

MONT BLANC®



IMPLANTOLOGY CONTRA-ANGLE 20:1

16400X - 16400XL

10400X - 10400XL - 10400XLED

10401X - 10401XL - 10401XLED

10403X

US - INSTRUCTIONS FOR USE

Anthogyr
PRIME MOVER IN IMPLANTOLOGY

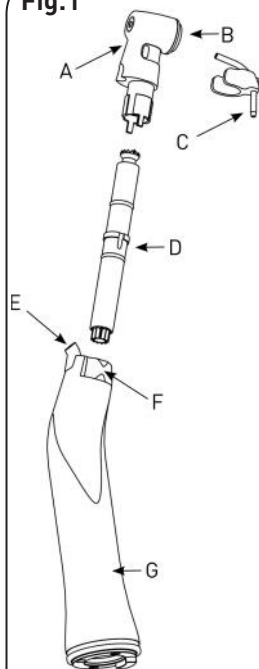
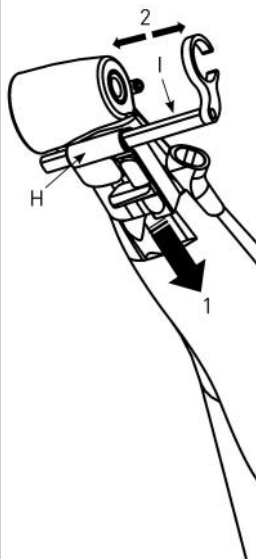
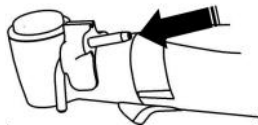
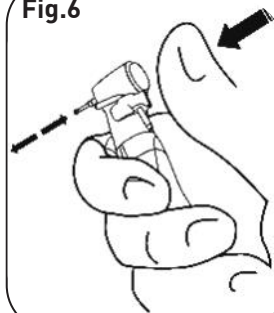
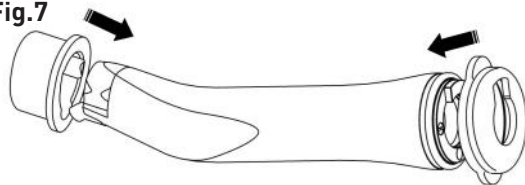
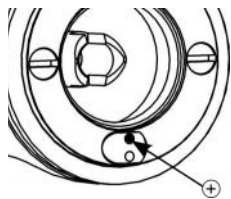
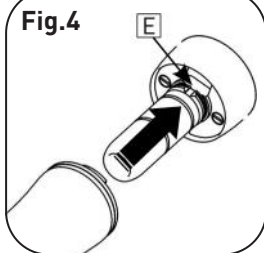
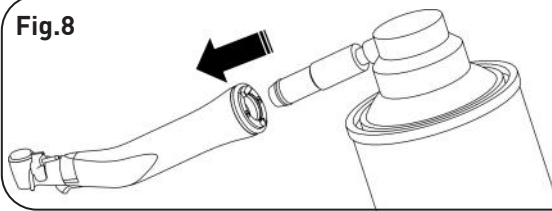
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I. MEANING OF SYMBOLS

	DANGER !		Sterilisable up to 135°C
	Visual inspection		Wear gloves
	General information		Device reference
	Fibre optic device for motor with a light source		Device serial number
	Single Use		Date of manufacture
	Non sterile device		Name of manufacturer
	Thermo-disinfectable		Medical device
	Device with light emitting diode		Do not throw in the domestic dustbin

II. INDICATIONS FOR USE

Anthogyr's fully autoclavable contra-angles Implantology « Mont Blanc » are devices intended for a wide range of dental procedures including : Implant surgery such as perforating the bone, tapping and threading procedures.

III. SCOPE OF USE

Surgical treatment for hard organic substances : drilling, tapping, screwing of dental implants, screwing of the prosthetic parts.

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, personal 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 an **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.

IV. 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).

Warning : this **MD** has a ball bearing system.

The power is maintained :

- For motors having a torque calibration system (like the IMPLANTEO®): you must calibrate the contra-angle as directed by the manufacturer. The motor must have been calibrated for the used contra-angle.
- For any other motors: make sure that the displayed torque values are right.

A tapping or a screwing torque which is too high (above 35N.cm) may increase risks of necrosis or of bone fissuring. Furthermore, the implant and the instrument may be damaged: implant manufacturer's prescriptions have to be respected.

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 another 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.

V. TECHNICAL CHARACTERISTICS

5.1 – Description of MD [Fig.1 and 2]

Code	Description
A	Head
B	Push button
C	Spraying nozzle
D	Collar cartridge
E	Fibre optic or LED outlet
F	Locking system
G	Body
H	Depth stop system
I	Depth stop

5.2 – Characteristics of MDs

References	10400X	10401X	10403X	16400X	10400XL	10401XL	16400XL	10400XLED	10401XLED	
Advertised reduction	20 :1									
Actual ratio	20 :1									
Colour code	green									
Weight [g]	90		80		96		86		96	
Total length (mm)	103		86		103		86		103	
Head height (mm)	12.9									
Light	No				Yes					
Type of light	/				Quartz bar				LED	
Adjustable depth top system	No	Yes	Yes	No	No	Yes	Yes	No	Yes	
Motor connection standard	Coupling		NF EN ISO 3964:2016							
			Long		Short		Long		Short	
	Type	1		4				4 ⁽¹⁾		
Maximal speed of motor [rpm]		40 000								
Maximum tool torque [Ncm]		80 ⁽²⁾								
Tool diameter (mm) and type according to NF EN ISO 1797-1		Ø2.35 — Type 1								
Maximum length recommended by Anthogyr (mm)		40 ⁽³⁾								
Maximum diameter of the active part of the tool recommended by Anthogyr (mm)		10 ⁽³⁾								
Irrigation system		External by clip + Internal by Kirschner-Meyer needle								
Spray water flow according to ISO 7785-2 (ml/min)		>50 ⁽⁴⁾								

¹: INTRAmatic LUX® connection system - Kav® registered trademark

²: IMPLANTEO LED® Anthogyr connection system.

³: The torque can be reached providing the motor used is powerful enough: for example, the Implanleo motor by Anthogyr. In general, it is possible to limit the motor torque on the operating unit.

⁴: Values obtained with at least 50% flow programmed on the IMPLANTEO LED® and XPERT UNIT® motors/operational

Recommended operation mode for LED models :

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

VI. INSTALLATION OF MD



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

Before first use, the **MD** must be cleaned, decontaminated and sterilized (see § VII)

6.1 – 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** on the same axle.



• Turn the **MD** until the retractable catch lodges in the E notch of the motor (**Fig 4**).

• 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.

6.2 – Connection of the irrigation (Fig. 5)

Attach the spraying nozzle to the head of the **MD**.

Connect the extremity of the irrigation pipe to the nozzle entry.

6.3 – 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.

6.4 – 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.

• As the maxi torque given by this **MD** is very high, this may damage the tool's driving part. In any case, the compatibility of your instruments has to be checked. Please follow the manufacturer's instructions and limit the torque of the unit if necessary. We strongly advise that you use instruments having a shaft made out of hardened steel.
• Check regularly that the push button is set properly by applying a slight unscrewing torque.

Insertion of rotary instrument

• 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 6**)



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

6.5 – Adjustment of the depth stop

It is imperative that the depth stop is adjusted outside of the patient's mouth.

To adjust the depth stop: move the sliding block backward (1) and move the stop to the required position (2). Loosen the sliding block.

• After each adjustment, check the stop has been correctly placed using the ruler.
• Before each use, exercise a slight traction on the stop in order to verify that it is correctly installed.

• Do not use the depth stop for tapping: the bone may be damaged in the event of late stop of the driving motor.

The specific depth stops marked AX may only be used for placing Axiom® implants with the Axiom® guided surgery. Verify the position of the depth stop properly in relation to the instrument reference lines.

MD lifecycle

If used in a proper manner, all MD parts have a lifecycle corresponding to 250 sterilization cycles.

However, these indications are not a warranty because wear may appear prematurely, depending on how the MD is maintained (cleaning and sterilization).

VII. HYGIENE AND MAINTENANCE

 Sterilization of medical devices must be done by properly trained and protected staff, in compliance with current regulations. The sterilization 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.

 Spraying nozzles Ref. 10476 (the green ones) cannot be sterilized: change them after each surgery.

After patient care, the MD should be processed within the next two hours.

7.1 – 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 § 6.6),
- Remove the largest organic contaminants with disinfectant wipes.
- If cleaning cannot be carried out quickly, then lubricate the MD in accordance with § 6.3.

7.2 – Reprocessing preparation

Disassembly of MD (Fig 1):

- Remove the rotary instrument,
- Disconnect the MD from the motor,
- Remove the rotary instrument and the spraying nozzle.
- 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.

7.2.1 – Manual reprocessing preparation

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 meticulously with a soft brush (example: nylon) under tap water at room temperature under there is no visible trace of contaminants.
- Completely submerge in a detergent and disinfectant solution following the manufacturer's instructions for time, temperature, and concentration⁵, in particular. (Possibly used ultrasound tank)

LED Lighting lens (LED or Fibre optic):

- Avoid scratching the LED or the optical fibre; to do this, clean each MD (Medical Device) sub-assembly with a disinfecting wipe.

-  • Friction of parts between them or with the tank can cause appearance defects,
- Install light input/output protections on the body (Fig 7) to protect the fronts of the fibre optic or the emitting surface of the LED,

Rinsing and drying:

- Empty the spray pipe (Fig 4).
- Rinse⁶ with purified water for at least one minute.
- Dry immediately, carefully, with a soft lint-free cloth.

7.2.2 - Automatic reprocessing preparation

-  • Only tools engraved with the thermal disinfection logo.
- 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 § 6.2) and immobilise each part. Otherwise, put the MD mounted on the pipe.
 - The thermal disinfection cycle

	Temperature	Duration	Cleaning agent	Detergent and concentration used by Anthogyr to approve protocol
Pre-wash	Cold water	4 min.	Water	Not applicable
Washing	55°C	5 min.	Enzymatic detergent	Neodisher Mediclean Dental (2mL/L)
Neutralization	55°C	3 min.	Neutralizer	Neodisher Z Dental (2mL/L)
Rinsing	40°C	2 min.	Water	Not applicable
Thermal disinfection	95°C	10 min.	Not applicable	Not applicable
Final rinsing	40°C	2 min	Rinsing liquid	Neodisher Mielclear (0.2mL/L)
Drying	140°C	10 min.	Not applicable	Not applicable

-  • 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 7.1.

Re-assembly of MD:

Only assemble parts with the same serial number⁷.

- 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),
- or
- Fit the neck cartridge D in holder G until fully inserted (turn the cartridge slightly to find the notches).
- Insert the head assembly on holder G with the neck cartridge in place (fit a clean tool in the head turn it slightly to engage the pinion).
- Bring the F lever to the central position, until ratcheting. Make sure that the depth stop system is in the right position.

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

⁵: Anthogyr used the following products and detergents to approve the various protocols: Cidegray (Johnson&Johnson) for 3 minutes at a concentration of 8mL/L. However, other products and detergents may be used according to local availability. Approval of these products is the responsibility of the user.

⁶: Temperature < 38°C, distilled water is recommended instead of running water if this has too much chlorine (cf. FD89-135 standard).

⁷: Exception: If the After-Sales Service has to replace a part, the serial number may be different.

7.3 - 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 sterilization (once a day minimum):

- Remove the rotary instrument.
- Insert the tip to the back of the **MD** (Fig 8).
- 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.

7.4 - 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.

7.5 - Sterilization

- The instruments are to be sterilized before first use and after each use.
- Only sterilize cleaned, lubricated and tested instruments.
- Independently put each **MD** in a sterilization bag that complies with current standards and the size of the **MD**.
- Comply with the space between the bags and do not overload the autoclave.



• These **MDs** and their accessories (apart from the accessories marked with the  logo which are for single use) can be sterilised at 132°C for 3 minutes (time of sterilisation). The drying time is 10 minutes. The single-use sprayer clips (green) must not be sterilised.



• Check that the device is completely dry at the end of the cycle.



Other products and detergents may be used according to local availability.
Approval of these products is the responsibility of the user.

7.6 - Storage



Keep the **MD** in a sterilization bag in a clean and dry place.

VIII.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.

IX.GUARANTEES

This **MD** is guaranteed for parts and labour against all manufacturing defects for 12 months from the date of invoice. This guarantee does not apply to wear.

All changes or additions to the product without the expressed 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 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.

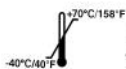
Delivery charges incurred when sending an instrument back to Anthogyr for repair will be paid by the client, even if the repair itself is covered by the guarantee. Postage and packing fees when returning the instrument to the client are covered by the guarantee.

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**.

X.ACCESSORIES

Description	Reference	10400X 16400X	10400XL 10400XLED 16400XL	10401X 10403X	10401XL 10401XLED
Sterilisable Spraying nozzle	10475	X	X	X	X
Pack of 10 single use spraying nozzles	10476D	X	X	X	X
Sterilisable coupling	10420	X	X	X	X
Needle for internal spray	10430	X	X	X	X
Clip for irrigation line	2044	X	X	X	X
Depth stop holder + depth stop	10415			X	X
Depth stop for Axiom® guided surgery	10418_SAFE			X	X
Ruler	6458			X	X
Protective caps for lighting system	10436		X		X
Spray caustic cleaner	9205	X	X	X	X
Silicone tube Ø1 x Ø3	6309M	X	X	X	X

XI.CONDITIONS OF STORAGE AND TRANSPORT



XII.DISPOSAL

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

Comply with legislation and national standards and guidelines for disposal.



For the LED models:

As regards electric or electronic equipment, product disposal must be processed via a specialised collection, removal and recycling or destruction (particularly on the European market, with reference to Directive No. 2002/96/EC of 23/01/2003). When the product has reached end-of-cycle, we recommend you contact your dental supply retailer, and inquire on the course of action.



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