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Anthogyr instruments

Instructions for use for standard or guided surgery instruments used with the Axiom® BL – Valid only in the United States

Table of Contents

1. Instructions for use for Anthogyr instruments

Caution: U.S. federal law restricts this device to sale by or on the order of a dental professional.

1.1 Product description

Figure 1

1. Axiom® initial drill
2. Axiom® gauge
3. Axiom® step drill
4. Cortical drill

Anthogyr instruments are part of the Anthogyr Axiom® 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.

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.

Materials:

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

1.2 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.

1.3 Indications for use

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 for use

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.

1.4 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.

1.5 Contraindications

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

1.6 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	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
	Axiom® step drills	1000
	Axiom® cortical drills	1000
Preparation of the bone crest post-drilling, non-guided	Axiom® BL countersink	50
Tapping, guided and non-guided	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 Axiom® implants with a diameter greater than 4.6mm and a length greater than 14mm.

The Integral guided surgery protocol is not applicable to the preparation of implant sites for 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® PX implant	15
	Axiom® X3 implant	15

Axiom® implant screwing instruments:

- The Axiom® BL 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 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 motorized 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.

1.7 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.

1.8 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 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

1.9 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®	Ø2.4	/
Red	Axiom®	Ø3.0	Ø3.4
Yellow	Axiom®	Ø3.6	Ø4.0
White	Axiom®	Ø4.2	Ø4.6
Blue	Axiom®	Ø4.8	Ø5.2
Purple	Axiom®	Ø5.4	/
Brown	Axiom®	Ø6.0	/

The cortical drills are differentiated from other instruments by two black lines laser marked.

Compatibility of the Axiom® implant screwing instruments:

Marker	Compatible implant types
Grey instruments	Axiom® BL implant

Warning: The use of instruments that are not suitable for the implant can damage the implant connection. The grey instruments are intended for use with Axiom® BL implants. Anthogyr cassettes contain gold screwing instruments which are part of Axiom® TL system (for information, Axiom® TL implants are not registered in United States).

Compatibility of the prosthetic tightening instruments:

Marker	Compatible component types
"HEXA" marking	Screw with hexagonal recess
"BALL" marking	Screw 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
Instruments with a blue dot	Sleeve Ø3.6
Instruments with a purple dot	Sleeve Ø4.2
Instruments with a brown dot	Sleeve Ø5.0

Compatibility of drill and bur stops:

Components	Compatible instrument types
Pink Axiom® stops	Lindemann bur
	Axiom® initial drills
	Axiom® Ø2.0/2.4 and Ø2.4/3.0 step drills
Yellow Axiom® stops	Axiom® Ø3.0/3.6 step drills
Grey Axiom® stops	Axiom® Ø3.6/4.2 step drills
Blue Axiom® stops	Axiom® Ø4.2/4.8 step drills
Purple Axiom® stops	Axiom® Ø4.8/5.4 step drills
Brown Axiom® stops	Axiom® Ø5.4/6.0 step drills
Stop pin (Ref. OPFFP)	Axiom® BL Ø4.5, Ø5.3 and Ø6.6 countersinks

Compatibility of the INGPPA drilling guide:

The drilling guide (Ref. INGPPA) is only compatible with Axiom® BL implants.

The drilling guide is only compatible with the Ø1.5 mm pointer drill (Ref. OPPO15).

1.10 Cleaning and disinfection

Point-of-Use: Never let surgical residues (blood, secretion, tissue residues) dry on an instrument, clean immediately after surgery.

The instruments that go in the cassette are sold included in the cassette or separately.

A flow chart to summarize the cleaning process is available in appendix 1.

Anthogyr instruments are delivered non-sterile.

They must be cleaned and decontaminated before use and after each use for reusable components (except X-ray templates). Do not use the components if the packaging is opened or damaged. Before treatment, remove the components from their packaging.

Before every use, the device must be carefully checked for proper function and damage.

If applicable, for cleaning, the device must be disassembled.

Anthogyr recommends following the protocol described below.

Remove the instruments from the tray and clean separately.

Manual cleaning

- Cleaning

1. Thoroughly clean the devices with the following steps.
2. Brush meticulously all surfaces with a soft brush (example: nylon) under tap water at room temperature for at least 1 minute.
   Use an adapted soft-nylon brush to each lumen or hole at least one time.
3. Completely submerge in a detergent and disinfectant solution for at least 5 minutes following the manufacturer's instructions temperature, and concentration (paragraph below).
   Flush each lumen or hole with detergent solution at least one time.
4. Whilst immersed, brush meticulously all surfaces with a soft brush (example: nylon) for at least 1 minute or until there is no visible trace of contaminants.
   Use an adapted soft nylon brush to each lumen or hole for 20 seconds.
5. During immersion, move the devices by making 3 back and forth movements.

- Rinsing and drying

6. Rinse with critical water (per AAMI TIR34) for at least 1 minute.
7. During rinsing, brush meticulously all surfaces with a soft brush (example: nylon) for at least 30 seconds using an adapted nylon brush to hard-reach areas.
   Flush each lumen or hole with tap water at least one time.
8. Rinse with critical water (per AAMI TIR34) at room temperature for at least 1 minute.

A visual inspection, an inspection end point on the instrument. If the user sees visual contamination on the cassette, he must restart the cleaning process.

- Products and detergents

Anthogyr used the following products and detergents to approve the various protocols. However, other products and detergents may be used according to local availability. Approval of these products is the responsibility of the user.

◊ Cidezyme (ASP) at a concentration of 8mL/L.
For sterilization, see the "Sterilization" section.

Automated cleaning

- Manual pre-cleaning

1. Thoroughly clean the devices with the following steps.
2. Soak the device in a detergent and disinfectant solution for at least 5 minutes following the manufacturer's instructions, temperature, and concentration (paragraph below).
3. Whilst immersed, brush all surfaces of the test article for at least 30 seconds using a soft nylon bristle. For each lumen or hole, use an adapted soft nylon brush during 30 secondes.

- Automatic cleaning

1. Pre-wash with cold tap water (<45°C) for 2 min.
2. Wash at heated water (50-60°C) C for 5 min with an enzymatic detergent (paragraph below).
3. Neutralization at heated water (50-60°C) for 1 min with an appropriate neutralizer (paragraph below).
4. Intermediate rinsing at cold water (<45°C) for 1 min.
5. Thermal rinsing at 90°C for 5 min with critical water (per AAMI TIR34).
6. Drying at 60°C for 10 min.
7. A visual inspection, an inspection end point on the instrument. If the user sees visual contamination on the cassette, he must restart the cleaning process.

- PRODUCTS AND DETERGENTS

Manual pre-cleaning

◊ Cidezyme (ASP) at a concentration of 8mL/L.

Automatic cleaning

◊ Enzymatic detergent: Neodisher Mediclean Dental (DrWeigert) at a concentration of 2mL/L.

◊ Neutraliser: Neodisher Z Dental (DrWeigert) at a concentration of 1mL/L.

After cleaning, check all instruments for corrosion, visible dirt, damaged surfaces, blunt cutting edges, chipping and contamination. Critical areas such as handle structures, joints or holes must be inspected carefully.

Instruments with illegible markings/labelling must be replaced.
For sterilisation, see the "Sterilisation" section.

1.11 Function test

Process contaminated instruments and remove damaged instruments. Damaged instruments must be cleaned and disposed of separately.
After cleaning, check all instruments for corrosion, visible dirt, damaged surfaces, blunt cutting edges, chipping and contamination. Critical areas such as holes must be inspected carefully.
Instruments with illegible markings/labelling must be replaced.
Before every use, the device must be carefully checked for proper functioning and damage.
For USA - Configuration: Wrapped in two layers of Halyard Health (H200-510(k) K082554) polypropylene wrap using simultaneous envelope folding techniques.

1.12 Sterilisation

Anthogyr instruments delivered non-sterile must be sterilised before use (except X-ray templates). Anthogyr recommends following the protocol described below:
Users should ensure that the sterilizer and all sterilization accessories (sterilization wraps, pouches, sterilization trays, biological indicators and chemical indicators) are cleared by the FDA for the intended sterilization cycle.
ATTENTION: This product cannot be autoclaved in its original packaging.

Grouping name	Method	Conditions	Drying Time
	For the United States:		
Anthogyr Surgical and Prosthetic Cassette	Moist Heat (Autoclave) Pre-vacuum	132°C (270°F) for 4 min	20 min[2]
INTEGRAL Guided Surgery Cassette	Moist Heat (Autoclave) Pre-vacuum	132°C (270°F) for 4 min	30 min[2]

[2] Nevertheless, a drying time shorter than defined time cannot be applied.

After the sterilisation was done, asepsis rules must be followed.

1.13 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.

1.14 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	Ø2.0 pin drill	10 uses
	Pointer drills	10 uses
	Initial drills	10 uses
Integral	Ø2.0 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
Axiom® Multi Level®	Countersinks	20 uses
	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

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, deterioration of the coating, signs of corrosion, etc.).

Range	Type of device	Product lifespan
First Drill and Integral guided surgery	Ø2.0 fixation pin	250 uses, except in the case of breakage or significant deterioration causing the tool to malfunction
	Sleeves	Single use
Axiom® Multi Level®	Drill stops	250 uses
	Guiding pin	250 uses
	Gauges	250 uses
	Drilling guides	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
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
Axiom® Multi Level®	AA screw gripper	Single use

One use is equivalent to one reprocessing cycle.

1.15 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 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)*

Axiom® Multi Level®:
- *Axiom® Multi Level® surgical user guide (AXIOM-MLC_NOT)*
- *Axiom® Multi Level® Prosthetic user guide (AXIOM-MLP_NOT)*

Others:
- *Cleaning and sterilisation user guide (NETT-STE_NOT)*

1.16 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.

1.17 Waste treatment

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

1.18 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.

1.19 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.

1.20 Validity

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

1.21 Availability

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

1.22 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	ISO 15223-1
	Date of manufacture	ISO 15223-1
	Catalogue number	ISO 15223-1
	Batch code	ISO 15223-1
	Serial number	ISO 15223-1
	Consult instructions for use or consult electronic instructions for use	ISO 15223-1
	Medical Device	ISO 15223-1
	CE marking- compliance with current regulations	Directive 93/42/CEE ———————— MDR (EU) 2017/745
	U.S.federal law restrics this device to sale by or on the order of a dental professional.	21 CFR 801.109(b)(1)
	Use-by date	ISO 15223-1
	Single sterile barrier system	ISO 15223-1
	Single sterile barrier system with protective packaging inside	ISO 15223-1

Symbol	Description of symbol	Source of symbol
	Sterilised using irradiation	ISO 15223-1
	Do not resterilise	ISO 15223-1
	Non-sterile	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	ISO 15223-1
	Keep away from sunlight	ISO 15223-1
	Do not re-use	ISO 15223-1
	Caution	ISO 15223-1
	Contains hazardous substances	ISO 15223-1
	Screwing torque	Anthogyr
	Axiom® BL countersink + pin	Anthogyr

2. Instructions for use for Anthogyr Surgical and prosthetic cassettes

Caution: U.S. federal law restricts this device to sale by or on the order of a dental professional.

2.1 Product description

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

Kits:

- Anthogyr Cassettes: guided surgical kits, Axiom® Multi Level® surgical kits, Axiom® Multi Level® prosthesis kits, and empty kits (list in Table 1)
- INTEGRAL Guided Surgery Cassettes: INTEGRAL surgical kit and empty kits (list in Table 1)

Anthogyr cassettes are reusable rigid containers, comprising a case bottom (base), one or more removable inner tray base (tray) and a tray lid (lid). The trays are composed of grommets made of medical grade silicone, namely grommets used to maintain the Anthogyr dental instruments in place during the surgical or prosthetic procedure and during sterilization. The base and trays have markings and/or colors code to indicate either the surgical workflow, or the position of the instruments in the kit. The lid holds all the instruments securely in place during treatment.

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.

The notion of "cassette" as the same meaning of the notion of "kit".

Materials:

Stainless steel, medical grade silicone and PolyPhenylSulphone (PPSU).

2.2 Intended use

Anthogyr cassettes are intended to organize instruments, and secure instruments during the sterilization phase.

2.3 Indications for use

The Anthogyr Surgical Cassettes are designed to hold various dental surgical drills and tools in order to organize, steam sterilize, and protect the instruments that are sterilized by healthcare provider. The cassette is to be enclosed in an FDA cleared steam sterilizable pouch. The cassettes are not intended on their own to maintain sterility.

The cycle of sterilization is INMODOPS3, INMODOPS3L, INMODOPP3, INMODIGM, INMODOPS3V, INMODOPS3LV, INMODOPP3V, INMODIGMV: Pre-vacuum steam: 132°C (270°F) during 4 minutes with 20 minutes drying time

The Anthogyr Surgical Cassettes have been validated for a maximum load of (with the associated instruments).

The worst-case recommended load is 412g.

The device dimensions are listed below for Anthogyr Surgical and Prosthetic Cassettes:

- INMODOPS3, INMODOPS3V, INMODOPS3L, INMODOPS3LV, INMODOPP3, INMODOPP3V: 130x155x47 mm
- INMODIGM, INMODIGMV: 76x155x47 mm

The cycle of sterilization, for Anthogyr INTEGRAL Guided Surgery Cassettes, uses pre-vacuum steam: 132°C (270°F) during 4 minutes with 30 minutes drying time.

Anthogyr INTEGRAL Guided Surgery Cassettes have been validated for a maximum load of with the associated instrument. The worst-case recommended load is: 886 g.

The device dimension of Anthogyr INTEGRAL Guided Surgery Cassettes is 290x176x62 mm.

The cassettes are not intended to be stacked during sterilization process.

2.4 Contraindication

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

2.5 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 anesthesia, paranesthesia, and dysesthesia.
- Do not exceed the recommended insertion torques as this may cause bone necrosis and fracture.

Specific warning:

The First Drill guided surgery protocol is not applicable to the preparation of implant sites for 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 Axiom® 2.8 and Axiom® implants with a diameter greater than 4.6 mm and a length greater than 14 mm.

Follow the loading chart instructions for guidance on loading the cassettes. Do not exceed the maximum loading. Anthogyr cassettes have been validated for the following maximum loads (including instruments and cassette):

Grouping name	Material	Description	Max. weight load incl. Cassette (g)
Anthogyr Surgical and Prosthetic Cassette	INMODOPS3	AXIOM MULTI LEVEL SURGERY KIT	407
	INMODOPS3V	Empty Axiom ML Surgery Kit	407
	INMODOPS3L	AXIOM ML SURGERY KIT + LARGE Ø	412
	INMODOPS3LV	EMPTY AXIOM ML SURG KIT + ØL	412
	INMODIGM	GUIDED SURGERY INITIAL M KIT	259
	INMODIGMV	EMPTY ID GUIDED SURGERY KIT	259
	INMODOPP3	AXIOM MULTI LEVEL PROSTH KIT	408
	INMODOPP3V	EMPTY AXIOM ML PROSTH KIT	408
INTEGRAL Guided Surgery Cassette	MODGS3642	INTEGRAL SURG KIT Ø3.6-4.2	886
	MODGS36	INTEGRAL SURG KIT Ø3.6	802
	MODGS42	INTEGRAL SURG KIT Ø4.2	825
	MODGS50	INTEGRAL SURG KIT Ø5.0	866
	MODGS3642V	INTEGRAL SURG KT Ø3.6-4.2 EMPT	886
	MODGS36V	INTEGRAL SURG KIT Ø3.6 EMPTY	802
	MODGS42V	INTEGRAL SURG KIT Ø4.2 EMPTY	825
	MODGS50V	INTEGRAL SURG KIT Ø5.0 EMPTY	866

Table 1: Cassettes references with grouping name

2.6 Caution / Precaution

It is essential to handle the Anthogyr cassettes according to the basic information documentation for the applicable surgical and prosthetic procedure. Ensure sterile handling.

Never use potentially contaminated components. Only use adequately processed devices if indicated for multiple uses. The Anthogyr Surgical and Prosthetic Cassette have been validated to withstand 250 processing cycles provided that the recommended conditions of use are followed.

The INTEGRAL Guided Surgery Cassette have been validated to withstand 100 processing cycles provided that the recommended conditions of use are followed.

2.7 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

2.8 Compatibility information

Anthogyr cassettes are suitable to enclose Anthogyr instruments according to marking and color coding provided on the tray of the reusable containers.

Make sure only to use original Anthogyr instruments with the cassettes. Storage and organization of non-Anthogyr instruments and components can lead to mechanical and/or instrument failure.

2.9 Cleaning and disinfection

Point-of-Use Processing: Never let surgical residues (blood, secretion, tissue residues) dry on an instrument; clean immediately after surgery.

The instruments that go in the cassette are sold included in the cassette or separately.

A flow chart to summarize the cleaning process is available in appendix 1.

Anthogyr instruments and cassettes are delivered non-sterile. Clean this product according to the following instructions after each use:

- Remove the instruments from the tray and clean separately. The instruments must be used according to their own Instructions for Use (available in ifu.anthogyr.com).
- Totally disassemble the tray before cleaning: disassemble the parts of the cassettes as in appendix 2 and in appendix 3.

2.9.1 Manual cleaning

A. Cassettes

a. Cleaning

1. Thoroughly clean the devices with the following steps.
2. Brush meticulously all surfaces under tap water at room temperature for at least 1 minute using an adapted soft brush (nylon) to hard reach areas.
3. Completely submerge in a detergent and disinfectant solution for at least 3 minutes following the manufacturer's instructions temperature, and concentration (paragraph below).
4. Whilst immersed, brush meticulously all surfaces with a soft brush (example: nylon) for at least 1 minute using an adapted nylon brush to hard-reach areas.
5. During immersion, move the devices by making 3 back and forth movements.

b. Rinsing and drying

6. Rinse with critical water (per AAMI TIR34) for at least 1 minute.
7. During rinsing, brush meticulously all surfaces with a soft brush (example: nylon) for at least 30 seconds using an adapted nylon brush to hard-reach areas.
8. Dry immediately, carefully, with a soft lint-free cloth.
9. A visual inspection, an inspection end point on the cassette or the instruments. If the user sees visual contamination on the cassette. The practitioner must restart the cleaning process.

B. Instruments in Anthogyr Surgical and Prosthetic Cassettes

a. Cleaning

1. Thoroughly clean the devices with the following steps.
2. Brush meticulously all surfaces with a soft brush (example: nylon) under tap water at room temperature for at least 1 minute.
   Use an adapted soft-nylon brush to each lumen or hole at least one time.
3. Completely submerge in a detergent and disinfectant solution for at least 5 minutes following the manufacturer's instructions temperature, and concentration (paragraph below).
   Flush each lumen or hole with detergent solution at least one time.
4. Whilst immersed, brush meticulously all surfaces with a soft brush (example: nylon) for at least 1 minute or until there is no visible trace of contaminants.
   Use an adapted soft nylon brush to each lumen or hole for 20 seconds.
5. During immersion, move the devices by making 3 back and forth movements.

b. Rinsing and drying

6. Rinse with critical water (per AAMI TIR34) for at least 1 minute.
7. During rinsing, brush meticulously all surfaces with a soft brush (example: nylon) for at least 30 seconds using an adapted nylon brush to hard-reach areas.
   Flush each lumen or hole with tap water at least one time.
8. Rinse with critical water (per AAMI TIR34) at room temperature for at least 1 minute.
9. A visual inspection, an inspection end point on the instrument. If the user sees visual contamination on the cassette, he must restart the cleaning process.

C. Products and detergents

Anthogyr used the following products and detergents to approve the various protocols. However, other products and detergents may be used according to local availability. Approval of these products is the responsibility of the user.

◊ Cidezyme (ASP) at a concentration of 8mL/L.

For sterilization, see the "Sterilization" section.

2.9.2 Automated cleaning

A. Cassettes

a. Manual pre-cleaning

1. Thoroughly clean the devices with the following steps.
2. Soak the device in a detergent and disinfectant solution for at least 5 minutes following the manufacturer's instructions, temperature, and concentration (paragraph below).
3. Whilst immersed, brush all surfaces of the devices for at least 30 seconds using a soft brush (example: nylon).

b. Automatic cleaning

i. Anthogyr Surgical and Prosthetics Cassettes

1. Thoroughly clean the devices with the following steps.
2. Pre-wash with cold tap water (<45°C) for 2 min.
3. Wash at heated water (50-60°C) C for 5 min with an enzymatic detergent (paragraph below).
4. Neutralization at cold water (<45°C) for 1 min with an appropriate neutralizer (paragraph below)
5. Intermediate rinsing at cold water (<45°C) for 1 min.
6. Thermal rinsing at 90°C for 5 minutes with critical water (per AAMI TIR34).
7. Drying at 60°C for 10 min.
8. A visual inspection, an inspection end point on the cassette. If the user sees visual contamination on the cassette. he must restart the cleaning process.

ii. INTEGRAL Guided Surgery Cassette

1. Thoroughly clean the devices with the following steps.
2. Pre-wash with cold tap water (<45°C) for 4 min.
3. Wash at heated water (50-60°C) C for 5 min with an enzymatic detergent (paragraph below).
4. Neutralization at heated water (50-60°C) for 3 min with an appropriate neutralizer (paragraph below).
5. Intermediate rinsing at cold water (40°C) for 2 min.
6. Thermal rinsing at 95°C for 10 minutes with critical water (per AAMI TIR34).
7. Final rinsing at cold water (40°C) for 2 min with critical water (per AAMI TIR34).
8. Drying at 140°C for 10 min.

9. A visual inspection, an inspection end point on the cassette. If the user sees visual contamination on the cassette. he must restart the cleaning process.

B. Instruments in Anthogyr Surgical and Prosthetic Cassettes

a. Manual pre-cleaning

1. Thoroughly clean the devices with the following steps.
2. Soak the device in a detergent and disinfectant solution for at least 5 minutes following the manufacturer's instructions, temperature, and concentration (paragraph below).
3. Whilst immersed, brush all surfaces of the test article for at least 30 seconds using a soft nylon bristle.
   For each lumen or hole, use an adapted soft nylon brush during 30 secondes.

b. Automatic cleaning

4. Pre-wash with cold tap water (<45°C) for 2 min.
5. Wash at heated water (50-60°C) C for 5 min with an enzymatic detergent (paragraph below).
6. Neutralization at heated water (50-60°C) for 1 min with an appropriate neutralizer (paragraph below).
7. Intermediate rinsing at cold water (<45°C) for 1 min.
8. Thermal rinsing at 90°C for 5 min with critical water (per AAMI TIR34).
9. Drying at 60°C for 10 min.
10. A visual inspection, an inspection end point on the instrument. If the user sees visual contamination on the cassette. he must restart the cleaning process.

C. Instruments in INTEGRAL Guided Surgery Cassettes

a. Automatic cleaning

1. Pre-wash with cold tap water (<45°C) for 2 min.
2. Wash at heated water (50-60°C) C for 5 min with an enzymatic detergent (paragraph below).
3. Neutralization at heated water (50-60°C) for 1 min with an appropriate neutralizer (paragraph below).
4. Intermediate rinsing at cold water (<45°C) for 1 min.
5. Thermal rinsing at 90°C for 5 min with critical water (per AAMI TIR34).
6. Drying at 60°C for 10 min.
7. A visual inspection, an inspection end point on the instrument. If the user sees visual contamination on the cassette. he must restart the cleaning process.

D. PRODUCTS AND DETERGENTS

Manual pre-cleaning

◊ Cidezyme (ASP) at a concentration of 8mL/L.

Automatic cleaning

◊ Enzymatic detergent: Neodisher Mediclean Dental (DrWeigert) at a concentration of 2mL/L.

◊ Neutraliser: Neodisher Z Dental (DrWeigert) at a concentration of 1mL/L.

For sterilization, see the "Sterilization" section.

2.9.3 Function test

Process contaminated instruments and remove damaged instruments. Damaged instruments must be cleaned and disposed of separately.

After cleaning, check all cassette parts and instruments for corrosion, visible dirt, damaged surfaces, blunt cutting edges, chipping and contamination. Critical areas such as handle structures, joints or holes must be inspected carefully.

Instruments with illegible markings/labelling must be replaced.

Before every use, the device must be carefully checked for proper functioning and damage.

After functional testing, assemble the device for sterilization (as in Appendix 2 and in Appendix 3).

For USA - Configuration: Wrapped in two layers of Halyard Health (H200-510(k) K082554) polypropylene wrap using simultaneous envelope folding techniques.

2.10 Sterilization

Anthogyr cassettes are delivered non-sterile. Anthogyr recommends the following procedure for sterilization prior to use.

A flow chart to summarize the sterilization process is available in appendix 1.

ATTENTION: This product cannot be autoclaved in its original packaging.

Grouping name	Method	Conditions	Drying Time
	For the United States:		
Anthogyr Surgical and Prosthetic Cassette	Moist Heat (Autoclave) Pre-vacuum	132°C (270°F) for 4 min	20 min[2]
INTEGRAL Guided Surgery Cassette	Moist Heat (Autoclave) Pre-vacuum	132°C (270°F) for 4 min	30 min[2]

[2] Nevertheless, a drying time shorter than defined time cannot be applied.

Precautions:

The sterilizer must

- offer a pre-vacuum method with sufficient device drying time and be compliant with EN 13060 or EN 285
- be validated according to EN ISO 17665 (valid IQ/OQ and product-specific performance assessment (PQ)).

Always observe the operating instructions of the manufacturer of the sterilizer, especially with regard to loading weight, operating time and functional testing.

When loading the sterilizer, place the cassette on the sterilizer rack in such a way that under no circumstances does it come into contact with the walls of the sterilizer.

Do not put the cassette on its side or upside down with the lid facing down. Do not place corroded or rusty instruments in the cassette for sterilization. These contaminate the water circulation system of the sterilizer with rust particles. During every subsequent sterilization cycle, these rust particles cause rust on instruments that were originally intact.

If visible signs of moisture are present (damp spots on sterile packaging, pooled water in the load) at the end of the sterilization cycle, repackage and resterilize using a longer drying time.

After sterilization, pack the instruments at a dry and dust-free place.

Sterilized devices should be used immediately after sterilization. In case of storage, strictly follow the manufacturer's instructions of the sterilization accessories and storage containers.

***For United States only:**

Users in the United States should ensure that the sterilizer and all sterilization accessories (sterilization wraps, pouches, sterilization trays, biological indicators and chemical indicators) are cleared by FDA for the intended sterilization cycle.

2.11 Protocol for use

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

2.12 Lifespan of products

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.)

Type of device as in table 1	Product lifespan
Anthogyr Surgical and Prosthetic Cassettes	250 uses
Anthogyr INTEGRAL Guided Surgery Cassettes	100 uses

2.13 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.

2.14 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.

2.15 Disposal

Disposal should be handled in an environmentally sustainable manner according to local regulations. Hazardous waste from contaminated devices or sharps should be disposed of in appropriate containers which meet specific technical requirements.

2.16 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.

2.17 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 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.

2.18 Validity

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

2.19 Availability

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

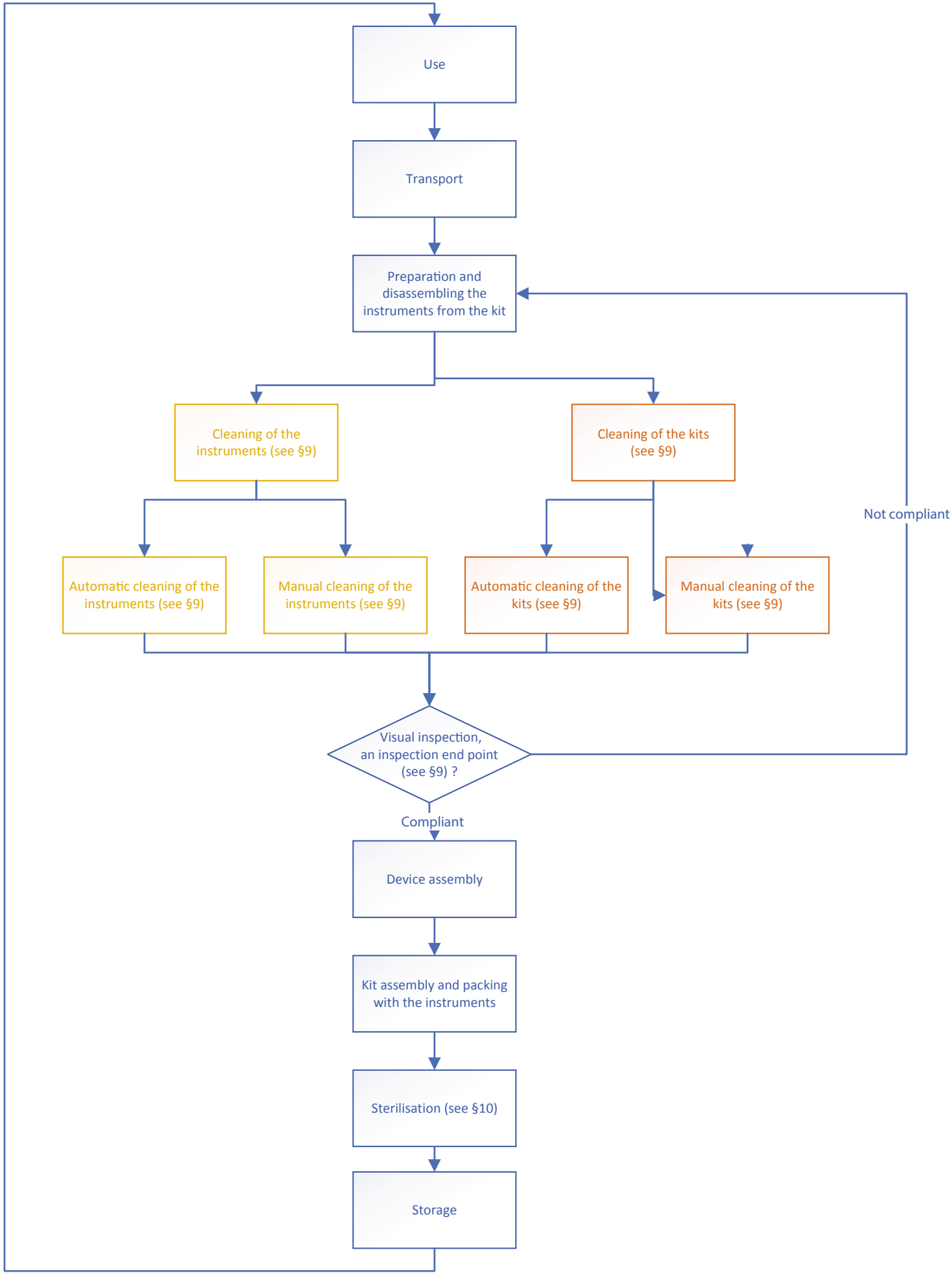
2.20 Symbols

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	ISO 15223-1
	Date of manufacture	ISO 15223-1
	Catalogue number	ISO 15223-1
	Batch code	ISO 15223-1
	Serial number	ISO 15223-1
	Consult instructions for use or consult electronic instructions for use	ISO 15223-1
	Medical Device	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	ISO 15223-1
	Single sterile barrier system	ISO 15223-1

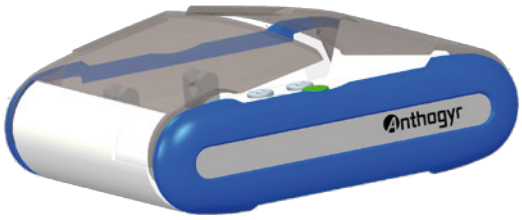
Symbol	Description of symbol	Source of symbol
	Single sterile barrier system with protective packaging inside	ISO 15223-1
	Sterilised using irradiation	ISO 15223-1
	Do not resterilise	ISO 15223-1
	Non-sterile	ISO 15223-1
	Sterilisable in a steam steriliser (autoclave) at temperature specified	ISO 7000-2868
	Non sterilisable in a steam steriliser (autoclave) at temperature specified	Anthogyr
	Do not use if packaging is damaged and consult instructions for use	ISO 15223-1
	Keep away from sunlight	ISO 15223-1
	Do not re-use	ISO 15223-1
	Caution	ISO 15223-1
	Contains hazardous substances	ISO 15223-1
	Screwing torque	Anthogyr
	Axiom® BL countersink + pin	Anthogyr

Appendix 1 – Flow chart of cleaning and sterilization process



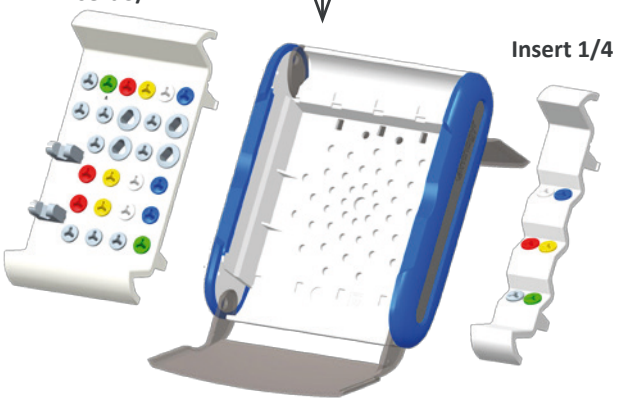
Appendix 2 – Disassembly of the Anthogyr Cassettes

→ Open the covers.

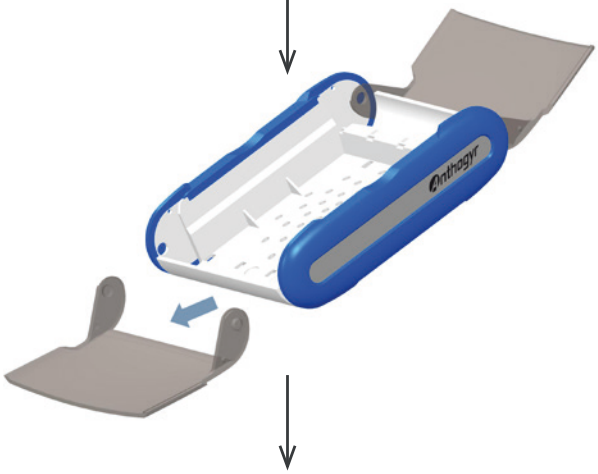


→ Unclip the insert pegs located on the back of the kit.

→ Remove the ¼ and ¾ inserts from the main kit body.



→ Carefully remove the side arms from the main body.
→ Detach the transparent cover pivot pegs.
→ Remove the covers.



→ Remove the side covers from the main body.
→ Detach the side covers from the side of the kit.
→ Remove the side cover ends around the stainless steel plates.
→ Detach the silicone cover plates.

Repeat each stage in reverse order to assemble

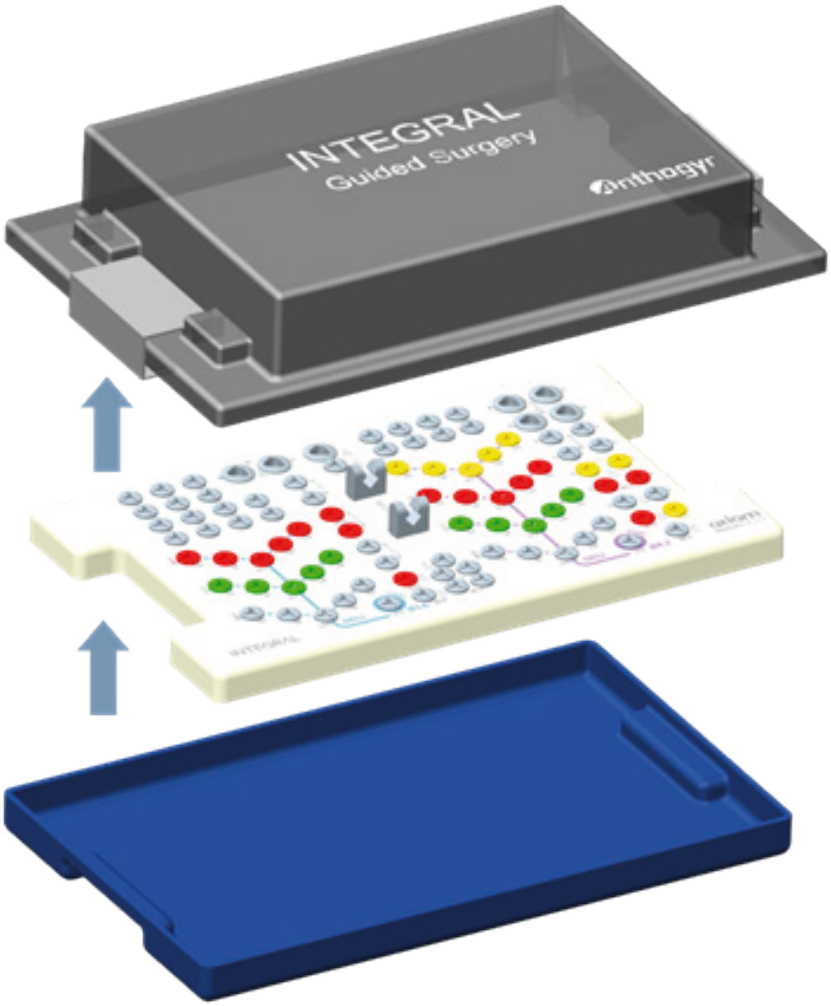
For the storage of the instruments in the cassette in sales configuration, see appendix 4.

Appendix 3 – Disassembly of INTEGRAL guided Surgery Cassettes

1. Remove the lid.

2. Remove the instruments.
For the storage of the instruments in the cassette in sales configuration, see appendix 4.

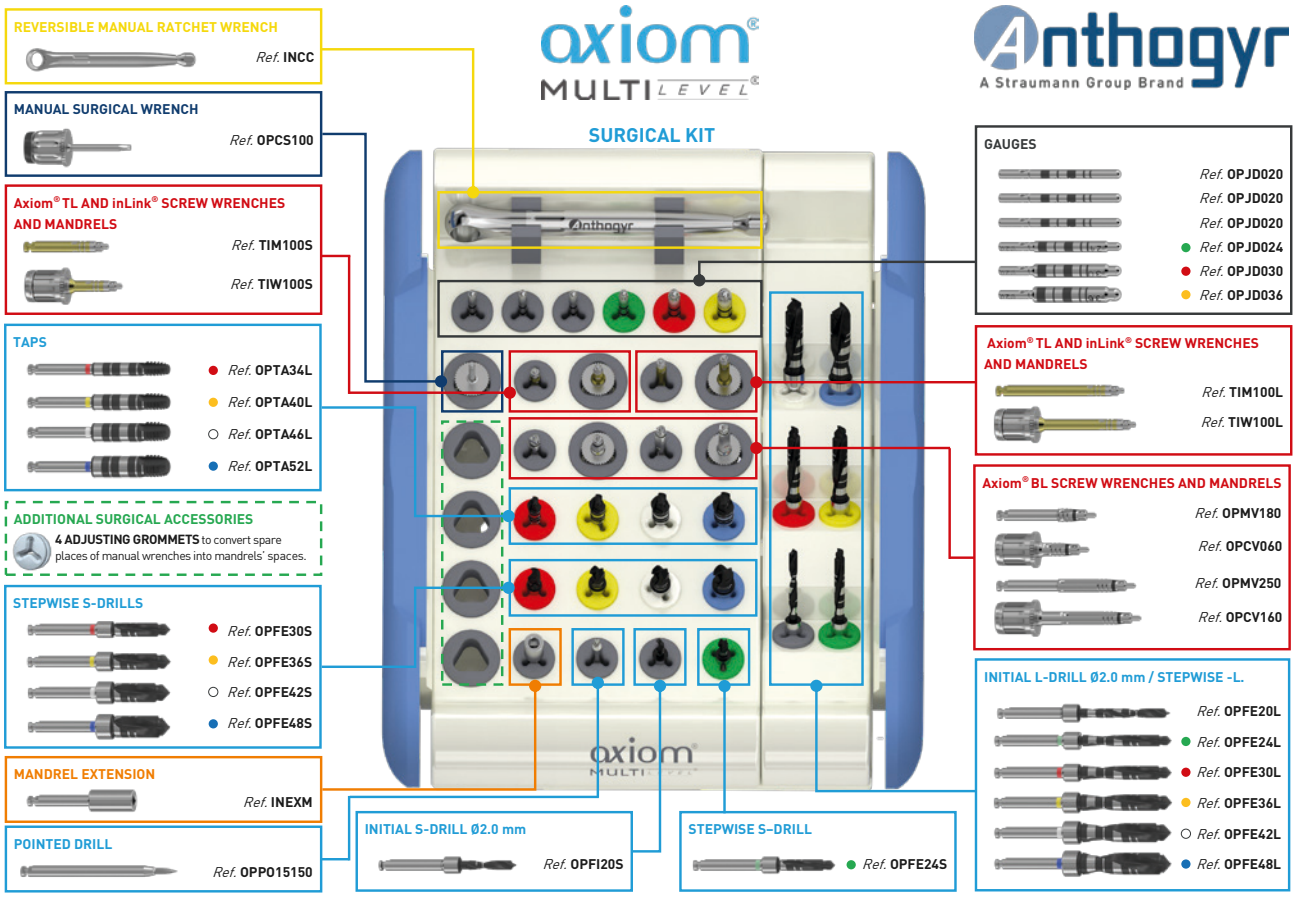
3. Remove the white tray



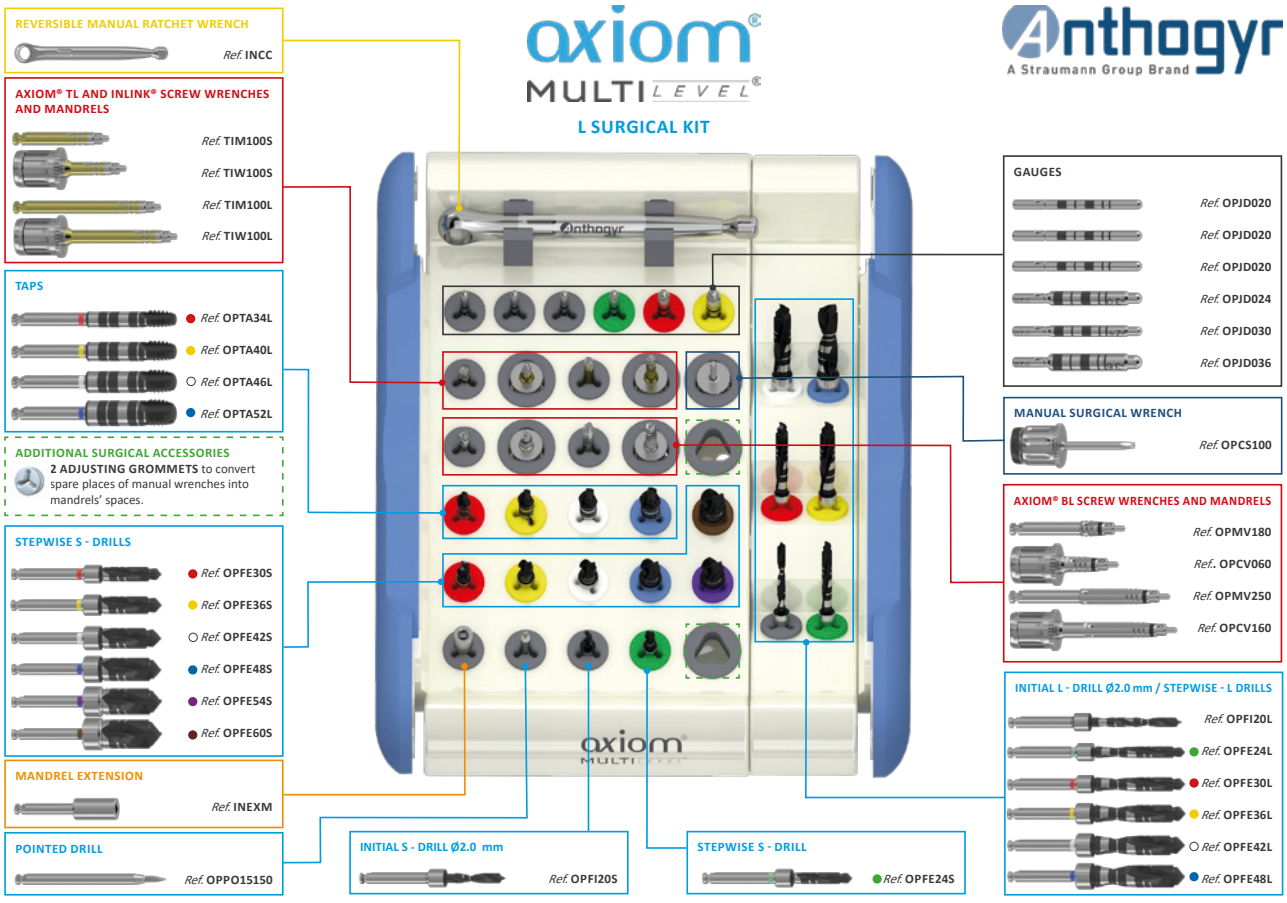
Repeat each stage in reverse order to assemble.

Appendix 4 – Storage of the instruments in the cassette in sales configuration

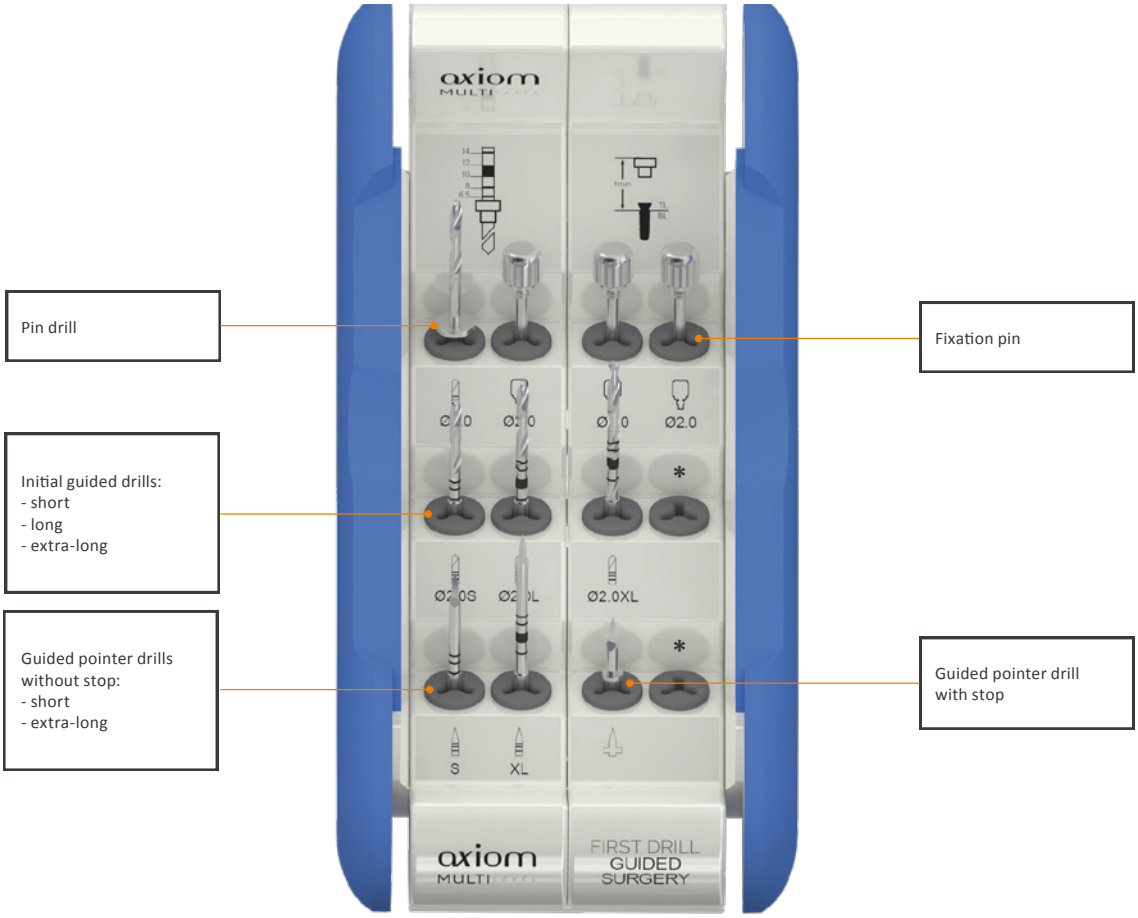
INMODOPS3:



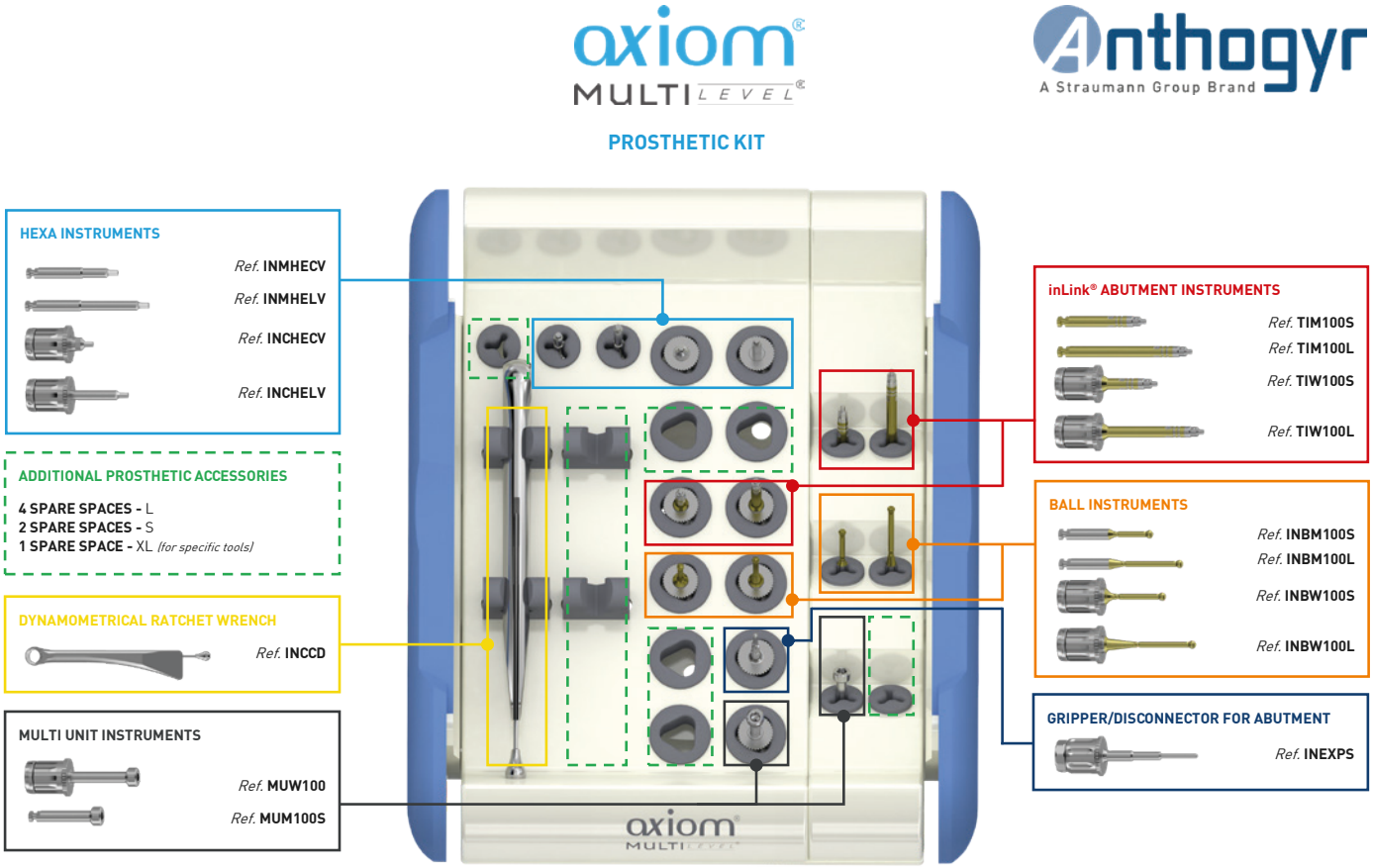
INMODOPS3L:



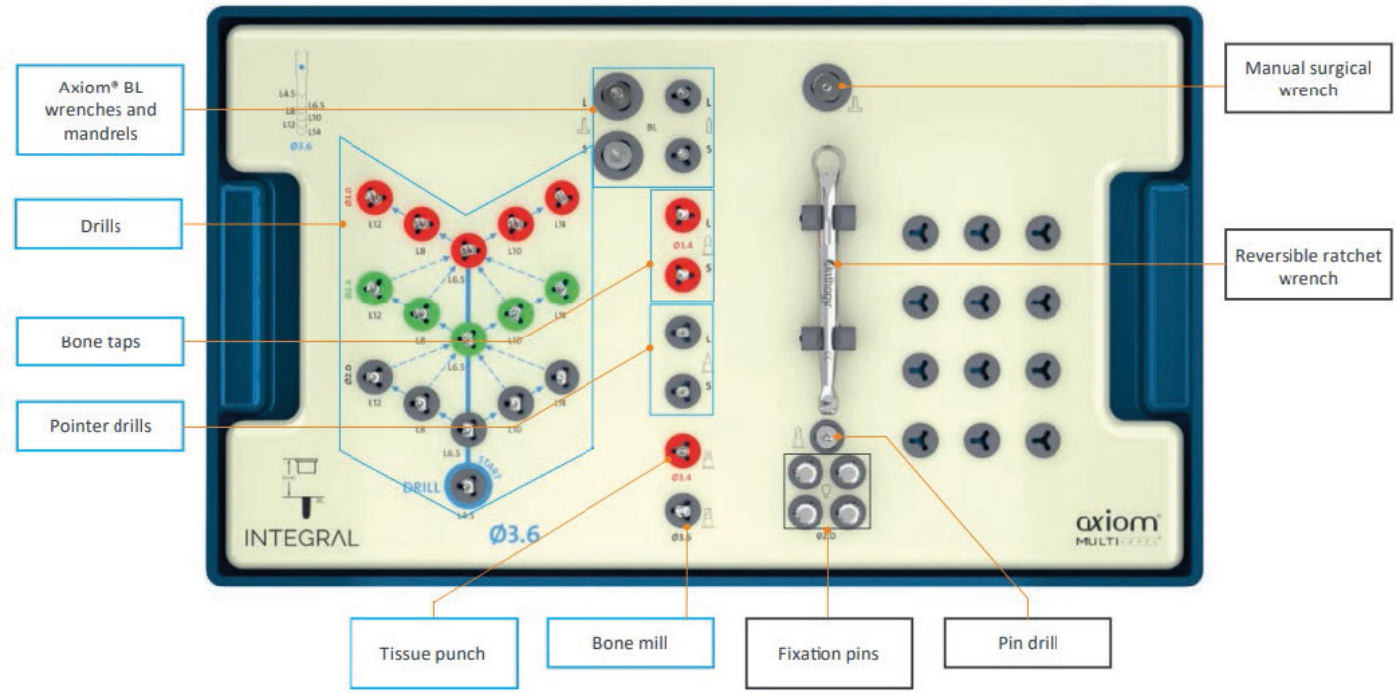
INMODIGM:



INMODOPP3:



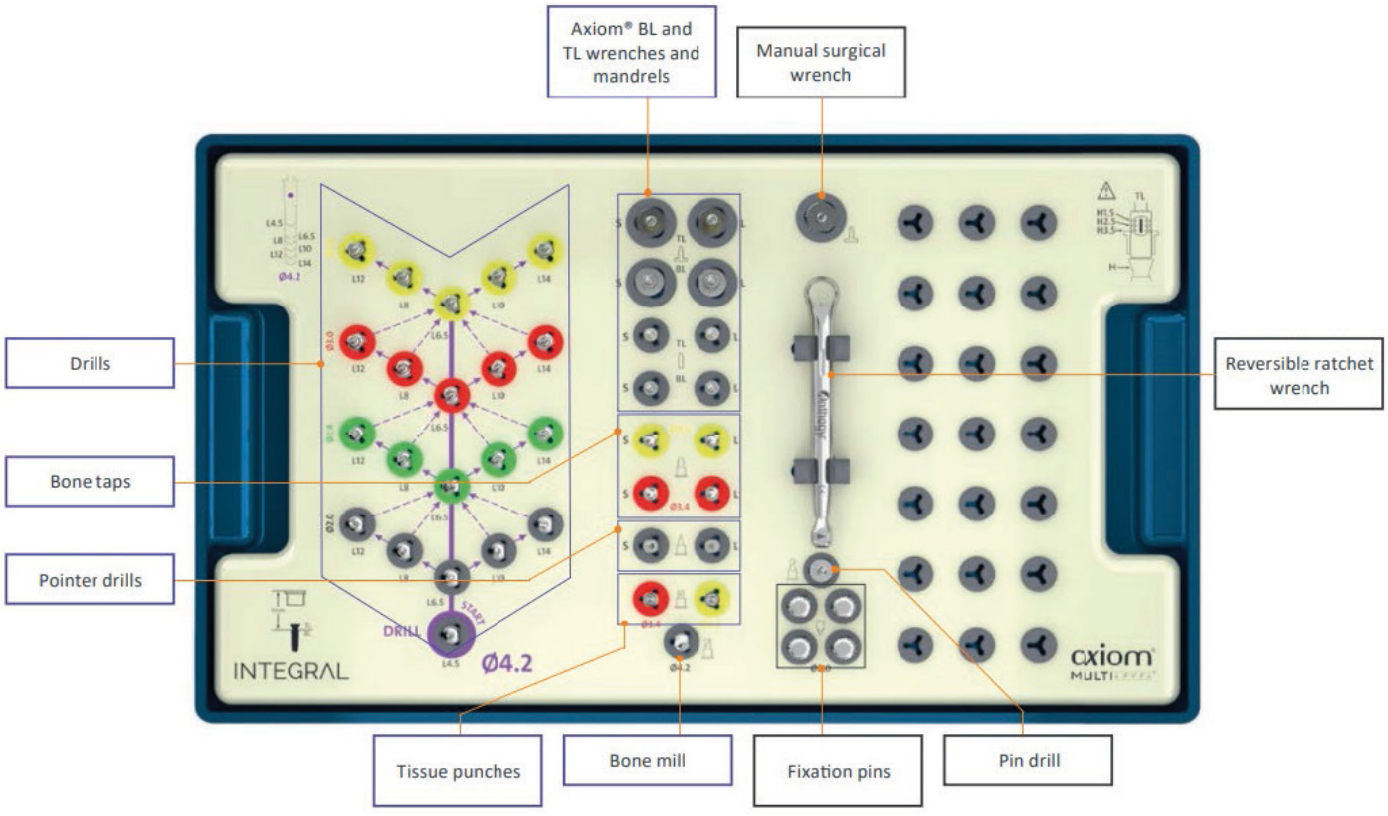
- Cassette for Ø 3.6 mm GUIDE SLEEVES



Legend

Ø 3.6 Guided instruments	Ø 4.2 Guided instruments	Ø 5.0 Guided instruments	Other instruments

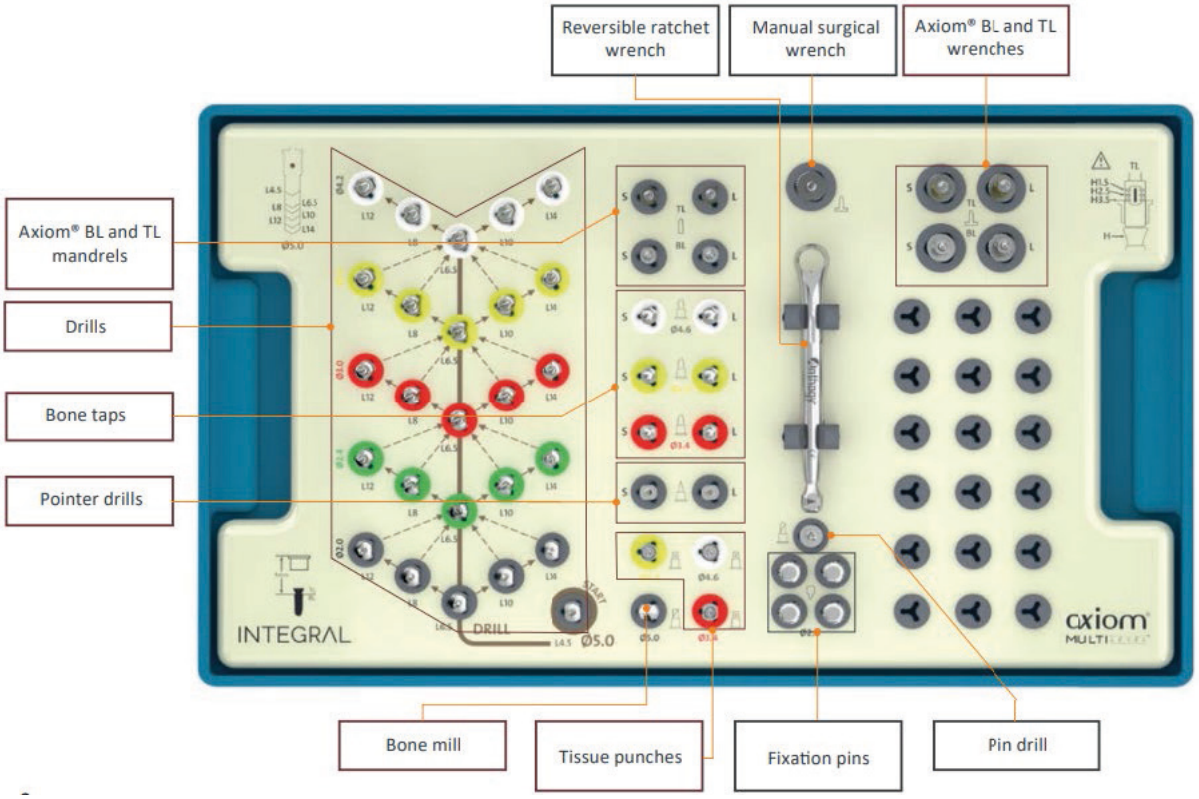
- Cassette for Ø 4.2 mm GUIDE SLEEVES



Legend

Ø 3.6 Guided instruments	Ø 4.2 Guided instruments	Ø 5.0 Guided instruments	Other instruments

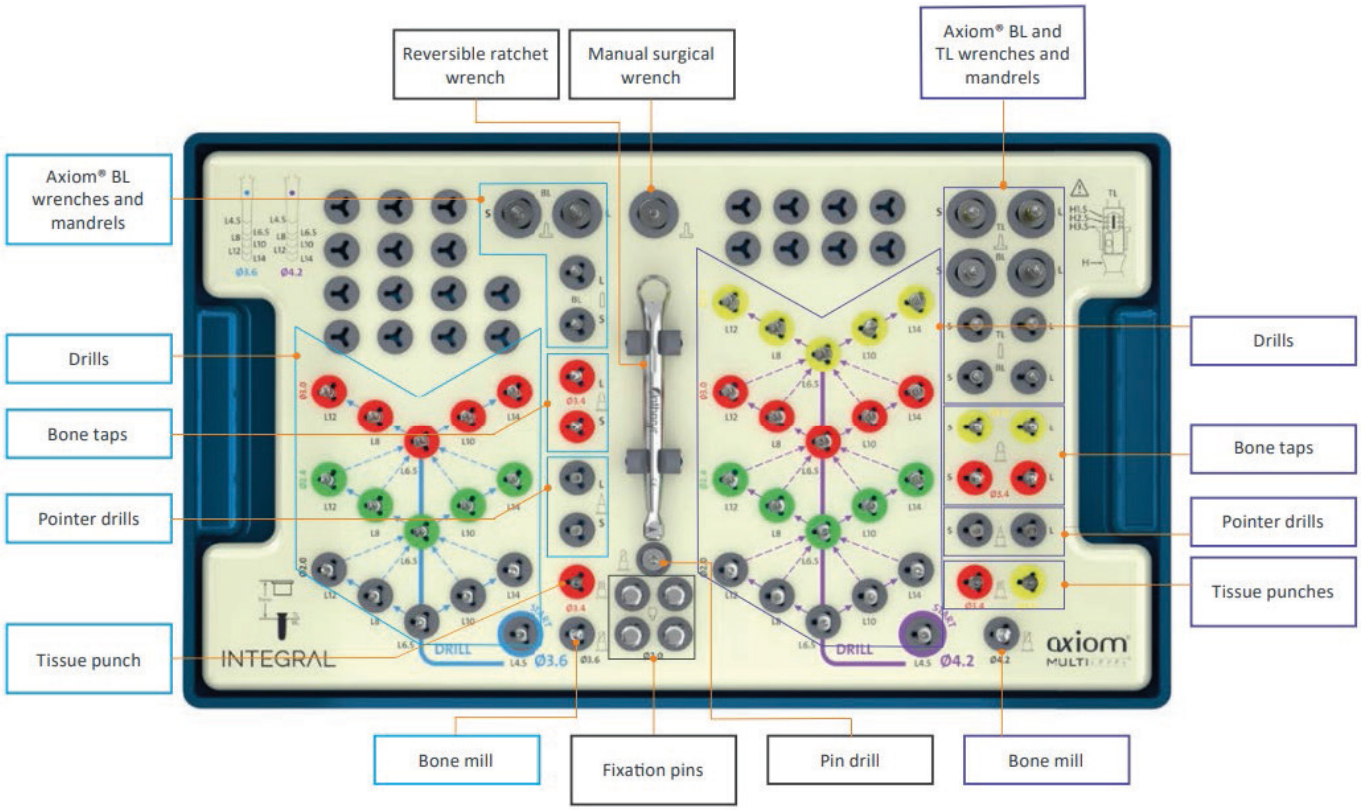
- Cassette for Ø 5.0 mm GUIDE SLEEVES



Legend

Ø 3.6 Guided instruments	Ø 4.2 Guided instruments	Ø 5.0 Guided instruments	Other instruments

- Cassette for Ø 3.6 mm and 4.2 mm GUIDE SLEEVES



Legend

Ø 3.6 Guided instruments	Ø 4.2 Guided instruments	Ø 5.0 Guided instruments	Other instruments