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Validity Date: 2024-09
REF: 063CICAT_NOT
Index: E01
SAP code: 707461

Healing and cover components

Instructions for use

1. Product description

	Cover components	Healing components	
	Cover screw / plug	Healing screw / plug	HealFit® SH Scannable healing screws
Axiom® Bone Level			
Axiom® Tissue Level			
Axiom® 2.8			-

The Anthogyr prosthetic range includes healing and cover components. These components are inserted in the implants and are available in a variety of shapes and sizes to meet the specific needs of every patient.

Materials:

Axiom® BL/TL: cover screw, healing screw, and scannable healing screw

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

Scannable healing screws are partially coated with ZrN (Zirconium Nitride).

Axiom® 2.8: cover plug and healing plug

Polyetheretherketone (PEEK):

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

2. Intended use

Cover components are intended to protect the inner configuration of the implant and stabilize the soft tissue during the healing phase.
Healing screws and Healing plugs are intended to protect the inner configuration of the implant and maintain, stabilise and form the soft tissue during the healing phase.
Scannable healing screws (HealFit® SH) are intended to protect the inner configuration of the implant and maintain, stabilise and form the soft tissue during the healing phase. They are also intended for conventional and digital impression taking to allow computer assisted design of a single-unit restoration on an Axiom® TL or an Axiom® BL implant.

3. Indications

Healing and cover components are indicated to be placed in fully or partially edentulous patients after implant placement.
Cover components protect the inner configuration of the implant and stabilise the soft tissue during the healing phase.
Healing components protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing phase.

Specific indications:

Scannable healing screws are only indicated for single-unit restorations.
All healing and cover components described in these instructions for use have a maximum duration of usage of 180 days.

4. Patient type and intended user

Healing and cover components are intended for adults requiring a single-unit or multiple-unit tooth restoration, except scannable healing screws which are only intended for adults requiring single-unit tooth restoration. These devices must be used only in patients who do not present any of the conditions listed among the "contraindications" sections.
Healing and cover components must be used by a surgeon trained in dental implantology.

5. Contraindications

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

6. 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.

7. 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.
- The healing screws or healing plugs must be fixed on a sufficiently stable implant.
- As far as possible, the prosthetic parts must be firmly fastened to avoid the inhalation or swallowing of parts during intraoral use.
- The healing and cover components must not be tightened with a dynamometric wrench or a rotating power instrument.
- Axiom® 2.8 healing and cover components must not be impacted.
- Do not use a healing and cover component after the expiry date indicated on the packaging.

Component rework:

All 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 Anthogyr Dental Implant System. Non-clinical testing demonstrates that these products are MR Conditional. A patient with an Anthogyr Dental Implant System product 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.

8. 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 healing and cover components 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

9. 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. The healing and cover component choice depends on the planned final restoration. To ensure the best fit, and 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 cover screw Axiom® BL healing screw HealFit® SH BL scannable healing screw	For the placement of the cover or healing screws: OPCS100 For the removal of the cover or healing screws: OPCS100 or INCHECV or INCHELV or INCHEXLV
Axiom® Tissue Level	InLink®	Axiom® TL cover screw Axiom® TL healing screw HealFit® SH TL scannable healing screw	
Axiom® 2.8	Conical	Axiom® 2.8 cover plug	OPCF100
		Axiom® 2.8 healing plug	For the placement of the healing plug: OPCF100 or OPOP028 For the removal of the healing plug: OPCF100

10. Cleaning and decontamination

Anthogyr sterile healing and cover components are supplied sterile (GAMMA sterilisation) in blue packaging and are identified with a STERILE R logo. They are intended for single use. Do not clean or sterilise the prosthetic components. Cleaning, decontamination and sterilisation can compromise the essential material and design features of the prosthetic components and result in device failure.

11. Sterilisation

Anthogyr healing and cover components are supplied sterile. Check that the entire packaging of the device is undamaged before opening. Prosthetic components with a damaged packaging must not be used. It is recommended to have a replacement component readily available for use. The intact blister pack protects the sterilised prosthetic component against any external influence and, if stored properly, guarantees sterility until the expiry date. The blister pack must not be opened before use of the prosthetic component. When removing the prosthetic component from the sterile packaging, asepsis rules must be followed.
Anthogyr declines all responsibility for re-sterilised components, regardless of who carried out the re-sterilisation or the method used. Under no circumstances should a previously used or non-sterile prosthetic component be placed in the patient's mouth. If the original packaging is damaged, Anthogyr will not accept the return of the content.

12. Protocol for use

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

A. Axiom® BL and Axiom® TL cover and healing screws

Step A.1: Removal of the component from the packaging

- ¬ Select the appropriate healing or cover component for the treatment.
- ¬ Remove the component from the sterile packaging on the sterile field.

Step A.2: Placement and removal of the component

- ¬ Connect the manual surgical wrench OPCS100 to the cover/healing screw. No other instrument must be used during this phase.
- ¬ Ensure that the instrument is sufficiently engaged in the healing component before placement.
- ¬ Before placing the healing component, ensure that the implant connection is free of any fluid or other substance that may compromise the proper fit of the healing component in the implant.
- ¬ Manually tighten <10 Ncm using the manual surgical wrench OPCS100, without forcing the cover/healing screw in the implant.
- ¬ Suture above the cover screw or around the healing screw to begin the healing phase.
- ¬ After the healing phase, connect a hexagonal wrench to the cover/healing screw.
- ¬ Manually unscrew it from the implant.

B. HealFit® SH scannable healing screws

Step B.1: Choice of the component

The HealFit® SH choice can be done either with digital library or HealFit® SH height gauge.
Please also refer to the user guide for more information on the recommended anatomical shape depending on tooth position, and for recommended compatibilities between HealFit® SH and Anthogyr titanium bases.

Planification using digital libraries:

- ¬ Use implant planning software with the HealFit® SH library to perform scannable healing screw planning.

Planification using height gauge:

- ¬ Clean and sterilise the height gauge (refer to Anthogyr instruments IFU listed in the "Further information" section).
- ¬ Place the BL side or the TL side of the height gauge into the Axiom® BL or the Axiom® TL implant to determine the most suitable HealFit® SH height. The grooves on the gauge correspond to the available HealFit® heights and correspond to the limit of the gingiva to ensure a 1.5 mm overhang.
- ¬ Choose the reference of the most suitable HealFit® SH, taking care that the selected reference will exceed the gingiva by at least select 1.5 mm.

Step B.2: Removal of the component from the packaging

- ¬ Select the appropriate HealFit® SH for the treatment.
- ¬ Remove the components from the sterile packaging on the sterile field.

Step B.3: Placement of the scannable healing screw on the implant

Axiom® BL scannable healing screw:

Note: The body and the M1.6 screw are provided disassembled for HealFit® SH BL.

- ¬ Before placing the HealFit® SH, ensure that the implant connection is free of any fluid or other substance that may compromise the proper fit of the HealFit® SH in the implant.
- ¬ Place the body of the HealFit® SH into the implant (with Axiom® BL abutment gripper INEXPS / INEXPL if needed), ensuring that the groove(s) located on the top surface of the HealFit® SH are orientated towards the vestibule.
- ¬ Connect the manual surgical wrench OPCS100 to the M1.6 screw of the HealFit® SH. No other instrument must be used during this phase.
- ¬ Ensure that the instrument is sufficiently engaged in the screw before placement.
- ¬ Place the M1.6 screw in the body of the HealFit® SH using the manual surgical wrench OPCS100.

Note: The body and the M1.6 screw of the HealFit® SH BL can also be assembled out of the patient's mouth prior to placement and transport together in patient mouth, taking care that the components do not fall when they are inserted in the patient mouth.

- ¬ Tighten the M1.6 screw of the HealFit® SH manually (<10 Ncm) using the manual surgical wrench OPCS100, without forcing the healing screw in the implant.
- ¬ Suture around the HealFit® SH to begin the healing period, ensuring that the coronal part exceeds the soft tissue by at least 1.5 mm to allow future impression taking.

Axiom® TL scannable healing screw:

Note: The body and the M1.6 screw are provided assembled for HealFit® SH TL.

- ¬ Before placing the HealFit® SH, ensure that the implant connection is free of any fluid or other substance that may compromise the proper fit of the HealFit® SH in the implant.
- ¬ Connect the manual surgical wrench OPCS100 to the M1.6 screw of the HealFit® SH.
- ¬ Ensure that the instrument is sufficiently engaged in the screw before placement.
- ¬ Place the HealFit® SH into the implant using the manual surgical wrench OPCS100, ensuring that the groove(s) located on the top surface of the HealFit® SH are orientated towards the vestibule.
- ¬ Tighten the M1.6 screw of the HealFit® SH manually (<10 Ncm) using the manual surgical wrench OPCS100, without forcing the healing screw in the implant.
- ¬ Suture around the HealFit® SH to begin the healing period, ensuring that the coronal part exceeds the soft tissue by at least 1.5 mm to allow future impression taking.

Step B.4: Impression taking

Note: The quality of the digital impression is the practitioner's responsibility. The design of the prosthesis will be based on the same digital impression, thereby determining the compliance and quality of the final prosthesis. If the HealFit® SH does not exceed the soft tissue by at least 1.5 mm, Anthogyr recommends removing the HealFit® SH and perform an impression taking on implant using a digital transfer to ensure a precise positioning of the implant during computer assisted design of the dental prosthesis.

- ¬ Ensure that the HealFit® SH is fully screwed into the implant. If in doubt, take peri-apical radiographs perpendicular to the connections.
- ¬ Ensure that the coronal part exceeds the soft tissue by at least 1.5 mm.
- ¬ Ensure that the HealFit® identification system is free of any fluid or other substance that may compromise the scan quality.
- ¬ Perform impression taking without removing the HealFit® SH using an intra-oral scanner. If necessary, it is possible to perform a conventional impression taking directly on the HealFit® SH. Then, perform a digital impression of the plaster model using a laboratory scanner.

Step B.5: Design and manufacture of the restoration

- ¬ Design the prosthesis with dental design software.
- ¬ Manufacture the prosthesis.

Step B.6: Removal of the scannable healing screw from the implant

After the healing phase:

- ¬ Connect a hexagonal wrench to the M1.6 screw of the HealFit® SH.
- ¬ Manually unscrew the M1.6 screw from the implant and remove the healing screw.
- ¬ If needed, the Axiom® BL abutment extractor INEXPS / INEXPL can be used after full removal of the M1.6 screw to ease the removal of a HealFit® SH BL stuck in an Axiom® BL implant.

C. Axiom® 2.8 cover and healing plugs

Step C.1: Removal of the component from the packaging

- ¬ Select the appropriate healing or cover component for the treatment.
- ¬ Remove the component from the sterile packaging on the sterile field.

Step C.2: Placement and removal of the component

Cover plug:

- Thread the threaded gripper wrench OPCF100 into the cover plug.
- Ensure that the instrument is sufficiently engaged in the healing component before placement.
- Before placing the healing component, ensure that the implant connection is free of any fluid or other substance that may compromise the proper fit of the healing component in the implant.
- Insert the cover plug into the implant.
- Apply moderate hand pressure to secure it in the implant.
- Remove the threaded gripper wrench OPCF100 by rotating it counterclockwise.
- Suture above the cover plug to begin the healing phase.
- After the healing phase, thread the threaded gripper wrench OPCF100 into the cover plug.
- Pull to remove it from the implant.

Healing plug:

- Thread the threaded gripper wrench OPCF100 into the healing plug or insert it into the prehensive wrench OPOP028.
- Ensure that the instrument is sufficiently engaged in the healing component before placement.
- Before placing the healing component, ensure that the implant connection is free of any fluid or other substance that may compromise the proper fit of the healing component in the implant.
- Insert the healing plug into the implant.
- Apply moderate hand pressure to secure it in the implant.
- Remove the threaded gripper wrench OPCF100 by rotating it counterclockwise or press the button on the prehensive wrench OPOP028 to release the healing plug.
- Suture around the healing plug to begin the healing phase.
- After the healing phase, thread the threaded gripper wrench OPCF100 into the healing plug.
- Pull to remove it from the implant.

13. Healing phase

Healing and cover components must be placed in sub-occlusion.
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.

14. 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 cover and healing components, please refer to:

- Axiom® Multi Level® surgical user guide (AXIOM-MLC_NOT)
  Search code on ifu.anthogyr.com: OPIM100
- Axiom® 2.8 surgical user guide (AXIOM2-8_NOT)
  Search code on ifu.anthogyr.com: OPIM028

For more specific information on the HealFit® SH, please refer to:

- HealFit® SH user guide (HEALFIT-SH_NOT)
  Search code on ifu.anthogyr.com: OPSHSC33

For more specific information on the HealFit® SH gauge, please refer to:

- Anthogyr instruments IFU (063INSTRU_NOT)
  Search code on ifu.anthogyr.com: OPJCSHS

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
Axiom® BL cover Screws	36633940103QM
Axiom® TL cover Screws	36633940104QP
Axiom® healing screws	36633940102QK
Axiom® 2.8 healing components	36633940004QJ
HealFit® SH scannable healing screws	36633940153R4

15. 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.

16. Waste treatment

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

17. 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.

18. 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.

19. Validity

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

20. Availability

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

21. 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
REF	Catalogue number	NF EN ISO 15223-1
LOT	Batch code	NF EN ISO 15223-1
SN	Serial number	NF EN ISO 15223-1
	Consult instructions for use or consult electronic instructions for use	NF EN ISO 15223-1
MD	Medical Device	NF EN ISO 15223-1
CE	CE marking - compliance with current regulations	Directive 93 / 42 / CEE ———— MDR (EU) 2017 / 745
Rx only	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
STERILE R	Sterilised using irradiation	NF EN ISO 15223-1
	Do not resterilise	NF EN ISO 15223-1
NON STERILE	Non-sterile	NF EN ISO 15223-1
135°C	Sterilisable in a steam steriliser (autoclave) at temperature specified	ISO 7000 - 2868
135°C	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
25 N.cm	Screwing torque	Anthogyr
	Axiom® BL cover screw	Anthogyr
	Axiom® BL cover screw	Anthogyr
	Axiom® TL cover screw	Anthogyr
	Axiom® 2.8 cover plug	Anthogyr
	Axiom® BL healing screw	Anthogyr
	Axiom® TL healing screw	Anthogyr
	Axiom® 2.8 healing plug	Anthogyr
	Axiom® BL HealFit® SH scannable healing screw	Anthogyr
	Axiom® TL HealFit® SH scannable healing screw	Anthogyr