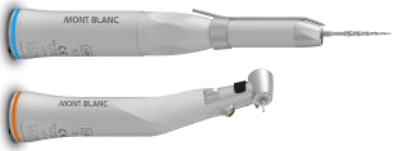
MONT BLANC®



CONTRA-ANGLE FOR SURGERY 1:3
12200X - 12200XL - 12200XLED

HANDPIECE FOR SURGERY 1:1
12400X- 12400XLED

EN - INSTRUCTIONS FOR USE

Anthogyr
A Straumann Group Brand

Fig. 1

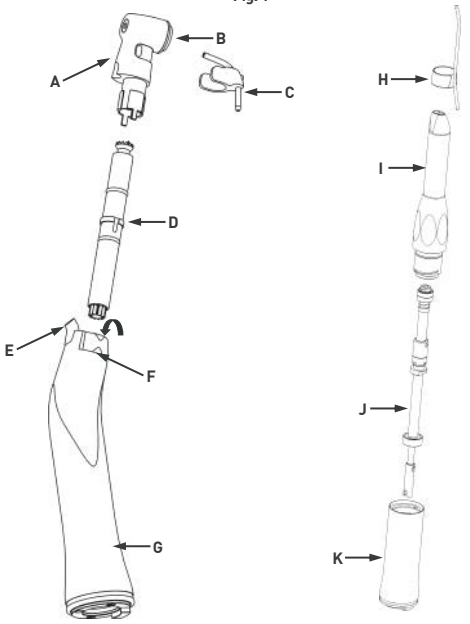


Fig. 2

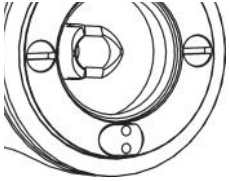


Fig. 3

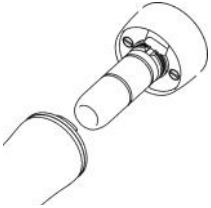


Fig. 4

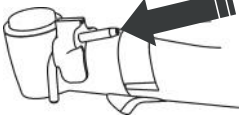


Fig. 5

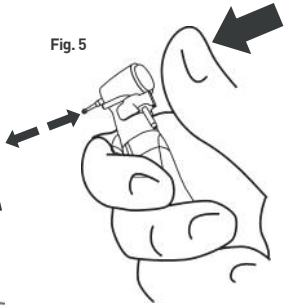


Fig. 6

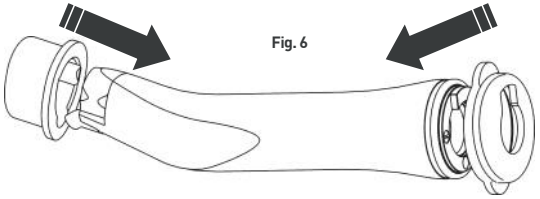


Fig. 7

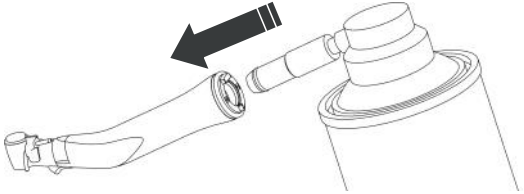


Fig. 8

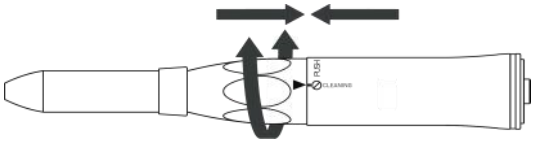


TABLE OF CONTENTS

I. DESCRIPTION OF SYMBOLS USED

DANGER !

Visual inspection

General information

Fibre optic device for motor with a light source

Non sterile device

Thermo-disinfectable

MD Medical device

Do not reuse.

LED Device with light emitting diode

135°C Sterilisable up to 135°C

Wear gloves

REF Device reference

SN Device serial number

Date of manufacture

Name of manufacturer

II.SCOPE OF USE

Surgical treatment for hard organic substances: apical resection, osteotomy, apical aeration, osteosynthesis, bone modelling, bone smoothing, wisdom teeth extraction, hemisection.

Inappropriate or indirect use could damage this device and be a risk to the user and third parties.

These **MDs** are for professional use only in the dental surgery field.
According to these instructions, the **MD** must only be used by a user with dental medicine experience, for the stated use, and in compliance with current guidelines regarding the prevention of accidents at work and work protection and the instructions in this leaflet. **MDs** must be prepared and maintained only by individuals who have been trained in preventing infections, auto-protection and patient protection.

According to these instructions, users must:
- Only use non-defective work instruments,
- Only use the **MD** in a unit that complies with the guidelines of the EN 60601 standard,
- Follow the correct use instructions,
- Protect oneself and patients and third parties against all dangers,
- Avoid all contamination by the product.

The following situations:
- Inappropriate use,
- Lack of maintenance,
- Use of removable accessories or parts not approved by Anthogyr,
- Using accessories from other devices on this **MD**,
- Change or addition to a **MD** not validated by Anthogyr.

Relieve Anthogyr of all guarantee obligations or other claims.

These **MDs** comply with the Community Directive 93/42/CEE as amended by the 2007/47/CEE directive.

III.GENERAL SAFETY INFORMATION

Prior to use, check that the device has not been damaged in any way and that no parts are missing.

Wear appropriate protection, especially gloves, a mask and glasses.

Do not use the **MD** and inform your distributor or Anthogyr After-Sales (AS) in the following situations:
- visible failure or damage,
- non-existent or insufficient irrigation (at least 50 ml/min, correctly tempered and oriented in an optimum manner),
- scratch or damage to the emitting side of the LED.

Risk of damage to the device and injury, wait until the motor has completely stopped to:
- connect/disconnect the **MD** from the motor,
- turn the assembly/disassembly system on,
- turn the locking/unlocking system for the rotary instrument on,
- handle the rotary instrument.

Assess the risk of septic substances penetrating tissue if used with a central air cooling motor (refer to the motor manufacturer's leaflet).

Risk of burning and injury:
- Apply pressure to the **MD** with a rotary instrument (refer to the manufacturer's instructions) without exceeding 2N (about 200g).

Risk of burning related to the LED overheating:
- Avoid all contact between the LED and soft tissue.

Risk of dazzle:
- Do not look at the light output directly (especially on the LED model).
- Do not point the beam directly at the eyes of the patient or third parties.

The lighting level can generally be adjusted in the dental unit.

Risk of electrical discharge due to **MD** being badly connected to an Anthogyr non-compatible system:
In the event of the **MD** being assembled and used in other manufacturer's treatment devices and installations, refer to "Protection against the risk of electrocution", "Leaking current" and "Non-earthing of use part" according to the IEC 60601-1 standard.

Do not use in explosive atmospheres.

A poorly maintened instrument may overheat and cause unusually severe burns.

IV.TECHNICAL CHARACTERISTICS

4.1 – Description of MD (Fig.1)

Contra-angle	
Code	**Name**
A	Head
B	Push button
C	Spraying nozzle
D	Collar cartridge
E	Fibre optic or LED outlet
F	Locking system
G	Body

Handpiece	
Code	**Name**
H	Spraying nozzle
I	Front part
J	Axle
K	Back part

4.2 - Characteristics of MDs

	Contra-angle			Handpiece	
Références	**12200X**	**12200XL**	**1200XLED**	**12400X**	**12400XLED**
Ratio	1:3			1:1	
Colour code	Orange			Blue	
Light	No	Yes (Fibre optic)	Yes (LED in the contra-angle)	No	Yes (LED in the handpiece)
Motor connection standard	ISO 3964	ISO 3964[1]	ISO 3964[2]	ISO 3964	ISO 3964[2]
Maximal speed of motor (rpm)	40 000				
Rotary instruments according to ISO 1797-1 **→ ø (mm)** **→ Lg max (mm)** **→ ø max in the active part (mm)**	Type 3 1,60 25[3] 2[3]			Type1 or 2 2,35 65[3] 10[3]	
Type of coupling (NF EN ISO 3964 :2016)	Type 1	Type 4		Type 1	Type 4
Coupling size (NF EN ISO 3964: 2016)	Long				
Spray water flow according to ISO 7785-2 (ml/min)	> 50				

S3 10% intermittent mode (1 min on / 9 min off). The authorised relative load duration is 1 minute per 9 minutes of pause.

V.INSTALLATION OF MD

The **MD** is supplied non-sterile.

Before first use, the **MD** must be cleaned, decontaminated and sterilised (see **§ VI**).

5.1 – Connection to the motor

Check that the **MD** is completely dry before connecting it to the motor.

Install the **MD** on the motor connection until ratcheting. For this, keep the motor and the **MD** in the same axle.

LED or : Turn the **MD** until the retractable catch lodges in the E notch of the motor (**Fig. 3**).

Apply light traction to the **MD** to check that it is properly attached to the motor connection. Operational test by switching on the motor; start at low speed, then gradually increase.

If you notice overheating, irregularities, vibrations, abnormal noises when using the **MD**, immediately contact your AS.

5.2 – Connection of the irrigation (Fig. 4)

Attach the spraying nozzle to the head of the **MD**.
Connect the extremity of the irrigation pipe to the nozzle entry.

5.3 – Disconnection of motor

Remove the **MD** by keeping it in the motor axle.
In the event of prolonged non use of the device, do not leave it connected to the motor. Risk of damaging the motor.

[1] : INTRAmatic LUX® connection system - Kavo® registered trademark

[2] : IMPLANTEO LED® Anthogyr connection system.

[3] : Indicative values. In the event of the use of longer or bigger rotary tools, the user is responsible for choosing the right operational conditions that avoids all risks to patients or third parties. Follow the instructions for use, in accordance with the tools manufacturer's instructions.

5.4 – Connection/disconnection of rotary instrument

For all handling of rotary instruments, wear protective gloves. Risk of cutting and contamination.

Only use rotary instruments in good condition. Risk of necrosis.

Insertion of rotary instrument

Contra-angle:
- Apply pressure using your thumb to the centre of the push button and simultaneously insert the rotary tool up to the stop in the claw of the **MD**.
- Release the thumb pressure on the push button (**Fig. 5**)

Handpiece:
- Bring the ▲ mark to the front of the ❍mark by turning the front part in relation to the back part
- Insert the rotary instrument up to the stop.
- Bring the ▲ mark to the front of mark ●.

For tool replacement: check the good condition of the rotary tool with light axial traction.

MD lifecycle

If used in a proper manner, all **MD** parts have a lifecycle corresponding to 250 sterilisation cycles.
However, these indications are not a warranty because wear may appear prematurely, depending on how the **MD** is maintained (cleaning and sterilisation).

VI.HYGIENE AND MAINTENANCE

Sterilisation of medical devices must be done by properly trained and protected staff, in compliance with current regulations. The sterilisation protocol must be appropriate to the infectious risk.

Wear appropriate protective clothing: risk of infection and injury.

Only use products for the maintenance of medico-surgical equipment compatible with stainless steel (no chlorinated content).
Forbid antiseptics that are intended for use on skin and mucous.
Forbid products containing aldehyde, alcohol or other products likely to bind proteins.

For each product used: refer to the manufacturer's instructions.
Comply with the concentrations, exposure durations, and life span of products. Do not mix the products and follow the instructions for their disposal.
After patient care, the **MD** should be processed within the next two hours.

6.1 – Preparation of MD in the place of use

To be done immediately after surgery:
- Disconnect the **MD** from the motor,
- Remove the rotary tool (see **§ 5.6**),
- Remove the largest organic contaminants with disinfectant wipes.

6.2 – Preparation for sterilisation

Disassembly of MD:
- Remove the rotary instrument,
- Disconnect the **MD** from the motor,
- Remove the rotary instrument and the spraying nozzle.

Contra-angle (Fig. 1):
- Pivot the F lever up to the stop (indifferently towards the right or towards the left),
- Pull the A head,
- Remove the collar cartridge D.

Handpiece (Fig. 1)
• Compress the handpiece (bring the front body towards the rear body) to allow rotation towards the disassembly position
• Bring the ▲ mark to the front of ⦸ mark,**(Fig. 8)**
• Remove the front I part, then the J axle by pulling axially.

6.2.1 – Manual preparation for sterilisation
Cleaning of irrigation pipe:
• Carefully clean the irrigation pipe and remove any impurities and deposits from it using the caustic cleaner spray.

⚠ • Risk of injury: use protective glasses.

By brushing:
Brush each part under running water with a soft brush.

LED Lighting lens (LED or Fibre optic):
• Absolutely avoid all scratches to the LED or the fibre optic.
• Wipe a disinfectant wipe over each of the **MD's** sub-units,
• Or Spray disinfectant on the **MD** and wipe with a clean cloth.

Or: by Ultrasound
• Use a low frequency ultrasound tank (25 to 50 kHz) and a detergent-disinfectant product compatible with this process and with the **MD**,
• Friction of parts between them or with the tank can cause appearance defects,
• Install light input/output protections on the body (**Fig. 6**) to protect the fronts of the fibre optic or the emitting surface of the LED,
• Immerse the components.

Rinsing and drying:
• Empty the spray pipe (**Fig. 4**).
• Rinse well[4],then dry each part.

6.2.2 - Automatic preparation for sterilisation
Only in a washing and disinfecting machine, appropriate for the treatment of this type of **MD**. Follow the manufacturer's instructions for the device.

• If the device is not equipped with pipes for contra angles / handpieces, then disassemble the **MD** (see **§ 5.2**) and immobilise each part. Otherwise, put the **MD** mounted on the pipe.
• The disinfection thermo cycle must be at least 10 minutes at 93°C (203°F).
• Check there is no residue and that all the parts of the **MD** are completely dry at the end of the cycle.
• If the washing and disinfecting machine is near the place of use, it is possible to also do step **6.1**.

Re-assembly of MD:
Only assemble parts with the same serial number[5].

Contra-angle:
• Attach the collar cartridge D to A head (only one direction possible) until it completely plates (turn the cog until connection if required),
• Insert the head – collar cartridge unit in the G sleeve (connect a clean tool in the head and turn it slightly so that the cog connects),
• Bring the F lever to the central position, until ratcheting.

Handpiece
• Insert the J axle in the back K part until ratcheting,
• Connect the front I part by cooperating ▲ and ⦸,
• Bring the ▲ mark to the front mark ↻ by compressing the handpiece.

⚠ Systematically check the condition of the front part by applying axial traction.

6.3 - Lubrication
⚠ Follow the spray lubricant manufacturer's instructions.

Wear appropriate protective clothing (splashes, etc.).

Keep away from all sources of heat or ignition.
In particular: do not smoke. Risk of inflammation.

After cleaning and before each sterilisation (once a day minimum):
• Remove the rotary instrument,
• Insert the tip to the back of the **MD** (**Fig. 7**),
• Cover the head of the **MD** with a soft cloth or paper or a wipe,
• Point the head towards the bottom,
• Spray several times by firmly holding the instrument,
• Wipe excess oil with a cloth or a wipe.

6.4 – Operational test
• Connect the **MD** to a micro-motor, point the head towards the bottom.
• Turn the micro-motor on at low speed for 30s. Gradually bring up to maximum speed.
• Wipe excess oil with a cloth or a wipe
If you notice overheating, irregularities, vibrations, abnormal noises when using the **MD**, immediately contact your AS.

6.5 - Sterilisation
• The instruments are to be sterilised before first use and after each use.
• Only sterilise cleaned, lubricated and tested instruments.
• We recommend sterilisation that complies with the EN 13060 standard, class B. All other methods are forbidden.
• Independently put each **MD** in a sterilisation sachet that complies with current standards and the size of the **MD**.
• Comply with the space between the sachets and do not overload the autoclave.

135°C • These **MDs** and their accessories (apart from accessories with the logo ⊗ which are single use) must be sterilised at 135°C for 18 minutes minimum (sterilisation time).
• Check that the device is completely dry at the end of the cycle.

6.6 - Storage
Keep the **MD** in a sterilisation sachet in a clean and dry place.

VII.REPAIR

In the event of breakdown, please contact your approved distributor or our after-sales department directly.

⚠ Repairs must only be carried out by an approved repairer or by Anthogyr After Sales Department, only with Anthogyr original replacement parts.

For all revisions or repairs, the **MD** must be returned complete and **sterile** with proof of sterility. It must be accompanied by a document outlining the problem and showing the complete contact details of the user.

The replacement of removable parts is covered for 7 years.

VIII.GUARANTEES

This **MD** is guaranteed parts and labour against all manufacturing defects for **12** months from the date of invoice. This guarantee does not apply to wear and tear parts and does not cover transport costs.
So that guarantee requests are taken into consideration, please attach a copy of the invoice or a copy of the delivery slip to the **MD**.
All changes or additions to the product without the express agreement of Anthogyr render this guarantee null and void.
The guarantee becomes null and void if the technical instructions are not followed.
Anthogyr cannot be held responsible for damage resulting from or which could

[4] : Temperature < 38°C, distilled water is recommended instead of running water if this has too much chlorine (cf. FD98-135 standard).

[5] : Exception : If the After-Sales Service has to replace a part, the serial number may be different.

result from normal wear, use, cleaning or incorrect maintenance, the non-observance of instructions for use or connection, scaling or corrosion, impurities in the water supply system or unusual chemical or electrical influences or non observance of the instructions, maintenance instructions and assembly of Anthogyr and other manufacturer's instructions.

IX.ACCESSORIES

To be ordered from your approved distributor.

Description	**Reference**
Sterilisable Spraying nozzle	12275
Sterilisable spraying nozzle for Surgery HP	12430
Protective caps for lighting system	10436
Spray caustic cleaner	9205

X.DISPOSAL

⚠ The **MD** must be sterilised before disposal. Risk of contamination of third parties.

Comply with legislation and national standards and guidelines for disposal.

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A Straumann Group Brand

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