



FR - CLÉ À CLIQUET DE CHIRURGIE
EN - SURGICAL RATCHET WRENCH
DE - CHIRURGISCHE RATSCH
ES - LLAVE DE CARRACA QUIRÚRGICA
IT - CHIAVE A CRICCHETTO CHIRURGICAL
PT - CHAVE DE CATRACA CIRURGIA
NL - OMKEERBARE RATELHENDEL

FR - NOTICE D'INSTRUCTION
EN - INSTRUCTIONS FOR USE
US - INSTRUCTIONS FOR USE
DE - GEBRAUCHSANWEISUNG
ES - INSTRUCCIONES DE USO
IT - FOGLIO D'ISTRUZIONI
PT - INSTRUÇÕES DE USO
NL - INSTRUCTIES VOOR GEBRUIK

Anthogyr
A Straumann Group Brand



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I. DESCRIPTION OF SYMBOLS USED



WARNING:
Important information !



General indications with no
danger to people or objects



Please wear gloves



Please read this !



Visual examination



Medical device



Name of manufacturer



Thermo-disinfectable



medical device complying
with European Directive
93/42/CEE



Sterilisable up to 135°C



Single Use

II. AREA OF APPLICATION

The prosthetic wrench (**MD**) is intended for dental applications in the fields of surgery and implant prosthetics. The INCC ratchet wrench is used for the rotation of tools with a “wrench” type connection and to apply the torques required for the execution of clinical procedures. Any form of incorrect use is prohibited and may be dangerous.

For this **MD**, we applied Community Directive 93/42/CEE (amended 2007/47), transposed by the French regulations on medical equipment (Official Bulletin - L169 – July 12, 1993).

The **MD** must be used by someone with experience of dental medicine, especially in implantology and in prosthesis on implants, 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.

In accordance with these provisions, the user must:



- only use working instruments without defects,
- observe the principle of correct use,
- protect themselves and the patient or third party against any danger,
- prevent any contamination by the product.

III. GENERAL SAFETY INFORMATION

Before use, check that the **MD** is not damaged and that no part is missing.



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.

Before using the prosthetic dynamometrical wrench, we strongly advise to test it outside of the patient's mouth.



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



In the event of any questions about the equipment, contact either approved distributor or the manufacturer.

IV. TECHNICAL SPECIFICATIONS

Reference	INCC
Weight (g)	15
Energy	Manual



The INCC ratchet wrench is for use with Anthogyr instruments only.

V. USING THE MD

The **MD** is supplied non-sterile. Before first using it, this **MD** must be decontaminated and sterilized (see § « Hygiene and maintenance »).

Before use, check that the **MD** is not damaged or that no part is missing.

5.1. Connecting / Disconnecting the instrument:

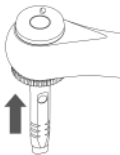


It is preferable to wear protective gloves for all tool handling.

Check the condition of the rotary instruments used and handle them cautiously and carefully.

5.2. Inserting and locking the rotary instrument:

- Insert the rotary instrument and turn it slightly until hearing a clicking sound and that the ratchet takes place in the groove.
- Check that the rotary instrument is correctly held with a slight axial movement each time the tool is changed.



5.3. Removing the rotary instrument:

Remove the instrument by pulling it out.

MD lifecycle:

If used in a proper manner, all **MD** parts have a two-year 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:

Remove the largest organic contaminants with disinfectant wipes.

6.2 – Reprocessing preparation

Disassembling the MD:

Disassemble the **MD** as described below:



Unscrew the head (1) and remove it from the main body (2).



Remove the set «ratchet (3) + rod (4)» from the body, by pushing slightly against each other the back wheel of the rod (4) and the ratchet (3) while simultaneously rotating the ratchet (3) ¼ turn anticlockwise in order to unlock the bayonet.



6.2.1 – Manual reprocessing preparation

- Brush thoroughly with a soft brush (such as nylon) under running tap water, at room temperature for 3 minutes. Use a smaller brush for hard-to-reach areas.
- Immerse it completely in 8mL/L Cidezyme solution, incubated at 38-40°C for 3 minutes.
- Rinse with purified water for at least one minute.
- Rinse again with purified water while brushing with a clean soft brush (such as nylon) for 1 minute.
- Dry immediately and carefully, with a soft lint-free cloth.

6.2.2– Automatic reprocessing preparation



The INCC ratchet wrench is designed to withstand thermal disinfection cleaning.

- 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	Néodisher Mediclean Dental (2mL/L)
Neutralization	55°C	3 min.	Neutralizer	Neodisher Z Dental (1mL/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.

Re-assembling the MD:

Repeat the disassembling operation above in reverse order.

Insert the set «rod (4) + spring (5)» through the back part of the body (2).

Fit the loose spring (6) around the rod (4) through the front part of the body (2).

Assemble the ratchet (3) by pushing it onto the rod (4) and rotating it ¼ turn clockwise to lock the bayonet.

Screw the head (1) onto the body (2).

6.3 Sterilisation:

- The instruments are to be sterilised before first use and after each use.
- Only sterilise cleaned, lubricated and tested instruments.
- Anthogyr recommends class B autoclave sterilisation according to standard EN 13060 for all devices bearing the logo



- 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.

- Run a sterilisation cycle according to the following parameters:

Country	Sterilisation parameters	Drying time
European Union	135°C (-1°C / +2°C) for 3 minutes	10 minutes
France	135°C (-1°C / +2°C) for 18 minutes	10 minutes
United States	132°C (0°C / +3°C) (270°F) for 3 minutes	16 minutes

- Allow to cool to room temperature for around 10 minutes.
- Indicate the sterilisation date and the expiration date on the package in accordance with the data from the package manufacturer (maximum 1 month).



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.

VII. REPAIRS

In the case of device failure, please contact your authorised distributor, or contact our after-sales service department directly.

Repairs may only be carried out by an authorised repair service or by the Anthogyr after-sales service department, and only using original Anthogyr replacement parts.

For any servicing or repair work, the prosthetic wrench must be returned complete and **sterile** with proof of sterility. It must be accompanied by a document that describes the problem in question and also includes the complete contact details of the practitioner who used the device.

Exchange of replacement parts is possible for 7 years after sales discontinuation.

CONTACT DETAILS: AFTER-SALES SERVICE

AFTER-SALES SERVICE DEPARTMENT

Anthogyr

2237 Avenue André Lasquin - 74700 Sallanches - FRANCE

Direct line: +33 (0)4 50 58 50 53

Mail: contact@anthogyr.com

VIII. WARRANTY

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**.

IX. ELIMINATION DISPOSAL

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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