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Instructions for use
Anthogyr Mini Implants

1. Product description

Anthogyr Mini Implant

Anthogyr Mini Implant is a single-component implant with an Optiloc® prosthetic connection.
The Anthogyr Mini Implant system includes instruments and prosthetic and surgical parts.
Anthogyr Mini Implants are implants with a BCP (Biphasic Calcium Phosphate) sandblasted endosseous surface and a DLC (a-C:H) coated connection.
The Optiloc® matrix system is a prefab connector for the retention of removable restorations on Anthogyr Mini Implants. The Optiloc® matrix is made of a housing and interchangeable plastic (PEEK) retention inserts with different colour-coded retention values or extraction forces.
These instructions for use apply to the following dental implants: Anthogyr Mini Implants.

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 Mini Implants are intended for oral implantation to replace missing tooth roots and to allow the stabilisation of removable full dentures.

3. Indications

Anthogyr Mini Implants are indicated for the stabilisation of complete removable dentures in the fully edentulous upper and/or lower jaw of adult patients to restore the function of a missing tooth .
They can be placed with immediate function in appropriate clinical situations (good primary stability).

4. Clinical benefits

Restore function of a missing tooth: stabilisation of removable prosthesis, restoration of masticatory function, aesthetic restoration, osseointegrate in the jawbone, be biocompatible.

5. Patient type and intended user

Anthogyr Mini Implants are intended for use in adult patients with fully edentulous upper and/or lower jaw, who do not present any of the conditions mentioned in the “Contraindications” section.
Anthogyr Mini Implants must be used by a surgeon trained in dental implantology.

6. Contraindications

Anthogyr Mini Implants are contraindicated in following cases:

- Implant divergence greater than 40° between two implants.
- D4 bones.
- 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 adiction, 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 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.

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 Anthogyr Mini Implant 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 Mini Implants must be used in combination with the corresponding Optiloc® system components and Optiloc® compatible overdentures.

Only use original parts with the Optiloc® connection to place Anthogyr Mini Implants. If unsuitable ancillary equipment is used: risk of injury, damage and malfunction of the implant, risk of damage to the ancillary equipment.

For more information, please refer to the manuals listed in the "Further information" section.

Type of implant	Type of connection	Compatible components	Compatible instruments
Anthogyr Mini implant	Optiloc®	Optiloc®	Optiloc® screwing instruments included in the kit.

11. Cleaning and decontamination

Anthogyr Mini 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 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 for the range.

A sufficient number of implants must be used to provide support and distribute the support loads:

→ A minimum of 4 mini implants Ø2.6 must be placed for mandibular restorations.

→ A minimum de 6 mini implants Ø2.6 must be placed for maxillary restorations.

Step 2: Preparation of the implant site

→ Mark the site with a pointer drill.

→ 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: 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 Anthogyr Mini Implant is packaged in a cardboard box with sterile packaging consisting of a sealed blister pack and a capped tube. They are delivered mounted in the cap which serves as an implant holder.

→ 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: Do not use an Anthogyr Mini Implant if it is detached from the cap after opening the blister.

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. Make sure that the implant does not touch the tube.

Step 4: Insert the implant

PRE-SCREWING THE IMPLANT:

Pre-screwing of the implant should be done manually using the packaging cap until more torque is required.

PLACEMENT USING A CONTRA-ANGLE:

→ Adjust the output speed of the contra-angle to the recommended speed of **15 rpm**.

→ Using the contra-angle and the Optiloc® adapter, screw the implant into the channel to the desired depth. The implant must be placed so that the Optiloc® connector is above the gum.

Warning: Check the tightening torque frequently to make sure it does not exceed **45 N.cm**. Untighten and retighten to reduce the screw pressure if needed.

MANUAL PLACEMENT:

Using the ratchet wrench (available in the kit):

→ Assemble the Optiloc® key adapter and the surgical ratchet wrench.

→ Screw the implant into the channel to the desired depth. The implant must be placed so that the Optiloc® connector is above the gum.

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: Fabrication of the prosthesis

The prosthesis must be fabricated according to the prosthetic techniques of removable restoration on mini implants.

For immediate loading, a minimum insertion torque of 35 N.cm is recommended.

Abnormal loading of the implant may result in implant fracture.

For more information on the prosthetic procedure, please refer to the "Further Information" section.

Step 6: Maintenance

MAINTENANCE BY THE CLINICIAN:

During periodic visits, please inspect the condition of each secondary part of the denture retention system. Always use plastic instruments during the visit. The proper seating of the prosthesis on the mucosa should be checked at least once a year and, if necessary, the prosthesis should be relined to avoid abnormal stress on the implant structure.

MAINTENANCE BY THE PATIENT:

(please pass on the following information to the patient):

The patient's attention should be drawn to the need for regular oral hygiene as well as the need to thoroughly clean the Optiloc® connection of the Mini Implants every day.

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.

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 Anthogyr Mini Implants, please refer to:

- *Anthogyr Mini Implants User Guide (MIO_NOT)*
  Search code on ifu.anthogyr.com: MIO26100

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
Anthogyr Mini implant	36633940015QP

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 the 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

Symbol	Description of symbol	Source of symbol
	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
	Anthogyr Mini Implant	Anthogyr