Angulation	0°	0°	0/10/15/25°	0°	10/15/25°	10/15/25°	0°	0/10/15/25°	-

1. Product description

The Axiom® temporary components range includes prosthetic parts used for Axiom® dental implant restorations. These components are offered in a variety of shapes and sizes to meet the specific needs of every patient.

These instructions for use are valid for the following Axiom® temporary prosthetic components:

Axiom® temporary abutments:

- Axiom® Bone Level (BL) temporary abutments
- Axiom® Tissue Level (TL) temporary indexed abutments
- Axiom® Tissue Level (TL) temporary non-indexed abutments
- inLink® temporary abutments
- Axiom® 2.8 temporary abutments

Axiom® temporary copings:

- AxIN® temporary copings
- Multi-Unit temporary copings with straight access
- Multi-Unit temporary copings with angulated access

Prosthetic screws:

- Axiom® TL prosthetic screws
- Axiom® BL prosthetic screws

A prosthetic screw is supplied with Axiom® BL temporary abutments, Axiom® TL temporary abutments and Multi-Unit temporary copings, in the same packaging.

A definitive inLink® lock is supplied with inLink® temporary abutments, in the same packaging.

A definitive inLink® lock and a try-in inLink® lock are supplied with inLink® try-in temporary abutments, in the same packaging.

Materials:

Axiom® BL, Axiom® TL and inLink® temporary abutments, AxIN® temporary copings, screws and some Multi-Unit temporary copings are made of Titanium-6Aluminium-4Vanadium ELI alloy:

Chemical components	Composition, % (mass/mass)
Aluminium	5.50 to 6.50
Vanadium	3.50 to 4.50
Iron	≤ 0.25
Oxygen	≤ 0.13
Carbon	≤ 0.08
Nitrogen	≤ 0.05
Hydrogen	≤ 0.012
Titanium	Balance

Axiom® 2.8 temporary abutments and some Multi-Unit temporary copings are made of polyetheretherketone (PEEK):

Chemical components	Composition, % (mass/mass)
Polyetheretherketone	100

2. Intended use

Axiom® temporary components can be used prior to the installation of the final components to maintain, stabilise and shape the soft tissue during the healing phase.

Axiom® temporary abutments are intended to be placed into Axiom® dental implants to provide support for temporary restorations.

Axiom® temporary copings are intended to be placed on abutments to provide support for temporary restorations.

Prosthetic screws are intended to be placed into Axiom® BL or Axiom® TL dental implants to attach the restoration.

3. Indications

Axiom® temporary components directly or indirectly connected to the dental implant are indicated to support temporary single-unit or multiple-unit restorations.

Prosthetic screws are indicated to attach temporary restoration through an abutment on Axiom® dental implants.

Specific indications

TS161P Axiom® TL prosthetic screw is also indicated to attach multiple-unit customised restoration on Axiom® TL dental implants.

	Indication		
	Single-unit	Multiple-unit	Full arch
Axiom® Temporary abutments and associated prosthetic screws			
Axiom® BL temporary abutments	•	•	•
Axiom® TL temporary indexed abutments	•		
Axiom® TL temporary non-indexed abutments		•	•
inLink® temporary abutments			•
Axiom® 2.8 Temporary abutments			
Axiom® 2.8 temporary abutments	•		

	Indication		
	Single-unit	Multiple-unit	Full arch
Temporary copings and associated prosthetic screws			
AxIN® temporary copings	•		
Multi-Unit temporary copings		•	•
Prosthetic screws for customised prosthesis			
Axiom® TL prosthetic screws		•	•

All components described in these instructions for use have a maximum duration of usage of 180 days.

4. Clinical benefits

The following clinical benefit concerns temporary abutments, temporary copings and prosthetic screws.

Temporarily restore function of a missing tooth: be biocompatible, withstand masticatory forces, and provide support for the prosthetic components.

5. Patient type and intended user

Axiom® temporary components are intended for partially or totally edentulous adults requiring a single-unit or multiple-unit tooth restoration and who do not present any of the conditions mentioned in the "Contraindications" section.

Design and preparation of the prosthesis:

Axiom® temporary components must be used by a surgeon and/or dental laboratory technician trained in dental implantology.

Placement of the prosthesis:

The prosthesis must be used by a surgeon trained in dental implantology.

6. Contraindications

Allergy or hypersensitivity to chemical components in the materials used and mentioned in the "Product description" section.

InLink® temporary abutments must not be used for unitary restoration or partial restoration or implant-supported overdenture with a prefabricated bar attachment system.

7. Warning

Implant surgery is a complex dental procedure. Incorrect techniques can cause implant failure and/or loss of bone support.

Appropriate training and qualification as well as a good knowledge of surgical techniques with Anthogyr products are required. Anthogyr offers specific trainings.

8. Caution/Precaution

Clinical use:

- Single-use devices: do not reuse or re-sterilise. Risk of contamination and risk of alteration of the functional surfaces.
- It is important to perform a pre-clinical assessment and treatment plan that takes into account the anatomical constraints of the future restoration.
- Axiom® temporary components must be fixed on a sufficiently stable implant.
- As far as possible, the prosthetic parts must be firmly fastened to avoid the inhalation or swallowing of parts during intraoral use.
- Axiom® temporary components must not be tightened with a contra-angle.
- Axiom® 2.8 temporary components must not be impacted.
- Do not use a prosthetic part after the expiry date indicated on the packaging.
- Do not remove Axiom® temporary components doing lateral movement to avoid mobilisation of the implant or the loosening of other components.
- inLink® locks should not be put in the oven.
- Use temporary cement for the attachment of temporary copings. Dental cement or any other material used for the attachment of the prosthetic components should be processed as specified by the manufacturer.
- inLink® and Axiom® TL temporary abutments cannot be used for impression taking, there is a risk that the disinsertion of the prosthesis is impossible.

Component rework:

Temporary components rework is prohibited except for modifying the coronary part when necessary. In that case, rework should be limited so as to ensure at least a 4-mm cementing height.

Safety information regarding magnetic resonance imaging (MRI):

Non-clinical testing and MRI simulations were performed by Institut Straumann AG to evaluate the dental implant system offered by Anthogyr. Non-clinical testing demonstrates that these products are MR Conditional. A patient with an Anthogyr Dental Implant System can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg and head average SAR of 3.2 W/kg, for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

The scanning conditions defined above will produce a maximum temperature increase of 4.9 °C in implants from the Anthogyr Dental Implant Systems after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by implants from an Anthogyr Dental Implant System extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

9. Residual risks and 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 Axiom® temporary components and may lead to additional dental treatment at the dental practice:

Residual risks:

- additional treatment at dentist's office
- bite/mastication/phonetic problems
- bone damage
- damage to adjacent/opposing tooth
- discomfort
- hyperplasia
- hypersensitivity/allergic reaction
- implant fracture
- injuries of gingiva
- irritation/inflammation
- local or systemic infection (including peri-implantitis, periodontitis, gingivitis, fistula)
- local pain
- longer recovery/healing time than expected
- loss of implant
- loss of prosthetic component
- poor aesthetic outcome
- possibility of prolongation of surgery
- possibility of surgical implant explantation
- possibility to swallow/inhale small parts during the procedure
- recall to the dentist's office

Side effects:

- swelling
- local inflammation
- bruising
- resorption of maxillary/mandibular ridge bone
- local infection
- minor bleeding

10. Compatibility information

Anthogyr implants and prosthetic components are available in a wide variety of configurations. Only Anthogyr parts that are compatible with the implant connection are suitable for use. For more information, please refer to the manuals listed in the "Further information" section.

Type of component		Compatible implant/abutment	Associated laboratory screw*	Associated fixation screw*	Compatible instruments
Temporary abutments	Axiom® BL	Axiom® BL implants	OPTS162	OPTS161	Hexagonal instruments
	Axiom® TL indexed	Axiom® TL implants	TS162 TS163	TS161	Hexagonal instruments
	Axiom® TL non-indexed	Axiom® TL implants	TS162P-2 TS163P-2	TS161P	Hexagonal instruments
	inLink®	Axiom® TL implants + inLink® abutments	ILL300	ILL100 / ILLG100 ILL100T-4 / ILLG100T-4 ILL110 / ILLG110	Ball instruments
	Axiom® 2.8	Axiom® 2.8 implants	-	-	Prehensive wrenches
Temporary copings	Axiom® BL AxIN®	Axiom® BL AxIN® bases	AXIN152-27SL1 AXIN152-27SL2	AXIN152-27-S1 AXIN152-27-S2	Ball instruments
	Axiom® TL AxIN®	Axiom® TL AxIN® bases	AXIN156-0X-SL	AXIN156-0X-S	Ball instruments
	Multi-Unit (straight access)	Axiom® BL or Axiom® TL Multi-Unit abutments	MU141 MUT101 MUT102	MU140Z	Hexagonal instruments
	Multi-Unit (angulated access)	Axiom® BL or Axiom® TL Multi-Unit abutments	MUAA142-4	MUAA141	Ball instruments
Prosthetic screws for customised prosthesis	Customised multiple-unit restoration	Axiom® TL implants	TS162P-2 TS163P-2	TS161P	Hexagonal instruments

*All references identified by "AA" are dedicated to Angulated Access.
All references identified by "P" at the end of the reference are dedicated to multiple-unit restoration.

11. Cleaning and decontamination

Sterile components:

Anthogyr sterile prosthetic components are supplied sterile (GAMMA sterilisation) in blue packaging and are identified with a STERILE R logo. They are intended for single use. Do not clean or sterilise the prosthetic components. Cleaning, decontamination and sterilisation can compromise the essential material and design features of the prosthetic components and result in device failure.

Non-sterile components:

Anthogyr non-sterile prosthetic components are supplied in white packaging and are identified with a ⚠ logo. Before treatment, remove the components from their packaging. Do not use the components if the packaging is opened or damaged. They must be cleaned and decontaminated before use and after each use for reusable components. Anthogyr recommends following the protocol described in the "cleaning and sterilisation" manual available at ifu.anthogyr.com or on request from Anthogyr at the above address.

For sterilisation, see the "Sterilisation" section.

12. Sterilisation

Sterile components:

For sterile prosthetic components, check that the entire packaging of the device is undamaged before opening. Prosthetic components with a damaged packaging must not be used. It is recommended to have a replacement component readily available for use. The intact blister pack protects the sterilised prosthetic component against any external influence and, if stored properly, guarantees sterility until the expiry date. The blister pack must not be opened before use of the prosthetic component. When removing the prosthetic component from the sterile packaging, asepsis rules must be followed.

Anthogyr declines all responsibility for re-sterilised components, regardless of who carried out the re-sterilisation or the method used. Under no circumstances should a previously used or non-sterile prosthetic component be placed in the patient's mouth. If the original packaging is damaged, Anthogyr will not accept the return of the content.

Non-sterile components:

Anthogyr prosthetic components delivered non-sterile must be sterilised before use. Anthogyr recommends following the protocol described in the cleaning and sterilisation manual available at ifu.anthogyr.com or on request from Anthogyr at the above address.

After the sterilisation was done, asepsis rules must be followed.

Please refer to the manufacturers' recommendations for restoration materials (superstructure and adhesive) regarding compatibility with sterilisation methods.

13. Protocol for use

Refer to the brochures listed in the "Further information" section for detailed step-by-step instructions.

A - Protocol for Axiom® BL and Axiom® TL temporary abutments

1. Clean and sterilise (See §Cleaning and decontamination and §Sterilisation) the temporary prosthesis.
2. Before screwing the abutment, ensure that the connection is free of any fluid or other substance that may compromise the proper fit of the prosthetic component in the implant.
3. Place the temporary abutment in the mouth.
4. Tighten the temporary screw to 25 Ncm with a hexagonal wrench and the prosthetic dynamometric wrench or with a hexagonal mandrel and the TORQ CONTROL®. Use the temporary screw, the definitive screw should only be used for definitive implant/abutment fixation.
5. Close the screw channel.

Over-tightening the abutment can deteriorate the implant connection and/or break the abutment.

Insufficient tightening of the abutment may result in the abutment falling into the patient's mouth.

B - Protocol for inLink® temporary abutments

1. Clean and sterilise (See §Cleaning and decontamination and §Sterilisation) the temporary prosthesis.
2. Before screwing the abutments, ensure that the connection is free of any fluid or other substance that may compromise the proper fit of the prosthetic component in the implant.
3. Place the temporary prosthesis with its new definitive locks in the mouth. To facilitate the placement of the prosthesis, screw the locks progressively starting with the guiding locks.
4. Tighten the screw to 25 Ncm with a ball wrench and the prosthetic dynamometric wrench or with a ball mandrel and the TORQ CONTROL®.
5. Close the screw channel.

Over-tightening the abutment can deteriorate the implant connection and/or break the abutment.

Insufficient tightening of the abutment may result in the abutment falling into the patient's mouth.

C - Protocol for Axiom® 2.8 temporary abutments

Option 1: Fixation of the crown in the mouth

1. Before installation of the abutment, ensure that the connection is free of any fluid or other substance that may compromise the proper fit of the prosthetic component in the implant.
2. Insert the temporary abutment into the implant using the prehensive wrench or the threaded gripper wrench, and hand press the abutment to lock it inside the implant.
3. Fix the temporary crown onto the temporary abutment.

Option 2: Fixation of the crown in the dental laboratory

1. Clean and sterilise (See §Cleaning and decontamination and §Sterilisation) the temporary prosthesis.
2. Before installation of the abutment, ensure that the connection is free of any fluid or other substance that may compromise the proper fit of the prosthetic component in the implant.
3. Place the assembly in the patient's mouth and hand press to secure it inside the implant.

Warning: To avoid disinsertion of the temporary abutment, the temporary prosthesis must be protected by a dental splint or by the positioning of a restraint on the adjacent teeth.

D - Protocol for AxIN® temporary copings

Assembly of the temporary prosthesis:

1. Clean and sterilise (See §Cleaning and decontamination and §Sterilisation) the temporary prosthesis.
2. Insert the definitive screw in the AxIN® base.
3. Place the temporary prosthesis on the resulting assembly, aligning the trilobe indexation in order to surround the screw.

Placement of the temporary prosthesis:

1. Before screwing the prosthesis, ensure that the connection is free of any fluid or other substance that may compromise the proper fit of the prosthetic component in the implant.
2. Position the prosthesis in the mouth.
3. Tighten the screw to 25 Ncm with a ball wrench and the prosthetic dynamometric wrench or with a ball mandrel and the TORQ CONTROL®.
4. Close the screw channel.

Over-tightening the coping can deteriorate the implant connection and/or break the abutment.

Insufficient tightening of the abutment may result in the abutment falling into the patient's mouth.

E - Protocol for Multi-Unit temporary copings with straight access

1. Clean and sterilise (See §Cleaning and decontamination and §Sterilisation) the temporary prosthesis.
2. Position the temporary prosthesis in the mouth.
3. Tighten the temporary screw to 15 Ncm with a hexagonal wrench and the prosthetic dynamometric wrench or with a hexagonal mandrel and the TORQ CONTROL®. Use the temporary screws, the definitive screws should only be used for definitive implant/abutment fixation.
4. Close the screw channel.

Over-tightening the coping can deteriorate the implant connection and/or break the abutment.

Insufficient tightening of the abutment may result in the abutment falling into the patient's mouth.

F - Protocol for Multi-Unit temporary copings with angulated access

1. Clean and sterilise (See §Cleaning and decontamination and §Sterilisation) the temporary prosthesis.
2. Position the temporary prosthesis in the mouth.
3. Tighten the temporary AA screw to 15 Ncm with a ball wrench and the prosthetic dynamometric wrench or with a ball mandrel and the TORQ CONTROL®. Use the temporary screws, the definitive screws should only be used for definitive implant/abutment fixation.
4. Close the screw channel.

Over-tightening the coping can deteriorate the implant connection and/or break the abutment.

Insufficient tightening of the abutment may result in the abutment falling into the patient's mouth.

G - Protocol for Axiom® TL prosthetic screws

1. Clean and sterilise (See §Cleaning and decontamination and §Sterilisation) the prosthesis and the definitive screw.
2. Before screwing the prosthesis, ensure that the connection is free of any fluid or other substance that may compromise the proper fit of the prosthetic component in the implant.
3. Place the prosthesis into the implant.
4. Tighten the definitive screw to 25 Ncm with a hexagonal wrench and the prosthetic dynamometric wrench or with a hexagonal mandrel and the TORQ CONTROL®.
5. Close the screw channel.

Over-tightening the screw can deteriorate the abutment connection and/or break the screw.

Insufficient tightening of the screw may result in the screw and/or the prosthesis falling into the patient's mouth.

14. Healing phase

The healing period required for osseointegration varies considerably and depends on the individual patient and treatment.

It is the sole responsibility of the surgeon to decide when the implant can be loaded.

The temporary restoration must be placed in sub-occlusion.

15. Further information

For more information on the use of Anthogyr products, please contact your local Anthogyr sales representative or contact Anthogyr customer service or visit ifu.anthogyr.com and www.anthogyr.com.

For more specific information on Axiom® temporary components, please refer to:

- *Axiom® 2.8 user guide (AXIOM2-8_NOT)*
  Search code on ifu.anthogyr.com: OPTP210
- *Axiom® Multi Level® Prosthetic user guide (AXIOM-MLP_NOT)*
  Search code on ifu.anthogyr.com: OPTP310
- *Cleaning and Sterilisation user guide (NETT-STE_NOT)*
  Search code on ifu.anthogyr.com: TS161

Subject to the availability of the European Medical Device Database (EUDAMED), the summary of safety and clinical performance characteristics (SSCP) is available at: https://ec.europa.eu/tools/eudamed.

Until EUDAMED is fully functional, the SSCP can be requested to Anthogyr at the following address: clinical@anthogyr.com.

Product Type	Basic UDI-DI
Axiom® 2.8 temporary abutments	36633940007QQ
Multi-Unit PEEK temporary copings with straight access	36633940012QH
Axiom® TL temporary non-indexed abutments inLink® temporary abutments	36633940009QU
Multi-Unit Titanium temporary copings with straight access Multi-Unit Titanium temporary copings with angulated access. Axiom® BL AxIN® temporary copings Axiom® TL AxIN® temporary copings	
Axiom® Bone Level BL temporary abutments	36633940105QR
Axiom® Tissue Level TL temporary indexed abutments	36633940107QV
Axiom® Unitary Prosthetic Screw	36633940109QZ
Axiom® Other Prosthetic Screw	36633940005QL

16. Storage

Store these products in a clean, dry area, at ambient temperature. Improper storage may compromise the essential characteristics of the materials and design, which may lead to device failure.

17. Waste treatment

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

18. Information to be provided to the patient

Information on contraindications, warnings, precautions, side effects and complications with Anthogyr devices should be provided to the patient.

The patient must be informed about MRI compatibility regarding the Anthogyr product used.

Patients must accept regular medical follow-ups and should consult their doctor in the event of any unexpected change in the performance of the prosthetic reconstitution.

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

Patient must be advised to remain cautious for the first few weeks after surgery.

Traceability information is available to patients via the detachable labels on the device.

19. Notes

The practitioner must have the necessary knowledge to practice dental implantology and must be familiar with the handling instructions for Anthogyr products as described in this document in order to use Anthogyr products safely and in accordance with their instructions for use.

Anthogyr products must be used in accordance with the manufacturer's instructions for use. The dental surgeon is solely responsible for the proper use of Anthogyr products in accordance with their instructions for use and to determine whether the product is suitable for the individual patient's situation.

Anthogyr products are part of a complete range and must be used in combination with the corresponding original components and instruments distributed by Anthogyr, its parent company and any affiliates or subsidiaries of the parent company ("Straumann"). The use of third-party products not distributed by Anthogyr voids any warranty or other obligation, express or implied, of Anthogyr.

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. Anthogyr also offers an online complaint service in the countries concerned.

20. Validity

The publication of this document supersedes and replaces all previous versions.

21. Availability

Some components of the Anthogyr implant system are unavailable in certain countries.

22. Symbols

The following table describes the symbols that may be printed on the packaging label. Please refer to the label on the packaging for the applicable product symbols.

Symbol	Description of symbol	Source of symbol
	Manufacturer	NF EN ISO 15223-1
	Date of manufacture	NF EN ISO 15223-1
REF	Catalogue number	NF EN ISO 15223-1
LOT	Batch code	NF EN ISO 15223-1
SN	Serial number	NF EN ISO 15223-1
	Consult instructions for use or consult electronic instructions for use	NF EN ISO 15223-1
MD	Medical Device	NF EN ISO 15223-1
CE	CE marking - compliance with current regulations	Directive 93/42/CEE ——————— MDR (EU) 2017/745
Rx only	U.S. federal law restricts this device to sale by or on the order of a dental professional	21 CFR 801.109(b)(1)
	Use-by date	NF EN ISO 15223-1
	Single sterile barrier system	NF EN ISO 15223-1
	Single sterile barrier system with protective packaging inside	NF EN ISO 15223-1
STERILE R	Sterilised using irradiation	NF EN ISO 15223-1
STERILIZE	Do not resterilise	NF EN ISO 15223-1
NON STERILE	Non-sterile	NF EN ISO 15223-1
135°C	Sterilisable in a steam steriliser (autoclave) at temperature specified	ISO 7000 - 2868
135°C	Non sterilisable in a steam steriliser (autoclave) at temperature specified	Anthogyr
	Do not use if packaging is damaged and consult instructions for use	NF EN ISO 15223-1
	Keep away from sunlight	NF EN ISO 15223-1

Symbol	Description of symbol	Source of symbol
	Do not re-use	NF EN ISO 15223-1
	Caution	NF EN ISO 15223-1
	Contains hazardous substances	NF EN ISO 15223-1
25 N.cm	Screwing torque	Anthogyr
	Axiom® 2.8 temporary abutment	Anthogyr
	Axiom® BL temporary abutment + prosthetic screw	Anthogyr
	inLink® straight temporary abutment + standard inLink® lock	Anthogyr
	inLink® straight temporary abutment + guiding inLink® lock	Anthogyr
	inLink® angulated temporary abutment + standard inLink® lock	Anthogyr
	inLink® angulated temporary abutment + guiding inLink® lock	Anthogyr
	Axiom® TL temporary abutment + prosthetic screw	Anthogyr
	Axiom® TL non-indexed temporary abutment + prosthetic screw	Anthogyr
	AxIN® temporary coping	Anthogyr
	Axiom® Multi-Unit temporary Titanium coping + prosthetic screw	Anthogyr
	Axiom® Multi-Unit temporary PEEK coping + prosthetic screw	Anthogyr
	Axiom® Multi-Unit temporary coping with angulated access + prosthetic screw	Anthogyr
	Axiom® M1.6 prosthetic screw	Anthogyr
	Multi-Unit M1.4 prosthetic screw	Anthogyr