

MiCRO NiTi[®] NiTi CONTROL[®]



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10608	...
10608MBP	...
10616	...
10616MBP	...
10632	...
10632MBP	...
10664	...
10664MBP	...
10628	10664MBP-DA
10628MBP	10628MBP-DA

US - INSTRUCTIONS FOR USE

Anthogyr
A Straumann Group Brand

Fig 1

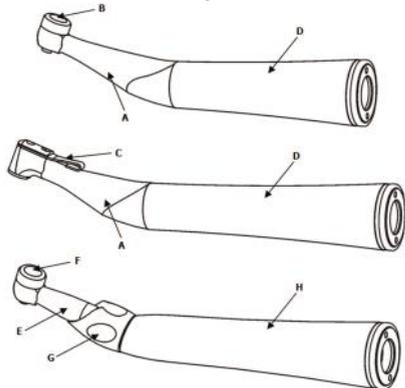


Fig 2

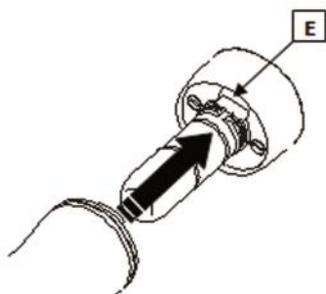


Fig 3

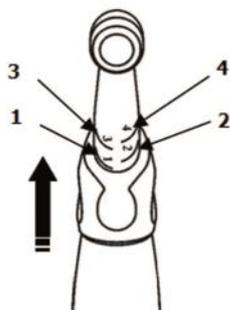


Fig 4



Fig 5

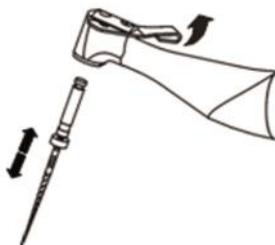


Fig 6

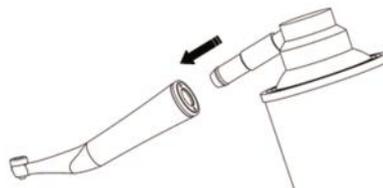


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I. MEANING OF SYMBOLS

	DANGER!		Wear gloves
	Visual inspection		Device reference
	General information		Device serial number
	Non sterile device		Date of manufacture
	Sterilizable up to 135°C		Nom of manufacturer
	Thermo-disinfectable	MD	Medical device (Contra-angle, hand piece, etc.)

II. INDICATIONS FOR USE

Anthogyr's fully autoclavable contra-angles and handpieces are devices intended for a wide range of dental procedures including Endodontic surgeries, such as root canal preparations.

III. SCOPE OF USE

Dental care in the field of endontology (for cleaning, preparation and obturation of the root canal).

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.

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.

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 locking/unlocking system for the rotary instrument on,
- handle the rotary instrument.

Risk of burning and injury:

- Apply pressure to the **MD** with a rotary instrument (refer to the manufacturer's instructions).

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.

V. TECHNICAL CHARACTERISTICS

5.1 - Description of MD [Fig. 1]

MiCRO NITI		NITI CONTROL [®]	
Code	Name	Code	Name
A	Head	E	Head
B	Push button	F	Push button
C	Latch	G	Torque adjusting ting
D	Body	H	Body

5.2 - Characteristics of MDs

References	MiCRO NITI		NITI CONTROL [®]		Colour code	Light	Motor connection standard	Maximal speed of motor	Rotary instruments according to EN ISO 1797-1	Rotary instruments according to EN ISO 3630-1	MAX motor speed when tool at 300 rpm (rpm)	MAX motor speed when tool at 600 rpm (rpm)	Coupling size (NF EN ISO 3944:2016)	Type of coupling (NF EN ISO 3944:2016)				
	10616 10408MBP	10616 10616MBP	10632 10632MBP	10644 10644MBP											10628 10628MBP	10628 10628MBP	10628 10628MBP	
	8-1	16-1	32-1	64-1	128-1	Green	No	150 3964	40 000 rpm	Ø 2.35 mm	instruments for root canals							
											2500	5000	10000	20000	40000	20000	40000	40000
											5000	10000	20000	40000	40000	40000	40000	40000
														Long				Type 1

VI. INSTALLATION OF MD

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

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

¹ - 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.

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** in the same axle. The motor must be at a complete standstill.

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, outside of the patient's mouth.

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

6.2 – Adjusting the declutching ring [Fig. 3]

The torque control system cannot in any way be a substitute for the practitioner's assessment and experience.

Increasing the declutching threshold :

- Push ring G towards Head E on the **MD**, notch by notch, until the right position is reached.

Decreasing the declutching threshold :

- Pull ring G towards the body H on the **MD**, notch by notch, until the right position is reached.

To adjust the declutching threshold (position 1, 2, 3, 4), start by setting it at its minimum torque (position 1).

If the **MD** keeps declutching, move up to a higher torque (Positions 2 to 4).

When the radicular instrument stops, a slight clicking sound may be heard; in that case, lower the pressure on the **MD**.

In the event that the instrument becomes wedged in the root canal, reverse direction of the motor rotation.

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. The tool must only be handled when the motor is at a standstill.

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

Insertion of rotary instrument

Contra angle with push button :

- Insert the rotary instrument into the head of the **MD** until it hits the stop.
- Turn the rotary instrument whilst maintaining a slight axial pressure until it clicks (Fig. 4).

Contra angle with latch :

- Open the latch.
- Insert the rotary instrument into the head of the **MD** until it hits the stop.
- Turn the rotary instrument whilst maintaining a slight axial pressure until it reaches the running slot on the drive plate.
- Lock the latch (Fig. 5).

 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 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 aluminium. Detergents and alkaline type solutions (pH > 7) damage aluminium based instruments. 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.

7.1 – Preparation of MD in the place of use

To be done immediately after surgery (maximum time of 2 hrs):

- Disconnect the **MD** from the motor,
- Remove the rotary tool (see § 6.6),
- Remove the largest organic contaminants with disinfectant wipes.

7.2 – Preparation for sterilization

- Disconnect the **MD** from the motor,
- Remove the rotary instrument.

7.2.1 – Manual preparation for sterilization

By brushing:

- Brush each part under running water with a soft brush.
- Wipe a disinfectant wipe over each of the **MD**'s subunits,
- Or Spray disinfectant on the **MD** and wipe with a clean cloth.

Rinsing and drying:

- Rinse well², then dry each part.

7.2.2 – Automatic preparation for sterilization

- Only in a washing and disinfecting machine, appropriate for the treatment of this type of **MD**. Follow the manufacturer's instructions for the device.
- Place the assembled **MD** on the nozzle for **MD**.
- 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 7.1.

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 6),
- 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 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.

²: Temperature < 38°C, distilled water is recommended instead of running water if this has too much chlorine (cf. FD78-135 standard).

- These **MDs** and their accessories (apart from accessories with the logo  which are single use) must be sterilized at 135°C [275°F] for 3 minutes minimum (sterilization time) with drying time of 16 minutes.



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

7.6 - Storage



Keep the **MD** in a sterilization sachet 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 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.
- 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**.

X. DISPOSAL



The **MD** must be sterilized before disposal.

Risk of contamination of third parties.

Comply with legislation and national standards and guidelines for disposal.



Anthogyr

2237 avenue André Lasquin
74700 SALLANCHES - FRANCE

Tél. +33 (0) 4 50 58 02 37

Fax +33 (0) 4 50 93 78 60

N°SAV / Repairs :

+33 (0) 4 50 58 50 53

E-mail : contact@anthogyr.com

www.anthogyr.com

CE 0459