

MONT BLANC®



CONTRA ANGLE FOR GENERAL DENTISTRY


EN - INSTRUCTIONS FOR USE

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I. DESCRIPTION OF SYMBOLS USED

 **WARNING** : important Information !

 Please wear gloves

 General indications with no danger to people or objects


 Please read this!


 Visual Examination

 Autoclave at 135°C

 Disinfectable by heat

 **NON STERILE**

 Contra-angle connectable to light motor

 Water + air spray

 **REF** Reference


 **SN** Serial number

 Manufacturer

 **Rx** Device Prescription


II. AREA OF APPLICATION

The contra-angles are intended for dental care (enamel work, removal of caries, preparation of cavities and crowns, removal of fillings, finishing and polishing dental and restoration surfaces). Any other form of use is forbidden and can cause danger. For this contra-angle, we applied Community Directive 93/42/EEC, transposed by the French regulations on medical equipment (Official Bulletin - L169 - 12 July 1993), as amended by the 2007/47/CEE directive.


 In accordance with these provisions, the contra-angle must only be used by someone with experience of dental medicine for the application described, and in compliance with the provisions in effect in relation to the prevention of accidents at work, protection of employment and the instructions for use. This medical device must be prepared and maintained only by people trained in the prevention of infection, self-protection and protection of patients.

In accordance with these provisions, the user must :


- only use working instruments without defects,
- only use the contra-angle on drive units which comply with the directives of Standard EN 60 601,
- observe correct use,
- protect themselves and the patient or third party against any danger,
- prevent all contamination by the product.


 Pressure must be adapted to the rotary instrument (refer to the manufacturer of rotary instruments). We recommend an effort <2N for all speeds above 40000 rpm.


III. GENERAL SAFETY INFORMATION


 Before use, check that the contra-angle is not damaged and that no part is missing. When inserting or changing the rotary instrument, make sure that the contra-angle is stationary. After insertion of a rotary instrument, check that it is correctly held by a slight rotary movement. Do not handle the rotary instrument during operation.

Only operate the locking system when the motor is stopped. The push button must never be used while the device is rotating to avoid dangerous overheating, which can cause severe burns. The soft tissues (lips, gums, cheeks, tongue, etc.) must be protected either by interposing a barrier between the medical device and the soft tissues or by lifting the soft tissues with a spacer or dental mirror. Pressing the push button during the operation of the instrument may cause the rotor to heat and the loss of the rotary instrument. In order to cool the treatment area, only an adapted and correctly tempered cooling spray should be used.

 Ensure that the spray is always sufficient and regular (if not there is a risk to the health of the tooth and the adjacent tissue). If there is no irrigation, the contra-angle must be taken out of use immediately.

 To prevent glare, avoid directing the beam of light (fibre optic) toward the eyes. If the nozzles are clogged in spite of cleaning, do not operate the contra-angle and contact the after-sales service department.

 In the event of visible malfunction or damage, immediately stop using the instrument and inform your approved distributor or the manufacturer.

 In the event of any questions on the equipment, contact either your approved distributor or the manufacturer. A poorly maintained instrument may overheat and cause unusually severe burns

IV. TECHNICAL CHARACTERISTICS

	10000XL	10000X	10200XL	10200X	10300XL	10300X
Rate of reduction / multiplication	1 : 5	1 : 5	1 : 1	1 : 1	5 : 1	5 : 1
Color code	Red	Red	Blue	Blue	Green	Green
Weight [g]	67	67	67	67	67	67
Light	Yes	No	Yes	No	Yes	No
Motor connection standard	ISO 3964					
Maximum motor speed [rpm]	40 000					
Tool type according to NF EN ISO 1797-1	Type 3	Type 3	Type 1	Type 1	Type 1	Type 1
Diameter of tools [mm] according to NF EN ISO 1797-1	1.6	1.6	2.35	2.35	2.35	2.35
Maximum total length of the tool recommended by Anthogyr lmm	25*	25*	34*	34*	34*	34*
Maximum diameter of the active part of the tool recommended by Anthogyr (mm)	2*	2*	25*	25*	25*	25*
Water spray output [ml/min]	>50					
Recommended water pressure [bar]	2					
Recommended air pressure [bar]	2					
Air motor cooling [N/min]	1.5-10					
Coupling size [NF EN ISO 3964: 2016]	Long					
Type of coupling [NF EN ISO 3964: 2016]	Type 3	Type 2	Type 3	Type 2	Type 3	Type 2

*Approximate values

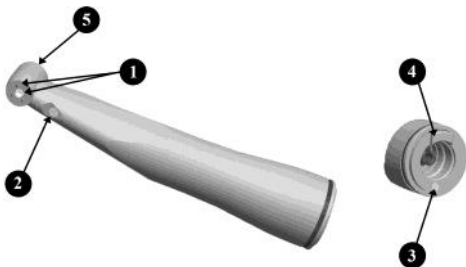
In the event of the use of rotational instruments which are longer and larger in diameter, the user is responsible for the appropriate choice of operating conditions

which will prevent any risk to the patient or to another person. The guidelines of use should be followed, in accordance with the instructions of the tool manufacturer. (Type 1 and Type3).

If maximum permitted rotation speed is exceeded, long thin instruments are subjected to tip vibrations which may result in fracture of the rotary instrument. Excessively high rotation speeds may cause high centrifugal forces and a risk of the instruments kinking or breaking. (The larger the diameter of the working part, the weaker the rotation speed).

The contra-angle with fibre optics operates on motors with **INTRAmatic LUX®** coupling. **INTRAmatic LUX®** is a registered trademark of Kavo®.

V. PRODUCT DESCRIPTION





- ① Spray nozzles
- ② Light output*
- ③ Light input*
- ④ Light indexation pin*
- ⑤ Push button

*only on the light contra-angles


VI. USING THE CONTRA-ANGLE

GENERAL RULES

 The contra-angle is supplied unlubricated and unsterilised. Before first use, the contra-angle must be lubricated and sterilised. [See "Hygiene and maintenance" §.].


 Before use, check that the contra-angle is not damaged and no part is missing. It is also important to operate the contra-angle slowly and increase the speed gradually.

For sprays:

-  • Ensure that the spray is always sufficient and regular (failure to do so creates risk for the viability of the tooth and neighbouring tissue).
- To cool the treatment area, only an appropriate correct temperature cooling spray must be used.
- If irrigation stops, the contra-angle must immediately be removed from use, failure to do so creates risk of burning for the practitioner and patient.
- If the nozzles are blocked despite cleaning, the contra-angle must not be used. Refer to the After-Sales Department.

- To avoid heating during preparation, sufficient cooling with the spray must be ensured (minimum 50 ml / min).


- 1:1 and 5:1 contra-angles can be used for some applications without using the spray. The practitioner alone, however, is responsible for this use and for any heating which may result.

 The contra-angle is to be used only with a motor equipped with ISO standard coupling and a cooling air output.

6.1. Connecting to the motor



 Contra-angle connectable onto light motor.

 **WARNING** : the contra-angle should only be connected to the motor when the motor is stationary.


- Lock the contra-angle on the motor coupling. Keep the motor and the contra-angle on the same axis. For certain motors, it is necessary to engage the side button to make the connection.


- Pull the contra-angle lightly before each use in order to check that it is correctly clipped to the motor coupling.


- For contra-angles with a light connection, keep the motor and the contra-angle on the same axis, direct the contra-angle tongue to face the rectangular hole of the motor and click in the contra-angle.




Operating test

 • Operate the motor and the spray and check that the motor / contra-angle connection is watertight.


 During the test, never start at maximum speed; increase progressively from minimum speed to maximum speed in order to prevent possible deposits of oil and possible overheating of the contra-angle.

 **NOTE** : if you notice heating, irregularities, vibrations or abnormal sounds during the operation of the contra-angle, immediately contact your approved technical department.


Disconnecting from the motor

 **WARNING** : the contra-angle must only be disconnected with the motor switched off.


Remove the contra-angle, keeping it along the axis of the motor. For some motors the side button needs to be engaged in order to be able to disconnect the contra-angle.

 **NOTE** : in the event of prolonged non-use of the contra-angle, do not leave it connected to the motor in order to avoid oil leakage into the motor.

6.2. Connection/disconnection of the rotating instrument

 The use of protective gloves is recommended each time the tools are handled. Check the condition of the rotating instruments to be used, and handle them properly and carefully.

It is essential that the motor is stopped before the instrument is inserted or removed.

 **NOTE** : Inspect the push button regularly to ensure that it is properly fixed. Insertion and tightening of the rotating instrument.



> **Insertion of a type 1 rotating instrument (contra-angle 1:1 and 5:1)**

- Apply pressure with the thumb to the center of the push button.
- Put the instrument into position by turning it slightly in both directions, until it engages, then release the push button.
- Check that the rotating instrument is properly attached, through a slight axial movement with

each tool change.

> **Insertion of a type 3 rotating instrument (contra-angle: 1:5)**

- Apply pressure with the thumb to the center of the push button.
- At the same time, insert the rotating instrument into the clamp as far as it will go.
- Release the pressure on the push button.
- Check that the rotating instrument is properly attached, through a slight axial movement with each tool change.

> **Removal of a type 1 or 3 rotating instrument**



- Apply pressure with the thumb to the center of the push button.
- At the same time, remove the rotating instrument.

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).

VII. HYGIENE AND MAINTENANCE

GENERAL RULES

- Refer to the manufacturer's instructions for each product used. Take particular care to adhere to the instructions regarding concentrations, lengths of exposure, the replacement of solutions, and the lifespan of the products.
- Only use products intended for the maintenance of medical and surgical equipment.
- Do not use antiseptics which are designed to be used on the skin and mucous membranes. Use only products which are pH neutral or alkaline (between 2.5 and 9.0 inclusive). Do not use products containing Aldehydes, alcohol or other products liable to set proteins.
- Use only products compatible with stainless steel (chlorine-free ingredients).
- Wear suitable protective clothing. In order to avoid any risk of infection and injury, it is vital to wear protective gloves. Furthermore, the motor must always be stopped before handling the equipment.



• Never immerse the contra-angle in any kind of solution. Never clean the contra-angle in an ultrasonic tank. The motor must always be disconnected or stopped before handling the equipment in any way.

• Sterilisation of reused medical appliances has to be done by someone who has been trained and is protected, and the regulations in force have to be adhered to. The sterilisation protocol must be adapted to the infectious risk.

- Never combine products. Adhere to the guidelines regarding the disposal of used products.



7.1. Preparation in premises where used

The device must be cleaned immediately after the procedure. The contra-angle must be removed from the motor. (see §6.1)

The rotary instrument must be removed from the contra-angle. (see § 6.2).

7.2. Decontamination

7.2.1. Manual cleaning



• The contra-angle can be cleaned either by meticulous scrubbing under running water and then by steaming or by using wipes treated with microbiologically tested detergent/disinfectant products (pH between 2.5 and 9).

- Regardless of the type of product used, observe the treatment time of the disinfectant product used.
- Do not use alkaline or chlorine-based disinfectant products.
- Do not immerse the contra-angles in disinfecting baths or in an ultrasound basin.
- Do not scratch the surface of the optical fiber, as there is a risk that this may alter the transmission of light.

7.2.2. Cleaning in machine

- Pre-wash with water.

• Wash with a substance at pH approximately 9 (weak alkaline), concentration 0.5% at 45°C for 5 minutes.



• Follow the thermal disinfector manufacturer's instructions for use, in particular the recommendations regarding products which may or may not be used with the device.

- Do not immerse the contra-angles.

7.2.3 Cleaning the sprays

In the event of an absence of liquid, the contra-angle must immediately be taken out of use.

- Clean the spray nozzles carefully, using the metallic wire ref. no. 9205, in order to remove dirt and residue.
- If the nozzles are blocked, please contact the After-Sales Department.



WARNING : Risk of injury from the metal wire (9205). Wear protective gloves and eyeprotection.

In order to avoid any stagnation of the water in the shaft of the contra-angle, we recommend that you blow air into the cooling liquid shaft. To do this, use one of the substances available to disinfect spray channels. Wear eyeprotection and a face mask.

7.2.4 Cleaning the fiber optics



Do not scratch the surface of the fiber optics, as there is a risk that this may alter the transmission of light.

7.3. Rinsing



Rinse the device in demineralised water.

7.4. Heat disinfection : heat disinfecter

• Heat disinfecter equipped with nozzles for contra-angles :
Engage contra-angle: in the heat disinfecter nozzle.

• Heat disinfecter not equipped with nozzles for contra-angles:



Place it in the heat disinfecter, head pointing upwards.
Direct the parts to avoid any retention of fluid. Immobilise each part.

• The heat disinfection cycle used is 10 minutes at 93°C [203°F].



• Follow the manufacturer's instructions for the heat disinfecter, and in particular recommendations about the substances which should be used or not used with the instrument.

• Respect the drying cycle (WARNING : do not exceed 140°C [284°F] during the drying cycle).

Drying

Dry carefully with sterile, soft fluffless wipes, possibly combined with medical quality pressurised air. Confirm that cleaning has removed all visible soiling, if not clean, repeat the cleaning procedure. Before continuing to prepare the contra-angle, confirm that it is completely dry.

7.5. Maintenance

7.5.1. Lubrication

Lubricate before initial use.

Always lubricate after each decontamination and before each sterilisation.



Keep away from any source of heat or ignition. In particular, do not smoke ! Wear a protective face mask. Remove the rotating instrument. [See §6.2] Insert the spray can into the rear of the contra-angle. Make sure that the nozzle of the can is the correct one to use on contra-angles. Cover the head of the contra-angle with a wipe. Point the head of the contra-angle downwards. Spray several times, holding the contra-angle firmly until the liquid coming out becomes clear. Wipe off the

excess oil with a soft cloth or wipe.



Operate the contra-angle slowly in order to get rid of the excess oil and avoid a build-up of oil which could damage the contra-angle.

Repeat these steps every 15 minutes for operations lasting a long time.

7.5.2. Operational test



This test must be performed prior to each sterilisation.

Connect the contra-angle to the motor ; point the head of the contra-angle downwards.

Operate the contra-angle slowly for 30 seconds in order to get rid of the excess oil, then at full speed for 30 seconds. Wipe the contra-angle with a disinfectant wipe if the oil has dripped.

NOTE : if you notice a rise in temperature, irregularities, vibrations, or abnormal noises during operation of the contra-angle, contact your approved technical service immediately.

7.6. Sterilisation



• The contra-angles should be sterilised before they are first used and following each use.

• The device should be sterilised at 135°C at 2.13 bars [275°F at 30.88 psi], in a steam steriliser only, for a minimum duration of 20 minutes [time for which sterilisation must be continued].

• We strongly recommend the use of an autoclave with pre-vacuum cycle.

• Any other method of sterilisation should be avoided.

• Read the instruction leaflet provided by the steriliser manufacturer.

• Remove the rotating instrument from the contra-angle prior to sterilisation. [See §6.2]

• Only sterilise instruments which have previously been disinfected, cleaned, lubricated and tested.

• Use sterilisation pouches suitable for the contra-angle and the steriliser, in accordance with the standard NF EN 868. Always use one single contra-angle per pouch.

• Adhere to the space specified between pouches and do not overload the steriliser.

• Make sure that the device does not have any areas of corrosion or cracks, and check that it is operating properly. Ensure that the product is dry ; if necessary, dry any residual water with medical quality pressurised air.

• After each sterilisation cycle, check that there is no water remaining on the inside and outside of the packaging. Make sure that the flow indicator has changed to the correct color.

• In order to avoid any retention of water, place the pouch in the steriliser in such a way that any concave parts are face down.

• Keep the devices in the sterilisation pouches away from light, moisture and any contamination. Follow the manufacturer's recommendations as seen on the packaging.

• The duration for which the device is kept after sterilisation should not exceed 1 month. Label the devices, specifying the expiration date.

After the expiration date, repeat the cleaning and sterilisation procedure.

VIII. REPAIR



These contra-angles can only be disassembled by people accredited to undertake repairs and by people authorized by the company's After-Sales Department.

Any attempt to disassemble or reassemble may result in damage to the contra-angles.

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



All repairs must be carried out with parts and subassemblies approved by the manufacturer.

For any revision or repair the instrument must be returned complete and sterile with proof of sterility. It must be sent together with a document stating the problem as well as the complete name and address of the dentist.

The equipment must be returned in a sterile condition to the after sales service department. For any claims to be considered under the warranty, please enclose a copy of the invoice or the delivery note with the equipment.

For every service or repair, send the complete contra-angle.

Replacement parts are available for 7 years beyond sales discontinuation.

AFTER-SALES DEPARTEMENT CONTACT DETAILS

Services S.A.V.
ANTHOGYR
2237, Avenue André Lasquin - 74700 Sallanches - FRANCE
Direct line: +33 (0)4 50 58 50 53
Mail : sav@anthogyr.com

IX. ACCESSORIES



To be ordered from your approved distributor.

Description

Metal wire DCB

Reference

9205

X. WARRANTY

This **MD** is guaranteed parts and labour against all manufacturing defects for 24 months from the date of invoice. This guarantee does not apply to wear.

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 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**.

XI. CONDITIONS OF STORAGE & TRANSPORT



XII. DISPOSAL OF THE PRODUCT

As far as is currently known, the product does not contain any substances which are harmful to the environment. The product must be sterilised before being disposed of. Observe national rules with regard to disposal.



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