Anthogyr Axiom Bone Level X3 Implants Instruction Manual

Contents

Anthogyr Axiom Bone Level X3 Implants

Product Description

- Axiom® Bone Level X3 (Axiom® BL X3) implants are part of the Axiom® Multi Level® system, an implant concept that 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 sanded bone attachment 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 X3 implants
    - A cover screw is supplied with the implant inside the packaging cap

Materials
Titanium-6aluminum-4vanadium alloy:

Chemical components	**Composition:** **% (mass/mass)**
Aluminium	5.50 to 6.50
Vanadium	3.50 to 4.50
Others (Fe, O, C, N, H)	Total 0.53
Titanium	Residual

Intended use

Axiom® BL X3 implants are intended for the replacement of missing tooth roots, and enable the stabilisation of removable dentures, the fixation of single-unit or multiple-unit dentures or the stabilisation of removable dentures.

Indications

Axiom® BL X3 implants can be used in one-stage or two-stage surgery. They are suitable for immediate or delayed implantation in the maxillary or mandible area of partially or totally edentulous patients, to restore the function of missing teeth. Axiom® BL X3 implants are designed for immediate use in suitable clinical situations (sufficient primary stability and appropriate occlusive loads).

Clinical benefits

- Restoration of masticatory function
- Aesthetic restoration

Patient type and intended user

Axiom® BL X3 implants are intended for use with partially or totally edentulous adult patients who do not present any of the conditions mentioned in the “Contraindications” section.
Axiom® BL X3 implants must be used by a surgeon trained in dental implantology.6.

Contre-indications

Axiom® BL X3 implants with a 3.4 mm diameter are not suitable for single-unit tooth restorations in the molar sector.

- 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 radia-tion therapy, etc.).
- Relative contraindications: bruxism, occlusal stress, parafunction, unfavorable bone anatomy, pregnancy, growth not finished, insufficient oral hygiene, smoking lack of motivation or co-operation, irradiated bone, uncontrolled periodontal disease, oral infections or inflammations.
- Localized contraindications: Excessive resorption and/or insufficient bone quality, local radicular residues.

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.

Caution/Precautions

- **Clinical use:**
  Single-use devices: do not reuse or re-sterilize. 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):**

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

Effets secondaires indésirables

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 X3 implants and may lead to additional dental treatment at the dental practice: swelling, hematoma, risk of swallowing/inhaling small parts during the procedure, phonetic problems, pain, hypersensitivity/allergic reactions, inadequate function or device failure (mobility, loss of integrity), esthetic problems, gingival injuries, damage to existing dentition, bone damage, loss of marginal bone, hyperplasia, exfoliation, dysesthesia, post-surgical paresthesia, perforation of sinus or alveolar plates, systemic or local infection (including peri-implantitis, periodontitis, gingivitis, fistula), local or systemic infections including bacterial endocarditis.

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 component**
Axiom® BL X3	Conical	Axiom® BL
Compatible instruments		
Axiom® BL implant screwing instruments in- cluded in the surgical kit (grey)		

An Axiom® BL implant can be made compatible with an Axiom® TL implant through the use of an InLink® abutment.

Cleaning and disinfection

Axiom® BL X3 implants are supplied sterile (GAMMA sterilization) and are intended for single use. Do not clean or sterilize the implants. Cleaning, disinfection and sterilisation can compromise the essential material and design features of the implants and result in device failure.

Sterilisation

Anthogyr dental implants are supplied sterile. The intact sterile packaging protects the sterilized implant from external contamination and, if stored properly, guarantees sterility until the expiry date. When removing the implant from the sterile packaging, asepsis rules must be followed. The sterile packaging must not be opened

before the insertion of the implant. Check that the sterile packaging of the device is not damaged before opening it. Do not use implants from damaged sterile packaging. It is recommended to have a replacement implant readily available for use. Anthogyr declines all responsibility for re-sterilized implants, regardless of who carried out the re-sterilization or the method used. Do not use a previously used or unsterile implant under any circumstances. If the original packaging is damaged, Anthogyr will not accept the return of the content.

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: Implant bed preparation**
  - 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 bone density. Make sure never to exceed the depth of the planned drilling: the presence of depth marks on each rotating 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. 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 and by controlling the torque.
- **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 stop-per have been opened. Make sure to keep the tube upright when handling, with the implanted 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 immobilize 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 immobilize the implant
3. Disconnect the implant tightening instrument from the implant
4. Release the packaging

- **Step 4: Inserting the implant PLACEMENT USING A CONTRA-ANGLE:**
  - Adjust the output speed of the contra-angle to the recommended speed of 15 rpm.
  - Using the contra-angle, screw the implant into the channel to the desired depth. The Axi-om® BL X3 surgical protocol provides for a 0.5 mm subcrustal 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 tri lobe 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. You can always untighten and retighten to reduce screw pressure.

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 X3 surgical protocol provides for a 0.5 mm subcrustal positioning of the implant. Implant wrenches have markings for the vertical positioning of the implant relative to anatomical structures.
- When tightening, orient the implant trilobite as closely as possible in the appropriate direction, depending on the desired prosthetic restoration and the way it is situated in the mouth. Implant wrenches have 3 sides, each with a visual mark corresponding to a trilobate connection for an implant.

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 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 X3 surgical protocol provides for a 0.5 mm subcrustal 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 trilobite 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 to 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
        - Connect the manual surgical wrench to the screw.
        - Pull to release it.
    - Tighten manually, without forcing the cover screw in the implant.
    - Suture to begin the integration period.

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

Further information

For more specific information on the Axiom® BL X3 implants, please refer to:

- Axiom® BL X3 Surgical User Guide (AXIOM-X3C_NOT)
- Axiom® Multi Level® Prosthetics User Guide (AXIOM-MLP_NOT

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**.

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 devise failure.

Waste treatment

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

Information patient

Le patient doit accepter un suivi médical régulier et doit consulter son médecin en cas de modifi-cation inattendue des performances de la re-constitution prothétique. L'attention du patient doit être attirée sur la nécessité d'une hygiène buccale régulière. Le patient doit être informé d'être vigilant pendant les premières semaines suivant la chirurgie. Les informations de traçabi-lité sont à disposition du patient via les éti-quettes détachables sur le dispositif.

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 organization together with the product in question. In the event of a serious incident, the user must file a report with the local Anthogyr organization and the appropriate competent authority in accordance with local regulations. Anthogyr also offers an online complaint service in the countries concerned.

Validity

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Availability

Some components of the Anthogyr implant sys-tem are unavailable in certain countries.

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.

- Manufacturer
- Date of manufacture
- Catalog number
- Batch code
- Serial number
- Consult instructions for use or consult electronic instructions for use
- Medical Device
- Unique Device Identifier
- CE marking – compliance with current regulations
- GOST-R logo for certification of the Russian Federation
- FDA certification logo
- Use-by date
- Single sterile barrier system
- Single sterile barrier system with protective packaging inside
- Sterilized using irradiation

- Do not resterilize
- Non-sterile
- Sterilizable in a steam sterilizer (autoclave) at a temperature specified
- Nonsterilizable in a steam sterilizer (autoclave) at a temperature specified
- Do not use if the packaging is damaged and consult instructions for use
- Keep away from sunlight
- Do not reuse.
- Caution
- Contains hazardous substances

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Documents / Resources

	**Anthogyr Axiom Bone Level X3 Implants** [pdf] Instruction Manual Axiom Bone Level X3, Implants, Axiom Bone, Level X3 Implants, Axiom Bone Level, X3 Implants, Axiom Bone Level X3 Implants

References

- **Home | Dental Implant Company | Anthogyr**

Manuals+,