

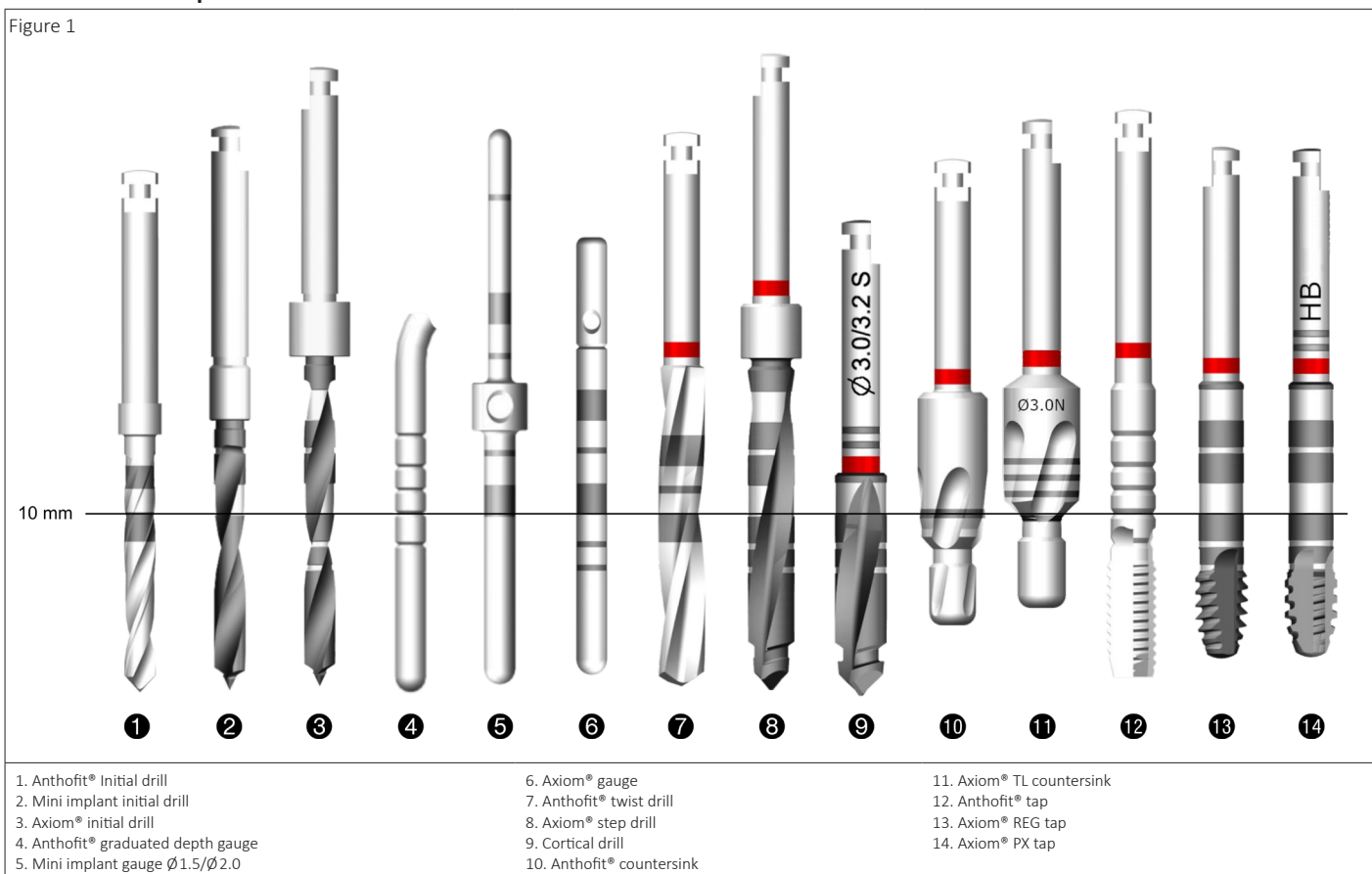


Anthogyr instruments

Instructions for use for standard or guided surgery instruments used with the Axiom® BL, Axiom® TL, Axiom® 2.8, Anthofit®, and Mini implant ranges

1. Product description

Figure 1



Anthogyr instruments are part of the Anthogyr Axiom®, Anthofit® and Mini implant systems and are divided into types according to use:

- **Planning:** X-ray templates.
- **Implant bed preparation:**
 - Guided cutting instruments: initial drills, step drills, pointer drills, taps, gingival cutters, bone mill, cortical bur.
 - Non-guided cutting instruments: initial drills, step drills, pointer drills, taps, gingival cutters, burs.
- **Auxiliaries instruments:** gauges, drill guides, drill stops, sliders/spoons, implant fixation screws, pins, sleeves.
- **Torque transmission instruments:** mandrel, wrench, implant holder, mandrel extension.
- **Gripper components:** gripper, gripping wrench, handling analog.
- **Kits:** guided surgical kits, Axiom® Multi Level® surgical kits, Axiom® 2.8 surgical kit, Mini implant

surgical kit, Anthofit® surgical kit, Axiom® Multi Level® prosthesis kits, Anthofit® prosthesis kit, stop kits, empty kits.

For a detailed product description, item reference number and dimensions, please consult the product label and the Anthogyr product catalogue.

For detailed information on the instruments, their specific indications for use, their use in specific procedures and their compatibility, please refer to the user manuals and brochures listed in the “Further Information” section.

Specific product description:

Kits:

Anthogyr kits are reusable containers consisting of two main components: a base with a cover and one or more inserts. The inserts are composed of other components made of silicone rubber, namely silico-

ne strips and holders used to maintain the Anthogyr instruments in place during the surgical or prosthetic procedure and during sterilisation.

The base and inserts have markings and/or colours code to indicate either the surgical workflow, or the position of the instruments in the kit. The cover holds all the instruments securely in place during treatment. Stop kits are reusable containers consisting of a drilled base to accommodate the stops and a cover to hold the stops in place during the treatment phases.

Materials:

Instruments are made of Titanium (Ti6Al4V ELI), Stainless steel, Polyetheretherketone (PEEK), Silicone, Polypropylene (PP), PolyPhenylSulphone (PPSU) or PVC.

2. Intended use

Anthogyr instruments are intended for the planning and the implant bed preparation, or for the placement of implants or prostheses from the Anthogyr implants systems for oral implantation.

Specific intended use:

Planning

X-ray templates are intended to facilitate the planning prior to the placement of Anthogyr implants.

Implant bed preparation

Implant site preparation instruments are intended to prepare the implant bed prior to implant placement.

Auxiliaries instruments

Auxiliaries instruments are intended for visual control or physical guidance during the implant bed preparation or implant placement.

Torque transmission

Tightening instruments are intended to apply or transmit torque to instruments, implants or prostheses.

Gripper components

Gripping instruments are intended for the manipulation of screws, prosthetic components or analogs.

Kits

Anthogyr kits are intended to organise instruments, and secure instruments during the sterilisation phase.

3. Indications

Anthogyr instruments are indicated for use in procedures to place implants or prostheses, from the Anthogyr implant systems, in fully or partially edentulous patients.

Specific indications

Planning

The X-ray templates represent the dimensions of the implants and provide guidance in the choice of the device to be placed, in accordance with the bone volume available.

Implant bed preparation

Cutting instruments are indicated for use in implant surgery to drill or cut into the upper or lower jaw and can be used to prepare bone and soft tissue.

Guided cutting instruments are used with the corresponding guided surgical auxiliaries to ensure better control of the direction and depth of cut.

Auxiliaries instruments

Depth gauges, drill stops, position and drill guides, guided surgery drilling template, guided surgery sleeves are used during implant bed preparation or implant placement and are indicated for visual control or physical guidance of the position, depth and direction of the implant channel or implant.

Torque transmission instruments

Screwing instruments are used to transport in the mouth instruments, implants or prosthetic devices and allow to transmit torque. They can be used with a ratchet or handpiece.

Gripper components

Gripping instruments are used to manually transport prosthetic components or analogs.

Kits

Anthogyr kits are used to store and secure instruments and auxiliaries between and during surgical and/or prosthetic manipulations, transportation and sterilisation. They are indicated for use in health facilities by health professionals.

These kits are indicated for use with a validated, legally marketed, double sterilisation bag to maintain the sterility of sealed devices.

4. Patient type and intended user

Anthogyr instruments are intended for use with partially or totally edentulous adult patients who do not present any of the conditions listed among the contraindications.

Anthogyr instruments are reserved for use by dental surgeons trained in implantology.

5. Contraindications

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

6. Warning

- Products must be protected against inhalation or swallowing when handled in the mouth. Aspiration of products can lead to infection or incidental physical injury.
- Do not use damaged, corroded or dull instruments. Always inspect instruments before use.
- Do not exceed the maximum number of uses for the device as detailed in the “Lifespan of products” section.
- Avoid the area of the mandibular nerve canal during the implant bed preparation and the insertion of the implant. Nerve damage can lead to anaesthesia, paraesthesia and dysaesthesia.
- Do not exceed the recommended insertion torques as this may cause bone necrosis and fracture.

Specific warnings

X-ray templates

- The precision of the X-ray template is +/- 2%.
- To avoid scaling errors, X-ray templates must not be copied.
- Use the implant-specific X-ray template.
- Do not use a damaged X-ray template (altered print, tear etc.).

Implant bed preparation

- Due to the design and function of the drills, the tip is a maximum of 0.5 mm longer than the insertion depth of the implant. This additional length should be taken into account in the planning phase and is represented by triangles on the X-ray template.
- Ensure that the drilling depth is correct by using the recommended surgical plans (including X-ray evaluation), depth marks on the drills, drill stops, depth gauges. Anthogyr instruments have depth markings that correspond to the available implant lengths (Figure 1).
- When measuring the depth of the implant channel, ensure that the depth gauge is inserted to the full depth of the drilling.

- Use the drills in order of increasing diameter with a clockwise rotation.
- Drill intermittently using external irrigation.

Bone quality must be taken into account when preparing the implant bed.

Do not exceed the following cutting speeds:

Surgical stage	Cutting instrument	Speed (rpm)
Preparation of the gum, guided and non-guided	Gingival cutter	50
Preparation of the alveolar crest, non-guided	Pointer drill	1500
	Round bur	1500
	Lindemann bur	1500
Preparation of the alveolar crest, guided	Cortical bur	500
	Bone mill	500
	INTEGRAL pointer drill	1000
	FIRST DRILL pointer drill	1500
Drill, guided and non-guided	Axiom® initial drills	1500
	FIRST DRILL initial drills	1500
	INTEGRAL initial drills	1000
	Anthofit® initial drills	1250
	AGS step drills	1000
	Axiom® step drills	1000
	Axiom® 2.8 step drills	1200
	Anthofit® twist drills	1000
	Mini implant twist drills	1500
Preparation of the bone crest post-drilling, non-guided	Axiom® cortical drills	1000
	Axiom® BL countersink	50
	Anthofit® countersink	500
Tapping, guided and non-guided	Axiom® TL countersink	50
	Anthofit® tap	50
	Axiom® tap	25

Drill for pin:

- Please note that 0.5 mm of apical over-drilling must be accounted for.

Guided surgical instruments:

- When inserting or removing a drill bit from a sleeve, the drill bit must not be in a rotated position. This could result in damage to the drill bit and/or guiding sleeve, and potentially lead to a blockage.
- The guided drills may only be used in combination with the corresponding sleeves and/or spoons inserted into the guides. Inspect the drill sleeves for operational safety before each surgical procedure. Inspect the adjustment, orientation and stability of the guide sleeves in their housing, as well as the placement of the guide before each surgical procedure.
- Ensure that the spoon is correctly positioned inside the sleeve inserted in the drilling guide.
- To insert a fixation pin, place the guide (on teeth or mucous membranes), create the pin housing by drilling with the corresponding drill bit in the corresponding sleeve up to the stop, insert and screw the pin into the sleeve.
- Avoid applying a radial load to the sleeves to ensure that they are properly retained in the drilling guide.

The FIRST DRILL guided surgery protocol is not applicable to the preparation of implant sites for Anthofit®, Mini implant and Axiom® implants with a diameter greater than 4.6 mm and a length greater than 14 mm. The INTEGRAL guided surgery protocol is not applicable to the preparation of implant sites for Anthofit®, Axiom® 2.8, Mini implant and Axiom® implants with

a diameter greater than 4.6 mm and a length greater than 14 mm.

Axiom® BL countersinks:

Ensure that the primary stability of the Axiom® BL implants is sufficient before using the countersinks. Throughout the entire rotation, maintain the alignment axis of the bur and the pin: do not exert any bending force on the tool.

Auxiliaries instruments

The pointer drill Ø1.5 mm (Ref. OPPO15) is not recommended for use without a ring or drilling guide.

Torque transmission

Do not exceed the following tightening speeds:

Surgical stage	Associated implant	Speed (rpm)
Tightening of the implant, guided and non-guided	Axiom® REG implant	25
	Axiom® PX implant	15
	Axiom® X3 implant	15
	Anthofit® implant	50
	Axiom®2.8 implant	25
	Mini implant	15

Axiom® implant screwing instruments:

- The Axiom® BL and Axiom® TL implant screwing wrenches and mandrels have a graduated marker for the vertical positioning of the implant against anatomical structures or to the bone in the case of flapless placement.
- The Axiom® BL and Axiom® TL implant screwing wrenches and mandrels have 3 sides, each with a visual marker corresponding to a side of the trilobate connection of the implant. At the end of screwing process, orient one of the markers as closely as possible in the appropriate direction, depending on the desired prosthetic restoration and the situation in the mouth.

Prosthesis screwing instruments:

- Do not use motorised rotating tools to screw/ unscrew prosthetic parts.
- Excessive pre-drilling with AATOOL instrument may result in breakage of the instrument.
- Do not apply bending forces to spherical instruments.

7. Caution/Precaution

Clinical use:

- The components must be handled in accordance with the instructions detailed in the manual of the implant range, listed in the “Further information” section.
 - Ensure that all handling is sterile.
- Inspect the instruments before use. Never use potentially contaminated components. Only use properly reprocessed instruments if they are suitable for multiple uses.
- Handle cutting instruments with care to avoid injury.

- Every time an instrument is changed, check its proper hold in the contra-angle or wrench by pulling on it slightly.
- Guided surgical sleeves, the analog positioning tool and Angulated Access screw gripper are for single use only: do not reuse or re-sterilise. Risk of contamination and risk of altering the functional surfaces.

Specific caution/precautions

Planning

During the surgical planning phase, ensure the proper use of an X-ray transparency in good condition.

Implant bed preparation

- Inspect the instruments before use. Always follow the recommended drilling speeds.
- To ensure proper drilling and alignment, use drill stops, drill guides and depth gauges.
- Taps should only be used in D1 bone.

Torque transmission

- Inspect the instruments before use.
- Use tools that are compatible with the system, for more information see the “Compatibility information” section.

Component rework:

The component must not be retouched in any way.

8. Residuals 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 the instruments and may lead to additional dental treatment at the dental practice:

Residual risks:

- additional treatment at dentist's office
- bite/mastication/phonetic problems
- bleeding
- bone compression
- bone damage
- damage to adjacent/opposing tooth
- discomfort
- hyperplasia
- hypersensitivity/allergic reaction
- 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
- swelling

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

Compatibility of instruments for implant bed preparation:

Anthogyr implant bed preparation instruments are equipped with a coloured ring indicating the drilling diameter. They are in line with the diameters of the implants. The drilling diameter is also marked on the instrument.

Ring colour	Range	Drilling diameter	Tap diameter
Green	Axiom®	Ø 2.4	/
Orange	Axiom®	Ø 2.6	Ø 2.8
Red	Axiom®	Ø 3.0	Ø 3.4
	Anthofit®	Ø 3.0	Ø 3.5
Black	Anthofit®	Ø 3.25	Ø 3.75
	Mini implant	Ø 1.5	/
Yellow	Axiom®	Ø 3.6	Ø 4.0
	Anthofit®	Ø 3.5	Ø 4.0
White	Axiom®	Ø 4.2	Ø 4.6
	Anthofit®	Ø 4.0	/
Blue	Axiom®	Ø 4.8	Ø 5.2
	Anthofit®	Ø 4.5	Ø 5.0
Purple	Axiom®	Ø 5.4	/
Brown	Axiom®	Ø 6.0	/

The coloured ring on the Axiom® TL countersinks corresponds to the colour of the ring of the last drill used (guiding diameter).

The hard bone instruments and the kit containing them are differentiated from other instruments and kits by two black lines laser marked.

Compatibility of the Axiom® implant screwing instruments:

Marker	Compatible implant types
Grey instruments	Axiom® BL implant
Gold instruments	Axiom® TL implant

Warning: The use of instruments that are not suitable for the implant can damage the implant connection.

Compatibility of the prosthetic tightening instruments:

Marker	Compatible component types
"HEXA" marking	Screw with hexagonal recess
	Novaloc® abutment
"BALL" marking	Screw or lock with ball recess

Compatibility of the INTEGRAL range guided surgical instruments:

Each guided instrument is guided in only one sleeve diameter. A coloured dot on the instrument indicates the compatible sleeve. The colour of the dot is identical to the colour of the sleeve.

Marker	Compatible instrument types
Instruments with a blue dot	Sleeve Ø 3.6
Instruments with a purple dot	Sleeve Ø 4.2
Instruments with a brown dot	Sleeve Ø 5.0

Compatibility of drill and bur stops:

Components	Compatible instrument types
Pink Axiom® stops	Lindemann bur
	Axiom® initial drills
	Axiom® Ø 2.0/2.4 and Ø 2.4/3.0 step drills
Yellow Axiom® stops	Axiom® Ø 3.0/3.6 step drills
Grey Axiom® stops	Axiom® Ø 3.6/4.2 step drills
Blue Axiom® stops	Axiom® Ø 4.2/4.8 step drills
Purple Axiom® stops	Axiom® Ø 4.8/5.4 step drills
Brown Axiom® stops	Axiom® Ø 5.4/6.0 step drills
Stop pin (Ref. OPFFP)	Axiom® BL Ø 4.5, Ø 5.3 and Ø 6.6 countersinks
Mini implant stops	Mini implant twist drill and initial drill

Compatibility of the INGPPA drilling guide:

The drilling guide (Ref. INGPPA) is only compatible with Axiom® BL implants. Using the guide for Axiom® TL implants could damage the internal connection of the implant.

The drilling guide is only compatible with the Ø 1.5 mm pointer drill (Ref. OPPO15).

10. Cleaning and disinfection

Anthogyr instruments are delivered non-sterile. They must be cleaned and decontaminated before use and after each use for reusable components. Do not use the components if the packaging is opened or damaged. Before treatment, remove the components from their packaging. Anthogyr recommends following the protocol described in the cleaning and sterilisation manual available at ifu.anthogyr.com or on request from Anthogyr at the above address.

For sterilisation, see the "Sterilisation" section.

11. Sterilisation

Anthogyr instruments delivered non-sterile must be sterilised before use. Anthogyr recommends following the protocol described in the cleaning and sterilisation manual available at ifu.anthogyr.com or on request from Anthogyr at the above address. After the sterilisation was done, asepsis rules must be followed. Anthogyr declines all responsibility for re-sterilised components, regardless of who carried out the re-ste-

rilisation 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. Anthogyr instruments are devices intended for temporary use in the oral cavity and intended for continuous use for less than 60 minutes.

13. Lifespan of products Planning

X-ray templates can be used for up to 5 years unless the information is illegible.

Implant bed preparation

The instruments can be reused in accordance with the maximum number of uses defined in the table below, except in cases where there are signs of deterioration (illegibility of markings or markers, deterioration of the coating, signs of corrosion, etc.).

Range	Type of device	Product lifespan
FIRST DRILL	Ø 2.0 pin drill	10 uses
	Pointer drills	10 uses
	Initial drills	10 uses
INTEGRAL	Ø 2.0 pin drill	10 uses
	Gingival cutters	10 uses
	Bone mill	10 uses
	Cortical bur	10 uses
	Pointer drills	10 uses
	Initial drills	10 uses
	Step drills	10 uses
	Taps	10 uses
	Gingival cutters	10 uses
Anthogyr Guiding System	Step drills	10 uses
	Taps	10 uses
	Countersinks	20 uses
Axiom® Multi Level®	Pointer drills	20 uses
	Round bur	20 uses
	Lindemann bur	20 uses
	Initial drills	20 uses
	Step drills	20 uses
	Cortical drills	20 uses
	Taps	20 uses
	Drills	20 uses
	Tap	20 uses
Axiom® 2.8	Gingival cutter	20 uses
	Twist drills	20 uses
Mini implant	Countersinks	15 uses
	Initial drills	15 uses
	Twist drills	15 uses
	Taps	15 uses

One use is equivalent to one implant channel.

Auxiliaries instruments

The instruments can be reused in accordance with the maximum number of uses defined in the table below, except in cases where there are signs of deterioration (illegibility of markings or markers, etc.).

Range	Type of device	Product lifespan
FIRST DRILL and Integral guided surgery	Ø 2.0 fixation pin	250 uses, except in the case of breakage or significant deterioration causing the tool to malfunction
	Sleeves	Single use
Anthogyr Guiding System	Spoons	250 uses
	Sliders	250 uses
	Implant fixation screw	250 uses, unless thread damage occurs
Axiom® Multi Level®	Drill stops	250 uses
	Guiding pin	250 uses
	Gauges	250 uses
	Drilling guides	250 uses
Axiom® 2.8	Gauges	250 uses
	Gauge	250 uses
Mini implant	Drill stops	250 uses
	Gauges	250 uses

One use is equivalent to one reprocessing cycle.

Torque transmission

The instruments can be reused in accordance with the maximum number of uses defined in the table below, except in cases where there are signs of deterioration (illegibility of markings or markers, deterioration of the coating, signs of corrosion, etc.).

Range	Type of device	Product lifespan
INTEGRAL	Implant screwing wrenches	50 uses
	Implant screwing mandrels	50 uses
Anthogyr Guiding System	Implant screwing mandrels	250 uses
Axiom® Multi Level®	Implant screwing wrenches	250 uses
	Implant holder	250 uses
	Implant screwing mandrels	250 uses
	Universal instrument mandrels	100 uses
	Prosthetic screwing wrenches	250 uses
	Prosthetic screwing mandrels	250 uses
	Mandrel extension	250 uses

One use is equivalent to one reprocessing cycle.

Gripper components

The instruments can be reused in accordance with the maximum number of uses defined in the table below, except in cases where there are signs of deterioration (illegibility of markings or markers, deterioration of the coating, signs of corrosion, etc.).

Range	Type of device	Product lifespan
Anthogyr Guiding System	Analog positioning tool	Single use
Axiom® Multi Level®	AA screw gripper	Single use
Axiom® 2.8	Gripper tools	250 uses

One use is equivalent to one reprocessing cycle.

Kits

The instruments can be reused in accordance with the maximum number of uses defined in the table below, except in cases where there are signs of deterioration (illegibility of markings or markers, deterioration of the coating, signs of corrosion, etc.).

Range	Type of device	Product lifespan
FIRST DRILL	Guided surgical kit	250 uses
INTEGRAL	Guided surgical kits	50 uses
Anthogyr Guiding System	Guided surgical kit	250 uses
Axiom® Multi Level®	Surgical kits	250 uses
	Prosthesis kits	250 uses
	Stop kits	250 uses
Axiom® 2.8	Surgical kit	250 uses
Mini implant	Surgical kit	250 uses
Anthofit®	Surgical kit	250 uses
	Prosthesis kit	250 uses

One use is equivalent to one reprocessing cycle.

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 Anthogyr instruments, please refer to:

FIRST DRILL guided surgery:

- *Anthogyr FIRST DRILL Guided Surgery user guide (AXIOM-GID_NOT)*

INTEGRAL guided surgery:

- *Anthogyr INTEGRAL Guided Surgery user guide (AXIOM-INT_NOT)*

Anthogyr Guiding System:

- *Anthogyr Guiding System Axiom® BL user guide (AGS-R-PX_NOT)*

Axiom® Multi Level®:

- *Axiom® Multi Level® surgical user guide (AXIOM-MLC_NOT)*
- *Axiom® Multi Level® Prosthetic user guide (AXIOM-MLP_NOT)*
- *Axiom® BL X3 surgical user guide (AXIOM-X3C_NOT)*
- *Axiom® TL X3 surgical user guide (AXIOM-TLX3_NOT)*

Axiom® 2.8:

- *Axiom® BL 2.8 user guide (AXIOM2-8_NOT)*

Mini implant:

- *Mini implant user guide (MIO_NOT)*

Anthofit®:

- *Anthofit® HE surgical user guide (ANTHOFIT-HEC_NOT)*
- *Anthofit® HE prosthetic user guide (ANTH-HEP_NOT)*

Others:

- *Cleaning and sterilisation user guide (NETT-STE_NOT)*
- *Axiom® REG and PX User guide (AXIOMR-PX_NOT)*

15. 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.

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. Patient information

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.

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.

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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
	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
	FDA certification logo	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 re-sterilise	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® BL countersink + pin	Anthogyr