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Titanium bases

Instructions for Use

AxIN® bases		CEREC®* compatible bases		Single-unit X-Base® titanium bases				Multiple-unit X-Base® titanium bases		AxIN® protective caps	X-Base® titanium bases castable copings		Prosthetic screws	
Axiom® BL	Axiom® TL	Axiom® BL	Axiom® TL	Axiom® BL		Axiom® TL		Axiom® TL	Multi-Unit	Axiom® BL/TL	Axiom® BL/TL/ Multi-Unit		Axiom® BL	Axiom® TL
														

(* CEREC® is a brand of Dentsply Sirona Inc.)

1. Product description

The Axiom® Multi Level® prosthetic range includes prosthetic parts used for Axiom® Multi Level® 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® prosthetic components:

- AxIN® bases for Axiom® BL implants
- AxIN® bases for Axiom® TL implants
- CEREC®* compatible bases for Axiom® BL implants
- CEREC®* compatible bases for Axiom® TL implants
- X-Base® titanium bases for Axiom® BL implants
- X-Base® titanium bases for Axiom® TL implants
- X-Base® titanium bases for Multi-Unit abutments
- AxIN® protective caps
- X-Base® titanium bases castable copings
- Prosthetic screws

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A prosthetic screw is supplied with the titanium bases, in the same packaging.

Materials:

Bases and screws 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

Prosthetic screws are DLC (Diamond-Like Carbon) coated.

AxIN® protective caps are made of Polyetheretherketones (PEEK).

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

X-Base® titanium bases castable copings are made of Polymethylmethacrylate (PMMA).

2. Intended use

AxIN® bases are intended to be used with Axiom® dental implant to provide support for single-unit prosthetic restorations.

CEREC®* compatible bases are intended to support screw-retained restorations on Axiom® implants. (* CEREC® is a brand of Dentsply Sirona Inc.)

X-Base® titanium bases are intended to support screw-retained restorations on Axiom® implants or Multi-Unit abutments.

AxIN® protective caps are intended to protect the coronary part of the AxIN® bases.

X-Base® titanium bases castable copings are intended to prepare the restorations with casting technique. They are designed to fit the coronary part of the X-Base® titanium bases.

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

3. Indications

AxIN® bases are indicated to support temporary or definitive single-unit restorations that are customised and screw-retained on Axiom® BL or Axiom® TL implants with angulated access up to 25°.

CEREC®* compatible bases are indicated to support definitive, single-unit, customised restorations on Axiom® BL or Axiom® TL implants. (* CEREC® is a brand of Dentsply Sirona Inc.)

Single-unit BL and TL X-Base® titanium bases are indicated to support temporary or definitive, single-unit, customised restorations on Axiom® BL and TL implants respectively.

Multi-Unit X-Base® titanium bases and multiple-unit TL X-Base® titanium bases are indicated to support temporary or definitive multiple-unit, customised restorations on Multi-Unit abutments or Axiom® TL implants respectively.

AxIN® protective caps are indicated to protect the coronary part of the AxIN® bases. They can be used in case of fabrication of a temporary restoration at the dental office to protect the AxIN® base during laboratory work. Protective caps have a maximum duration of usage of 60 minutes.

X-Base® titanium bases castable copings are indicated to support wax addition before casting of the definitive restoration which is to be placed on X-Base® titanium bases.

Prosthetic screws are indicated to attach single-unit or multiple-unit restorations through a base on Axiom® dental implants.

	Single-unit restoration	Multiple-unit restoration
AxIN® bases	•	
CEREC®* compatible bases	•	
Single-unit BL X-Base® titanium bases	•	
Single-unit TL X-Base® titanium bases	•	
X-Base® titanium bases for Multi-Unit		•
Multiple-unit TL X-Base® titanium bases		•

(* CEREC® is a brand of Dentsply Sirona Inc.)

4. Clinical benefits

The following clinical benefit concerns bases and prosthetic screws.

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

5. Patient type and intended user

The devices covered by this IFU 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.

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

6. Contraindications

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

AxIN® base on Axiom® BL implant:

The AxIN® solution is contraindicated in the molar sector on an AxIN® base with a 1.5 mm height and a diameter of Ø 4.0 to Ø 5.0 mm.

AxIN® base on Axiom® TL implant:

The AxIN® solution is contraindicated in the molar sector on an Axiom® TL implant with a 1.5 mm neck height on platforms N and R.

X-Base® titanium bases for single-unit Angulated-Access restorations on Axiom® TL implant:

The X-Base® solution for single-unit Angulated-Access temporary and definitive restorations is contraindicated in the molar sector on an Axiom® TL implant with a 1.5 mm neck height on platforms N and R.

X-Base® titanium bases for single-unit Angulated-Access temporary restorations on Axiom® BL implant:

- X-Base® BL with 1,5 mm gingival height used for temporary single-unit restoration with angulated access are contraindicated in canine, premolar and molar sector.
- X-Base® BL with 2,5 mm and 3,5 mm gingival heights used for temporary single-unit restoration with angulated access are contraindicated only in molar sector.

X-Base® titanium bases on Multi-Unit abutment:

The X-Base® titanium bases on Multi-Unit abutment solution is contraindicated in the presence of an axis gap of more than 40° between two abutments: risk of impossibility to insert the prosthesis.

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 and 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.

X-Base® titanium bases for single-unit and angulated channel *restorations are available in two versions: Standard AA version and AA U version. The "U" design is made for practitioners who might not have placed the trilobe of the implant in the right position and who would need the window of the angulated access to be aligned with a flat portion of the trilobe.*

- The definitive prosthetic component must be fixed on a sufficiently stable implant.
- During cement process, take care to remove any excess cement.
- As far as possible, the prosthetic parts must be firmly fastened to avoid the inhalation or swallowing of parts during intraoral use.
- The prosthetic components must not be tightened with a rotating power instrument.

Component rework:

All the bases must not be modified (neither on the gingival portion nor on the crown portion). Any modification constitutes a risk of mechanical weakening of the part. Only the crown portion of the CEREC®* compatible bases is suitable for sandblasting, using corundum (Al_2O_3) with a granulometry of 50 µm to 125 µm, under 2 to 4 bar pressure, in cases where sandblasting is requested by the glue manufacturer. (* CEREC® is a brand of Dentsply Sirona Inc.)

X-Base® titanium bases castable coping can be reworked. Rework of X-Base® titanium bases castable copings must not affect the surfaces interfacing with the X-Base® titanium bases.

The other components must not be reworked in any way.

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 bases, AxIN® protective caps, X-Base® titanium bases castable copings and prosthetic screws 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.

11. Cleaning and decontamination

Anthogyr non-sterile prosthetic components are supplied in white packaging and are identified with a NON STERILE 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. Anthogyr recommends following the protocol described in the "cleaning and sterilization" manual available at ifu.anthogyr.com or on request from Anthogyr at the above address. For sterilisation, see the "Sterilisation" section.

12. Sterilisation

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. AxIN® bases

Choice of the AxIN® base

The definitive prosthetic restoration must be planned using try-in abutment and/or digital libraries.

Compatible information table

AxIN® bases							
Connection	Base Platform Ø [mm]	Gingival height [mm]	Prosthetic screw	Laboratory components	Lab rod	Compatible instruments	Associated protective cap
Axiom® BL	4.0/5.0	1.5	AXIN152-27-S1	AXIN152-27L41	CR20-4	Ball instruments	AXIN-PCC-40 AXIN-PCC-50
				AXIN152-27L51			
		2.5	AXIN152-27-S2	AXIN152-27L42			
				AXIN152-27L52			
Axiom® TL	4.0/4.8	-	AXIN156-0X-S	AXIN156-01-L			AXIN-PCC-40 AXIN-PCC-48
		-		AXIN156-02-L			

CEREC®* compatible bases							
Connection	Base Platform Ø [mm]	Gingival height [mm]	Prosthetic screw	Laboratory screw	DENTSPLY SIRONA® Scan body size/Block size	Selection of reference platform in CEREC®* software**	Compatible instrument
Axiom® BL	5.0	1.5	OPTS160	OPTS161	Size L	Dentsply Sirona Others NB RS 4.3	Hexagonal instrument
		2.5					
		3.5					
Axiom® TL	4.0	-	TS160	TS161	Size S	CAMLOG 3.3	
	5.0	-			Size L	Dentsply Sirona Others NB RS 4.3	

(* CEREC® is a brand of Dentsply Sirona Inc.)
*(** according to v.4.5.2)*

X-Base® titanium bases											
Connection	Indication	Channel	Base Platform Ø [mm]	Gingival Height [mm]	Coronary Height [mm]	Prosthetic screw	Laboratory screw	Hexagonal instru-ments	Ball instru-ments	Lab rod (CR25-4)	Associated castable coping
Axiom® BL	Single-unit	Straight	4.0/5.0/6.0	1.5/2.5/3.5	4.0/6.0	OPTS160	OPTS161 OPTS162	x			OPFLEXC406 OPFLEXC506 OPFLEXC606
	Single-unit	AA	4.0/5.0/6.0	1.5	4.0/6.0	OPFLEXS1-AA	OPFLEXSL1-AA		x	x	OPFLEXC4-AA15 OPFLEXC4-AA25 OPFLEXC5-AA15 OPFLEXC5-AA25 OPFLEXC6-AA15 OPFLEXC6-AA25
			4.0/5.0/6.0	2.5	4.0/6.0	OPFLEXS2-AA	OPFLEXSL2-AA		x	x	
			4.0/5.0/6.0	3.5	4.0/6.0	OPFLEXS3-AA	OPFLEXSL3-AA		x	x	
Axiom® TL	Single-unit	Straight	4.0/4.8	-	4.0/6.0	TS160	TS163 TS162	x			TFLEXC-N6 TFLEXC-R6
		AA	4.0/4.8	-	4.0/6.0	TFLEXS-AA	TFLEXSL-AA		x	x	TFLEXC-N-AA15 TFLEXC-N-AA25 TFLEXC-R-AA15 TFLEXC-R-AA25
	Multiple-unit	Straight	4.0/4.8	-	4.0/5.0	TS160P	TS163P-2 TS162P-2	x			TFLEXC-N5-P TFLEXC-R5-P
		AA	4.0/4.8	-	4.0	TFLEXS-PAA	TFLEXSL-PAA-2		x	x	TFLEXCNP-AA15 TFLEXCNP-AA25 TFLEXCRP-AA15 TFLEXCRP-AA25
Multi-Unit	Multiple-unit	Straight	4.0/4.8	-	4.0/5.0	MU140	MU141 MUT101 MUT102	x			MUNFLEXC MUFLEXC
		AA	4.0/4.8	-	4.0/5.0	MUAA140	MUAA142-4		x	x	MUNFLEXC-AA15 MUNFLEXC-AA25 MUFLEXC-AA15 MUFLEXC-AA25

When using a X-Base® titanium bases or CEREC®* compatible base for Axiom® BL implants, it is important to maintain the gingival profile of the previously used healing screw.
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.
(* CEREC® is a brand of Dentsply Sirona Inc.)

If the base must remain in the mouth during the fabrication of a temporary restoration at the dental office, place a protective cap on the AxIN® base and screw. The protective cap can be inserted and retrieved by hand or with tweezers. When placing the protective cap on the base, make sure to unscrew the prosthetic screw to prevent the wings of the AxIN® base from deploying. Tightening the prosthetic screw deploys the AxIN® retaining ring. The resulting friction between the protective cap and the base will make it difficult to place or remove the protective cap.

Design and fabrication of the restoration

It is recommended to use the laboratory base and the laboratory screw for the dental laboratory work. Do not use the AxIN® base and its definitive screw for the dental laboratory work. They are only used at the time of the assembly of the definitive components.

Prosthesis design

- Digitise the implant platform using the Scan-Adapter with a laboratory scanner certified by Anthogyr S.A., or using the appropriate Intra-oral transfer with an intraoral scanner, making sure to choose the correct CAD library, corresponding to the good CAD software.
- Prepare the Coping or crown using the CAD software in accordance with the dimensions of the base selected and the software manufacturer's instructions.
- Design the abutment with CAD software or a wax-up:
  - Angulated Access up to 25°.
  - Minimum prosthesis height on AxIN® base: 4.9 mm.
  - Minimum prosthesis diameter on AxIN® base: 4.5 mm.
- Machine the AxIN® prosthesis: order through the Anthogyr WebOrder by sending an STL file, a CAD file or a physical wax-up.

Preparation of the prosthesis

Finishing of the AxIN® prosthesis

- Reception of the AxIN® machined Zirconia prosthesis.
- On the master model obtained from the implant analog, assemble the laboratory base and its corresponding laboratory screw (see table in the "compatibility information" section).
- The resulting assembly allows the prosthesis to be easily assembled and disassembled during the various ceramisation cycles:
  - The machined prosthesis features a trilobe indexation that allows three possible positions of the definitive prosthesis on the laboratory base.
  - A very light manual tightening of the laboratory screw holds the definitive prosthesis on the laboratory base.
- If the machined prosthesis needs to be adjusted, the rework should be done using a diamond tipped drill bit on a rotary handpiece at 150,000-200,000 rpm and under abundant irrigation.
- Veneering of the prosthesis.

Assembly of the definitive components

- Insert the definitive screw in the AxIN® base.
- Place the AxIN® prosthesis on the resulting assembly, then check the alignment of the trilobe indexation.
- Check the orientation one last time on the master model with the definitive assembly before sending it to the practitioner.

Placement of the restoration

- Clean and sterilise (See §Cleaning and decontamination and §Sterilisation) the prosthesis.
- Install the prosthesis in the mouth.
- Before screwing of any prosthetic component, 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.
- Tighten the prosthetic screw to 25N.cm using the prosthesis dynamometric wrench and a ball wrench or the TORQ CONTROL® and a ball mandrel.
- Close the access channel after protecting the screw head.

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. CEREC®* compatible bases

(* CEREC® is a brand of Dentsply Sirona Inc.)

Design and fabrication of the restoration

For the design and fabrication of the restoration follow the instructions for use of the CADCAM system provider and material manufacturer. It is recommended to use a laboratory screw for the preparation work (prior to definitive placement). Do not use the screw delivered with the base.

- The prosthetic restoration has to be planned thanks to try-in abutment and / or digital libraries.
- Tighten the bases in the mouth with the laboratory screws (see table in the "compatibility information" section).
- Insert the DENTSPLY SIRONA® scanbody (see table in the "compatibility information" section) into the base and take the impression.
- Proceed with an intraoral scan to create a digital working model.
- Process the restoration in a block (see table in the "compatibility information" section) according to the material manufacturer's instructions for use. Always finalize the prosthetic restoration prior to bonding to the base prosthetic components.
- Ensure that the material wall thickness and other parameters of the restoration for the selected indication, as described in the instructions for use of the restoration material manufacturer, are followed.

Bonding of the restoration

Follow the instructions for use of both the dental material and bonding material manufacturers. To glue a ZIRCONIA superstructure, Anthogyr recommends the use of MULTILINK AUTOMIX by IVOCLAR VIVADENT or PANAVIA™ F2.0 by KURARAY DENTAL.

If sandblasting is required by the adhesive manufacturer, only the crown portion may be sandblasted with corundum (Al_2O_3) with a 50µm to 125µm particle size and under a pressure of 2 to 4 bars. During this step, the internal connection should be protected, and the abutment should be cleaned afterwards.

- ¬ Protect the connection of the base by attaching the base to an analog via laboratory screws (see table in the "compatibility information" section).
- ¬ For the following steps, we recommend handling the bases with a dental tweezers.
- ¬ Apply primer to the coronal part of the base and internal part of the prosthesis.
- ¬ Seal the access channel of the base with wax.
- ¬ Apply cement to the coronal part of the base, then place the prosthesis on the base to attach it. Allow to cure for a few seconds under a UV curing light. Remove excess cement.
- ¬ Unseal the access channel and clean.
- ¬ Photopolymerize the prosthesis in a UV cabinet for 5 min.
- ¬ Clean the restoration prior to further processing.

Placement of the restoration

- ¬ Clean and sterilise (See §Cleaning and decontamination and §Sterilisation) the prosthetic restoration and the prosthetic screw.
- ¬ Before screwing of any prosthetic component, 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.
- ¬ Place the prosthesis into the patient's mouth with the screw delivered with the base (see table in the "compatibility information" section), pre-tightening manually with a hexagonal wrench. Check that the prosthesis is correctly placed on all its platform.
- ¬ Tighten the prosthesis to 25 N.cm using the prosthesis dynamometric wrench and a hexagonal wrench or the TORQ CONTROL® and a hexagonal mandrel. Do not use a contra-angle to perform this procedure.
- ¬ Close the access channel after protecting the screw head.

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. X-Base® titanium bases

Choice of the X-Base® titanium bases

The prosthetic restoration has to be planned thanks to try-in abutment and / or digital libraries.

Design, fabrication and bonding of the restoration

Always make sure to protect the X-Base® titanium bases prosthetic connection by fixing it to an analog during lab procedures. It is recommended to use a laboratory screw for the dental laboratory work. Do not use the screw delivered with the base.

When using traditional workflow:

- ¬ Place the base into the analog on the master model by tightening the laboratory screws (see table in the "compatibility information" section).
- ¬ Fabricate the prosthetic restoration with press or casting techniques. Use Anthogyr castable coping which supports a clean and sharp-edged finish of the screw channel and a good fit to the X-Base® titanium bases.

When using a digital workflow:

- ¬ Digitise the implant platform using the Scan-Adapter with a laboratory scanner certified by Anthogyr S.A., or using the appropriate Intra-oral transfer with an intraoral scanner, making sure to choose the correct CAD library, corresponding to the good CAD software. CAD libraries can be downloaded from the www.anthogyr.com website.
- ¬ Design the prosthetic restoration using the CAD software.
- ¬ Process and finalize the prosthetic restoration according to the material manufacturer's instructions for use. Ensure to follow the selected prosthetic material wall thickness and parameters indicated in the Instructions for use of the material manufacturer.
- ¬ Lightly sandblast the internal part of the prosthesis, then steam-clean.

Note: Always finalize the prosthetic restoration prior to bonding to the X-Base® titanium bases prosthetic components.

Bonding:

It is not recommended to sandblast the X-Base® titanium bases coronary portion.

Follow the instructions for use of both the dental material and cement/bonding material manufacturer. Anthogyr recommends the use of PANAVIA™ V5 adhesive by KURARAY DENTAL.

Bonding the first base:

We recommend cementing the bases onto the most angulated analogs first.

a. Protect the connection of the base by attaching the base to an analog via laboratory screws (see table in the "compatibility information" section).
b. For the following steps, we recommend handling the bases with a dental tweezers.
c. Apply primer to the coronal part of the base and internal part of the prosthesis.
d. Seal the access channel of the base with wax.
e. Apply cement to the coronal part of the base, then place the prosthesis on the base to attach it. Allow to cure for a few seconds under a UV curing light. Remove excess cement.
f. Unseal the access channel and clean.
g. Photopolymerize the prosthesis in a UV cabinet for 5 min.

Bonding the other bases for multiple-unit restoration (if applicable):

- ¬ Attach the bases to the master cast using laboratory screws (see table in the "compatibility information" section).
- ¬ Repeat steps "c" to "g".
- ¬ Clean the restoration prior to sending it to the dentist.

Placement of the restoration

- ¬ Clean and sterilise (See §Cleaning and decontamination and §Sterilisation) the prosthetic restoration and the prosthetic screw.
- ¬ Before screwing of any prosthetic component, 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.

When placing a restoration with straight channel:

- ¬ Place the prosthesis into the patient's mouth with the screw delivered with the base (see table in the "compatibility information" section), pre-tightening manually with a hexagonal wrench. Check that the prosthesis is correctly placed on all its platforms.
- ¬ Tighten the prosthesis to the torque recommended in the table below using the prosthesis dynamometric wrench and a hexagonal wrench or the TORQ CONTROL® and a hexagonal mandrel. Do not use a contra-angle to perform this procedure.

When placing a restoration with angulated access (AA) channel:

- ¬ Place the prosthesis into the patient's mouth with the screw delivered with the base (see table in the "compatibility information" section), pre-tightening manually with a ball wrench.
- ¬ Optional: The angulated access screw gripper can also be used to place the screws in the mouth.
- ¬ Check that the prosthesis is correctly placed on all its platforms.
- ¬ Tighten the prosthesis to the torque recommended in the table below using the prosthesis dynamometric wrench and a ball wrench or the TORQ CONTROL® and a ball mandrel. Do not use a contra-angle to perform this procedure.

Connection	Tightening torque
Axiom® BL	25N.cm
Axiom® TL	
Multi-Unit	15N.cm

- ¬ Close the access channel after protecting the screw head.

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.

14. Healing phase

AxIN® bases (associated with AxIN® temporary copings) and X-Base® titanium bases may be used as support for temporary restorations which must be placed in sub-occlusion. After the soft-tissue healing phase, the temporary restoration is replaced with the appropriate final restoration.

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.

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 the bases, AxIN® protective caps, X-Base® titanium bases castable copings and prosthetic screws, please refer to:

- ¬ *Axiom® Multi Level® Prosthetic user Guide (AXIOM-MLP_NOT), for additional information on X-Base® titanium bases*
  Search code on ifu.anthogyr.com: OPFLEX414
- ¬ *Cleaning and Sterilization user guide (NETT-STE_NOT)*
  Search code on ifu.anthogyr.com: OPFLEX414
- ¬ *Customized prosthesis design manual (AXIOM-SIO_NOT), for information on intraoral scanning*
  Search code on ifu.anthogyr.com: 152-27-DT
- ¬ *Customised prosthesis design manual (MANUEL-CAD_NOT) available on the website www.anthogyr.fr, for information on digitalization and AxIN® prosthesis design*
- ¬ *Labside compatibility list (www.anthogyr.com), for information on which scan adapter and digital transfer to use*
- ¬ *Customized Labside User Guide Axiom® BL TL (LABSIDE_NOT) available on the website www.anthogyr.fr, for information on labside customized prosthesis design*

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, SSCP can be requested to Anthogyr at the following address: clinical@anthogyr.com.

Product Type	Basic UDI-DI
Multiple-unit base	36633940009QU
Multiple-unit Screw (DLC coated)	36633940010QD
Single-unit base	36633940107QV
Single-unit Screw (DLC coated)	36633940110QJ

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"), unless otherwise specified in these instructions for use. 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.

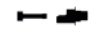
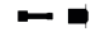
21. Availability

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
	Catalogue number	NF EN ISO 15223-1
	Batch code	NF EN ISO 15223-1
	Serial number	NF EN ISO 15223-1
	Consult instructions for use or consult electronic instructions for use	NF EN ISO 15223-1
	Medical Device	NF EN ISO 15223-1
	CE marking - compliance with current regulations	Directive 93/42/CEE ———— MDR (EU) 2017/745
	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
	Sterilised using irradiation	NF EN ISO 15223-1
	Do not resterilise	NF EN ISO 15223-1
	Non-sterile	NF EN ISO 15223-1
	Sterilisable in a steam steriliser (autoclave) at temperature specified	ISO 7000 - 2868
	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
	Do not re-use	NF EN ISO 15223-1
	Caution	NF EN ISO 15223-1
	Contains hazardous substances	NF EN ISO 15223-1
	Screwing torque	Anthogyr
	Axiom® BL AxIN® base + AxIN® prosthetic screw	Anthogyr
	Axiom® TL AxIN® base + AxIN® prosthetic screw	Anthogyr
	Axiom® BL CEREC®* base + prosthetic screw	Anthogyr

Symbol	Description of symbol	Source of symbol
	Axiom® TL CEREC®* base + prosthetic screw	Anthogyr
	Axiom® BL X-Base® titanium bases straight with coronal height 4 + prosthetic screw	Anthogyr
	Axiom® BL X-Base® titanium bases straight with coronal height 6 + prosthetic screw	Anthogyr
	Axiom® BL X-Base® titanium bases AA with coronal height 4 + prosthetic screw	Anthogyr
	Axiom® BL X-Base® titanium bases AA with coronal height 6 + prosthetic screw	Anthogyr
	Axiom® TL X-Base® titanium bases straight with coronal height 4 + prosthetic screw	Anthogyr
	Axiom® TL X-Base® titanium bases straight with coronal height 6 + prosthetic screw	Anthogyr
	Axiom® TL X-Base® titanium bases AA with coronal height 4 + prosthetic screw	Anthogyr
	Axiom® TL X-Base® titanium bases AA with coronal height 6 + prosthetic screw	Anthogyr
	Axiom® TL plural X-Base® titanium bases + prosthetic screw	Anthogyr
	Multi-Unit X-Base® titanium bases + prosthetic screw	Anthogyr
	Axiom® M1.6 prosthetic screw	Anthogyr
	AxIN® prosthetic screw	Anthogyr
	AxIN® protective cap	Anthogyr

(* CEREC® is a brand of Dentsply Sirona Inc.)