CE 0459

Anthogyr
2237 Av. André Lasquin
74700 Sallanches – France

www.anthogyr.com
E-mail: contact@anthogyr.com
Phone: +33(0)4 50 58 02 37

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Anthogyr Axiom® BL implants (REG/PX/X3 Implants)

Instructions for Use – Valid only in the United States

CAUTION: U.S. federal law restricts this device to sale by or on the order of a dental professional.

1. Product description

Axiom® Bone Level REG implants	Axiom® Bone Level PX implants	Axiom® Bone Level X3 implants
		

Axiom® Bone Level (BL) implants are part of the Axiom® Multi Level® system, an implant concept which offers a range of endosseous dental implants of various designs (length, diameter, thread profile, platform, etc.) and the corresponding prosthetic parts, healing components and ancillary instruments.
Axiom® Multi Level® implants are implants with a BCP (Biphasic Calcium Phosphate) sandblasted endosseous surface.
Axiom® Multi Level® dental implants can be used after extraction or after the loss of natural teeth to restore chewing function. The prosthetic restorations available include single crowns, bridges and partial or full dentures, which are connected to the implants via the corresponding abutments.
These instructions for use apply to the following dental implants:

- Axiom® BL REG implants
- Axiom® BL PX implants
- Axiom® BL X3 implants

A cover screw is supplied with the implant inside the packaging cap.

Materials:

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

2. Intended use

Anthogyr dental implants are suitable for endosteal implantation in the maxilla or mandible and for the functional and esthetic oral rehabilitation of patients with missing teeth.

3. Indications

Axiom REG:
Anthogyr AXIOM® REG implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures.
The Axiom dental system is indicated for one-stage or two-stage surgery.
It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading.
Prefabricated components are intended for use as accessories to dental implants to support implant-supported restorations.
Axiom® PX:
Anthogyr dental implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures.
Anthogyr dental systems are indicated for one-stage or two-stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading.
Axiom® X3:
The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.

4. Contraindications

Axiom® BL REG/PX/X3 implants are contraindicated in following cases:

- Allergy or hypersensitivity to chemical components in the materials used and mentioned in the "Product description" section.
- Absolute contraindications: serious diseases (tumours, heart disease, etc.), metabolism disorders, uncompensated haematologic diseases, drug addiction, alcoholism, psychosis, functional disorders, xerostomia, immune deficiency, leukocyte disorder, local or systemic treatments (steroid, anticoagulant, chemotherapy or radiation therapy, etc.).
- Relative contraindications: bruxism, occlusal stress, parafunction, unfavourable bone anatomy, pregnancy, growth not finished, insufficient oral hygiene, smoking lack of motivation or cooperation, irradiated bone, uncontrolled periodontal disease, oral infections or inflammations.
- Localised contraindications: Excessive resorption and/or insufficient bone quality, local radicular residues.

5. 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 training.
Specific warning language regarding implant bodies with implantable lengths less than 7 mm:
a. For short implants (i.e., strictly shorter than 7 mm), immediate restoration or loading on a single implant has not been studied and is not recommended for a terminal molar in an arch or cantilevering more than one pontic off a single implant.
b. Because of the reduced surface area for anchorage in the bone, implants shorter than 7 mm length should be used with caution because they present greater risks to failures compared to standard implants, and are recommended for the following situations:
i. As an additional implant together with longer implants to support implant-borne reconstructions.
ii. As an auxiliary implant for implant-borne bar constructions supporting full dentures in a seriously atrophied mandible.
c. When a short implant is the treatment of choice consider a two-stage surgical approach, splinting of implants, and placement of the widest possible implant. For short implants (i.e., strictly shorter than 7 mm), clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes in the implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length. If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. Allow longer periods for osseointegration.

d. Short implants (i.e., strictly shorter than 7 mm), should not be placed in patients who demonstrate untreated occlusal parafunction, such as bruxism or clenching.

6. Caution/Precautions

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.

Do not use an implant after the expiry date indicated on the packaging.

Always select the largest diameter implant that can be supported by the available bone thickness, bone quality, inter-dental spacing, and anticipated mastication forces. Particular care should be taken to assure proper implant alignment where comparatively high loads are expected. Small-diameter implants are not recommended for the posterior region. And for, Axiom® BL X3 implants with a 3.4 mm diameter are not recommended for single-unit tooth restorations in the molar sector.

Small-diameter implants and angled abutments are not recommended for the posterior region.

Axiom® PX implant placement is not recommended in D1 type bone.

Safety information regarding magnetic resonance imaging (MRI):

MR Conditional

Non-clinical testing and MRI simulations were performed to evaluate the dental implant system offered by Anthogyr. Non-clinical testing demonstrates that these products are MR Conditional. A patient with an implant from a 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 a 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.

7. 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® BL REG/PX/X3 implants and may lead to additional dental treatment at the dental practice:

Residual risks:

- additional treatment at dentist's office
- bite / mastication / phonetic problems
- bone compression
- 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
- nerve damage possibly resulting in chronic pain
- paraesthesia, dysaesthesia
- 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
- sinus perforation

Side effects:

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

8. 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 implant	Type of connection	Compatible components	Compatible instruments
Axiom® Bone Level	Conical	Axiom® BL	Axiom® BL implant screwing instruments (grey) *two length are included in the surgical kit*
		LOCATOR® (abutments) from ZEST DENTAL	

9. Cleaning and disinfection

Anthogyr dental implants are supplied sterile (GAMMA sterilization) and are intended for single use. Do not clean or sterilize the implants. Cleaning, disinfection and sterilization can compromise the essential material and design features of the implants and result in device failure.

10. Sterilization

Anthogyr dental implants are supplied sterile. Check that the entire packaging of the device is undamaged before opening. Implant with a damaged packaging must not be used. It is recommended to have a replacement implant readily available for use. The intact blister pack protects the sterilized implant against any external influence and, if stored properly, guarantees sterility until the expiry date. The blister pack must not be opened before implant use. When removing the implant from the sterile packaging, asepsis rules must be followed.

Anthogyr declines all responsibility for re-sterilised implants, regardless of who carried out the re-sterilisation or the method used. Under no circumstances should a previously used or non-sterile implant be implanted. If the original packaging is damaged, Anthogyr will not accept the return of the content.

11. Protocol for use

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

Step 1: Preoperative planning

The type, diameter and length of the implant, as well as the number of implants to be used and their positioning, must be determined in advance, taking into account the patient's anatomy and the oral environment.

For this purpose, use the X-ray templates available in the range or a digital library.

Step 2: Preparation of the implant site

- Mark the site with a pointer drill or a round bur.
- Each site should be prepared using a progressive sequence of drilling diameters in accordance with the implant diameter and the bone density. Make sure never to exceed the depth of the planned drilling: use of depth stops on each rotational instrument or use of drills with a stop or a contra-angle fitted with a stop system.

Please refer to the "step-by-step" guidelines listed in the "Further information" section. The practitioner must adapt the drilling/tapping sequences as best as possible to the clinical case (especially regarding the bone density).

Avoid overheating the bone when drilling and tightening the implant to reduce the risk of bone loss during the osteointegration phase. The risk of overheating the bone can be reduced by using irrigation.

Step 3: Removing the implant from the packaging

The implant is packaged in a cardboard box with sterile packaging consisting of a sealed blister pack and a capped tube.

- Remove the blister from the cardboard box outside of the sterile field.
- Open the seal without touching the inside of the blister.

- Let the capped tube gently fall on the sterile field.

Warning: All handling should be done so as to avoid direct contact with the exterior surface of the implant. When handling the implant, be very careful not to drop it in the patient's mouth.

The implant is movable once the tube and stopper have been opened. Make sure to keep the tube upright when handling, with the implant access pointing upward.

- Open the packaging with one hand
- Use the corresponding implant wrench or mandrel to pick up the implant directly.

1. Press the packaging on the indicated areas to immobilise the implant
2. Connect the implant tightening instrument into the implant

Ensure that the instrument is sufficiently engaged in the implant connection before removing it from the packaging, to do this, check that the laser marking is no longer visible.

3. Release the packaging to free the implant
4. Remove the implant from the packaging

REPLACE THE IMPLANT IN THE PACKAGING DURING SURGERY IF NECESSARY

1. Position the implant between the packaging sheets
2. Press the packaging on the indicated areas to immobilise the implant
3. Disconnect the implant tightening instrument from the implant
4. Release the packaging

Step 4: Insert the implant

PLACEMENT USING A CONTRA-ANGLE:

- Adjust the output speed of the contra-angle to the recommended speed of:
  - **15 rpm** for Axiom® BL **PX**
  - **15 rpm** for Axiom® BL **X3**
  - **25 rpm** for Axiom® BL **REG**
- Using the contra-angle, screw the implant into the channel to the desired depth. The Axiom® BL REG/PX/X3 surgical protocol provides for a 0.5 mm subcrestal positioning of the implant. Implant wrenches and mandrels have markings for the vertical positioning of the implant relative to anatomical structures.
- At the end of the screwing process, orient the implant trilobe as closely as possible in the appropriate direction, depending on the desired prosthetic restoration and the situation in the mouth. To do this, implant wrenches and mandrels have 3 sides, each of them represented by a visual mark on the instrument's body.

Warning: Check the tightening torque frequently to make sure it does not exceed 80 N.cm. Untighten and retighten to reduce the screw pressure if needed.

MANUAL PLACEMENT:

Using the ratchet wrench (available in the kit):

- Manually pre-tighten the implant into the implant channel using the implant wrench or implant manual screw wrench.
- Assemble the surgical ratchet wrench
- Screw the implant into the channel to the desired depth. The Axiom® BL REG/PX/X3 surgical protocol provides for a 0.5 mm subcrestal positioning of the implant. Implant wrenches have markings for the vertical positioning of the implant relative to anatomical structures.
- At the end of the screwing process, orient the implant trilobe as closely as possible in the appropriate direction, depending on the desired prosthetic restoration and the situation in the mouth. To do this, implant wrenches and mandrels have 3 sides, each of them represented by a visual mark on the instrument's body.

Using the universal surgical instrument:

The universal surgical instrument can be used in the anterior maxillary area to control and guide the insertion of the Axiom® BL REG/PX/X3 implant along the implant axis.

- Remove the implant from the packaging using the trilobed tightening mandrel.
- Screw the implant into the channel to the desired depth. The Axiom® BL REG/PX/X3 surgical protocol provides for a 0.5 mm subcrestal positioning of the implant. Trilobed tightening mandrels have markings for the vertical positioning of the implant relative to anatomical structures.
- At the end of the screwing process, orient the implant trilobe as closely as possible in the appropriate direction, depending on the desired prosthetic restoration and the situation in the mouth. To do this, implant wrenches and mandrels have 3 sides, each of them represented by a visual mark on the instrument's body.

Warning: When inserting the implant with the surgical ratchet wrench or universal surgical instrument, control of the tightening torque is not possible. However, the verification of the torque using a surgical dynamometric wrench to tighten the implant is possible.

A torque too high can damage the connection.

Untighten and retighten to reduce the screw pressure if needed.

Step 5: Soft tissue treatment, wound closure

- Select the appropriate healing component for the treatment
- Refer to the instructions for use for healing components.

USE OF THE COVER SCREW:

- Remove the cover screw from the implant packaging cap

1. Connect the manual surgical wrench to the screw.
2. Pull to release it.

- Tighten manually <10N.cm, without forcing the cover screw in the implant.
- Suture above the cover screw to begin the integration period.

12. 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. If temporary components are used during the healing phase, they must be placed in sub-occlusion.

13. 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 Axiom® BL REG/PX/X3 implants, please refer to:

- *Axiom® BL REG/PX/X3:*
  Axiom® Multi Level® surgical user guide (AXIOM-MLC_NOT)

14. Storage

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

15. Patient information

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

16. 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.

17. Validity

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

18. Availability

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

19. 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	ISO 15223-1
	Date of manufacture	ISO 15223-1
	Catalogue number	ISO 15223-1
	Batch code	ISO 15223-1
	Serial number	ISO 15223-1
	Consult instructions for use or consult electronic instructions for use	ISO 15223-1
	Medical Device	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	ISO 15223-1
	Single sterile barrier system	ISO 15223-1
	Single sterile barrier system with protective packaging inside	ISO 15223-1
	Sterilised using irradiation	ISO 15223-1
	Do not resterilise	ISO 15223-1
	Non-sterile	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	ISO 15223-1
	Keep away from sunlight	ISO 15223-1
	Do not re-use	ISO 15223-1
	Caution	ISO 15223-1

Symbol	Description of symbol	Source of symbol
	Contains hazardous substances	ISO 15223-1
	Screwing torque	Anthogyr
	Axiom® BL REG Implant + Cover screw	Anthogyr
	Axiom® BL PX Implant + Cover screw	Anthogyr
	Axiom® BL X3 Implant + Cover screw	Anthogyr