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Axiom® BL 2.8
Instructions for Use

1. Product description

Axiom® BL 2.8 implants

Axiom® Bone Level 2.8 (Axiom® BL 2.8) implants are part of the Axiom® 2.8 system, an implant concept which offers a range of endosseous dental implants of narrow (2.8 mm) diameter and various lengths (10, 12 and 14 mm), and the corresponding prosthetic parts, healing components and ancillary instruments.

Axiom® BL 2.8 implants are implants with a BCP (Biphasic Calcium Phosphate) sandblasted endosseous surface.

Axiom® BL 2.8 implants can be used after the loss or extraction of a natural tooth or in case of natural missing tooth to restore chewing and aesthetic functions. It enables the installation of single-unit prosthetic restorations supported by abutments which are locked into the implant with impaction.

These instructions for use apply to the following dental implants: Axiom® BL 2.8 implants.

A cover plug 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

Axiom® BL 2.8 implants are intended for oral implantation to replace missing tooth roots, and to provide support for dental restoration.

3. Indications

Axiom® BL 2.8 implants can be used in one-stage or two-stage surgeries to restore the function of a missing tooth. They are indicated for single replacement of mandibular incisors and lateral maxillary incisors in cases presenting a restricted mesiodistal space.

4. Clinical benefits

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

5. Patient type and intended user

Axiom® BL 2.8 implants are intended for use with partially edentulous adult patients who do not present any of the conditions mentioned in the "Contraindications" section.

Axiom® BL 2.8 implants must be used by a surgeon trained in dental implantology.

6. Contraindications

Axiom® BL 2.8 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.

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 resterilise. 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.

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 implants from 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® BL 2.8 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

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 implant	Type of connection	Compatible components	Compatible instruments
Axiom® Bone Level 2.8	Conical	Axiom® BL 2.8	Axiom® BL 2.8 implant screwing instruments *included in the Axiom® 2.8 kit*

11. Cleaning and decontamination

Axiom® BL 2.8 implants are supplied sterile (GAMMA sterilisation) and are intended for single use. Do not clean or sterilise the implants. Cleaning, decontamination and sterilisation can compromise the essential material and design features of the implants and result in device failure.

12. Sterilisation

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 sterilised 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.

13. Protocol for use

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

Step 1: Preoperative planning

The length 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 template 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 bone density. Make sure never to exceed the depth of the planned drilling (the use of contra-angle fitted with a stop system may be helpful).

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 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.

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 25 rpm.
- Using the contra-angle, screw the implant into the channel to the desired depth. The Axiom® BL 2.8 surgical protocol provides for a 0.5 mm subcrestal positioning of the implant. It is unnecessary to control the positioning of the implant's trilobe after insertion.

Warning: Check the tightening torque frequently to make sure it does not exceed 65 N.cm. Untighten and retighten to reduce the screw pressure if needed.

Manual placement:

- Manually pre-tighten the implant into the implant channel using the implant wrench.
- Assemble the surgical ratchet wrench.
- Screw the implant into the channel to the desired depth. The Axiom® BL 2.8 surgical protocol provides for a 0.5 mm subcrestal positioning of the implant. It is unnecessary to control the positioning of the implant's trilobe after tightening down.

Warning: When inserting the implant with the surgical ratchet wrench, 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 plug:

- Remove the cover plug from the implant packaging cap.

1. Connect the threaded gripper wrench to the plug.
2. Pull to release it.

- Insert the cover plug into the implant and apply moderate hand pressure onto the wrench to secure it in the implant.
- Remove the wrench by rotating it counterclockwise.
- Suture above the cover plug to begin the integration period.

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. If temporary components are used during the healing phase, they must be placed in sub-occlusion and must be protected by a dental splint or by the positioning of a restraint on the adjacent teeth.

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 Axiom® BL 2.8 implants, please refer to:

- *Axiom® 2.8 surgical user guide (AXIOM2-8 NOT). Search code on ifu.anthogyr.com: OP28100*
- *Cover plug: Healing components instructions for use (063CICAT_NOT) Search code on ifu.anthogyr.com: OPIM028*

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 Implant	36633940013QK

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.
Patients 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

Symbol	Description of symbol	Source of symbol
	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® 2.8 Implant + Healing plug	Anthogyr