



*Cleaning and sterilisation
user Guide*

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1. Introduction

A. RECOMMENDATIONS AND WARNINGS

All cleaning/disinfection and sterilisation protocols should only be undertaken by a properly trained and protected person, following all applicable regulations. To avoid any risk of infection or injury, it is imperative that they wear protective clothing (mask, gloves, and protective goggles).

All cleaning/disinfection and sterilisation protocols must be adapted to the risk of infection. The user or medical personnel must ensure that the protocol being implemented achieves the sterility goal. The protocol must eliminate all chemical and organic residue on the treated device (also, in particular, take care to rinse the used products thoroughly).

In order to not damage or harm the components, it is imperative to only use cleaning and decontamination products that are compatible with the various combinations of materials being treated.

Detergent and disinfection solutions should be pH neutral or slightly alkaline.

The cleaning and sterilisation protocols present in this manual have been approved by Anthogyr. Protocols prior to this document are obsolete and are replaced by those in this manual.

Other protocols or detergents may be equivalent to what is proposed in this manual; they must be approved by the user.

In the event of conflict with national recommendations, the national recommendations supersede the protocols suggested by Anthogyr.

WARNING!

All reusable products (instruments and kits) absolutely must be cleaned and sterilised before the first use and after each surgery.

All single-use products delivered non-sterile must be cleaned and sterilised before being used in the mouth.

All products delivered sterile (sterilised by gamma radiation) should not be re-sterilised. Pay attention to the sterile parts inside bags or blisters/packaging during unpacking, and place these contents in sterile areas. Pay attention to the product expiration date.

Kits should be completely disassembled for cleaning and disinfection, then reassembled and filled with instruments before sterilisation. Sterilisation cassettes are not disassembled.

For aluminium alloys, the use of lye or sodium hypochlorite (bleach) is formally prohibited; there is a significant risk of corrosion. For all materials, the use of hydrogen peroxide [H₂O₂] is formally prohibited; there is a risk of chemical reaction.

Do not use substances likely to set proteins (alcohol, aldehydes, etc.).

B. MEANING OF SYMBOLS



Manufacturer



Device sterilised



Manufacturing batch
Of the device



Device sterilised
by gamma irradiation



Sterilise by autoclave outside
of packaging



Do not re-use,
single use device



Do not sterilise by autoclaving



Read instructions



Non-sterile device



Warning : observe
instructions for use

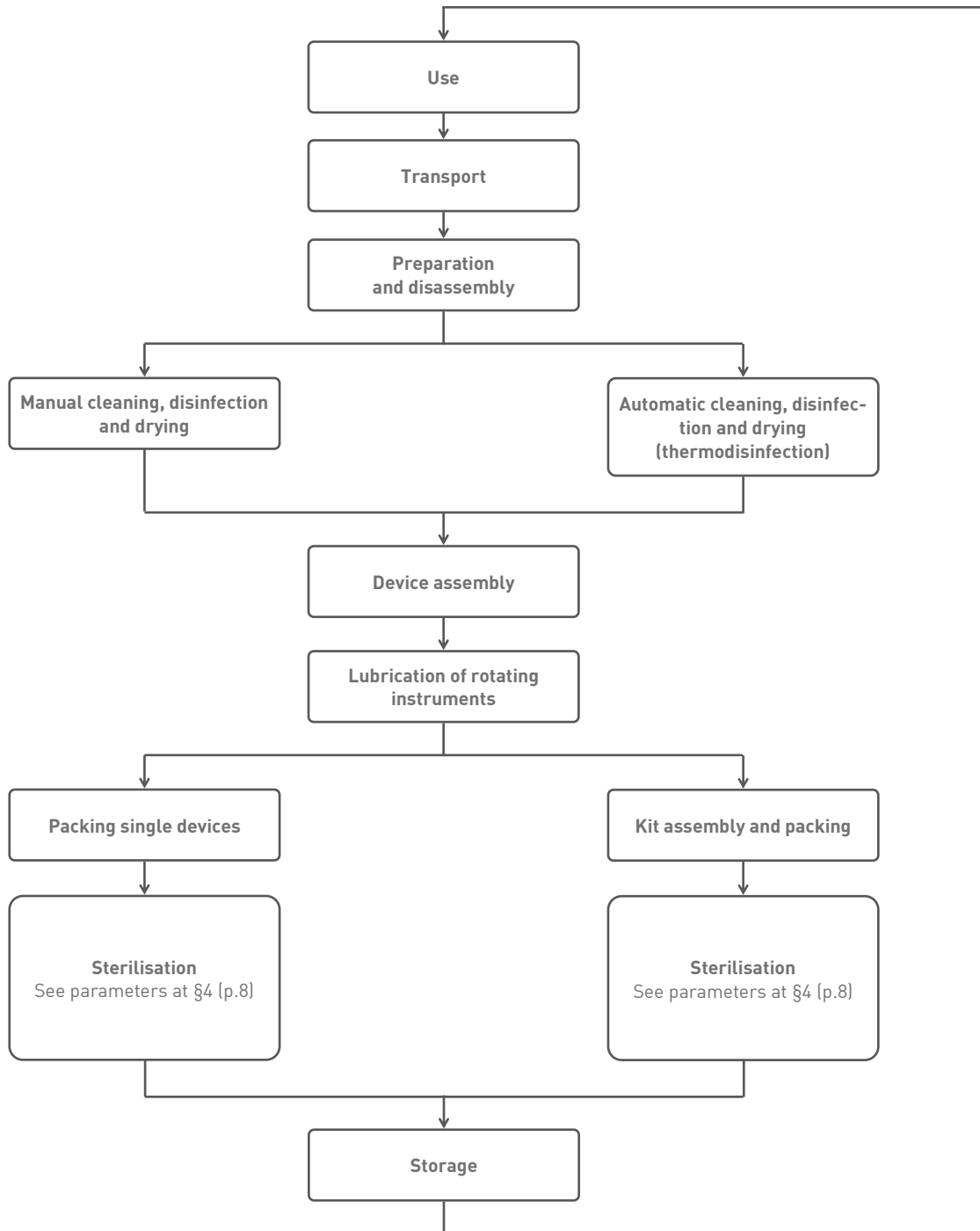


Expiration date of
the device



Thermodisinfection

C. CLEANING PROCESS



2. Disassembly preparation

During the various steps of the process, it is important to make sure to not shock cutting instruments or their cutting performance may be affected.

After use, it is important to minimise the waiting time before cleaning. It absolutely must be under 2 hours.

 To disassemble Anthogyr products, please refer to the instructions for each instrument.

They must be completely disassembled prior to manual cleaning.

Remove the tools (drills, burs, etc.) from rotating instruments (contra-angles, etc.).

A. STOP DRILLS *ART. NB. INKITOPDS*

→ Remove the cover and drills stops before cleaning.



B. REVERSIBLE PROSTHETIC RATCHET WRENCH *ART. NB. INCC*

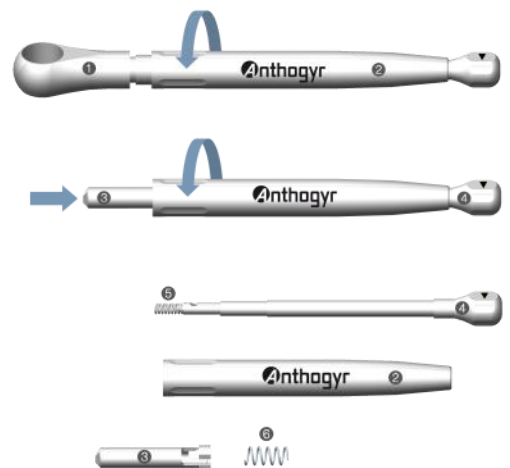
DISASSEMBLING / RE-ASSEMBLING

→ 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 anti-clockwise in order to unlock the bayonet.

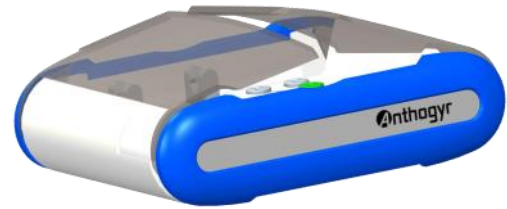
→ Repeat the disassembling operation above in reverse order. Insert the set « rod (4) + spring (5) » through the back part of the body (2). Fit the spring (6) around the rod (4) through the front part of the body (2). Assemble the ratchet (3) by pushing it onto the rod (4) and rotating it ¼ turn clockwise to lock the bayonet.

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

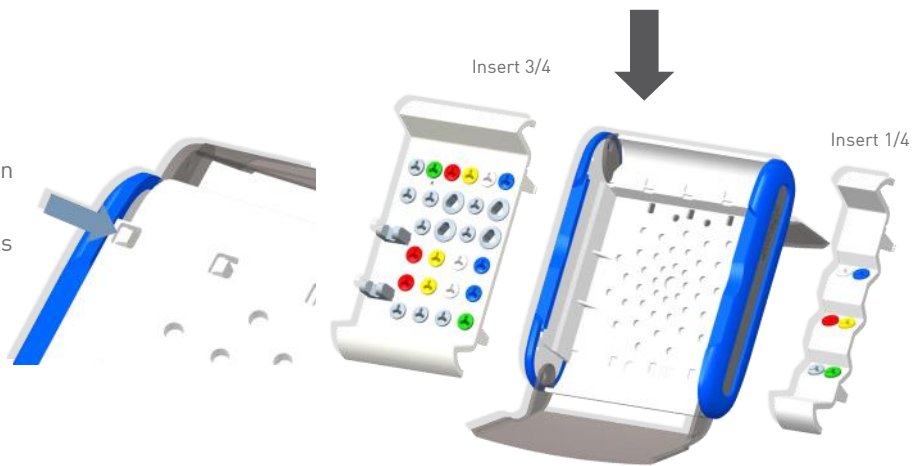


B. INSTRUMENT KIT

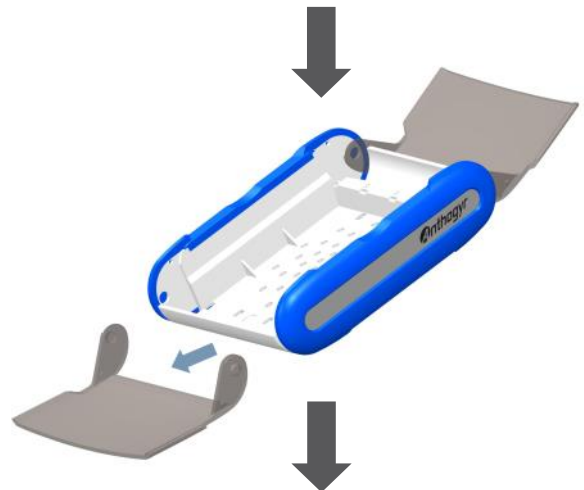
→ Open the covers.



- Unclip the insert pegs located on the back of the kit.
- Remove the 1/4 and 3/4 inserts from the main kit body.



- Carefully remove the side arms from the main body.
- Detach the transparent cover pivot pegs.
- Remove the covers.



- Remove the side covers from the main body.
- Detach the side covers from the side of the kit.
- Remove the side cover ends around the stainless steel plates.
- Detach the silicone cover plates.



Repeat each stage in reverse order to assemble

3. Cleaning

Anthogyr has approved two cleaning methods.

- Manual cleaning.
- Automatic cleaning automatic via thermal disinfectant.

WARNING!

Devices containing aluminium parts, must not be cleaned via thermal disinfectant (Torq Control®, Safe Relax®, Safe Lock®).

A. MANUAL CLEANING

→ Brush meticulously with a soft brush (example: nylon) under tap water at room temperature under there is no visible trace of contaminants.

→ For submersible devices :

Completely submerge in a detergent and disinfectant solution following the manufacturer's instructions for time, temperature, and concentration, in particular.

WARNING!

Instruments that cannot be disassembled are not submersible.

- Rinse with purified water for at least one minute.
- Dry immediately, carefully, with a soft lint-free cloth.

The products and detergents used by Anthogyr are listed in Appendix C.

B. AUTOMATIC CLEANING

Automatic cleaning is done with an appropriate washer/thermal disinfectant according to the following program. This may vary according to the type of machine used; refer to the instructions provided with the machine.

- Pre-wash with cold water for 4 minutes.
- Wash at 55°C for 5 min with an enzymatic detergent.
- Neutralisation at 55°C for 3 min with an appropriate neutraliser.
- Intermediate rinsing with 40°C water for 2 minutes.
- Thermal disinfection at 95°C for 10 min.
- Final rinsing at 40°C for 2 min with a rinsing liquid.
- Drying at 140°C for 10 min.

The products and detergents used by Anthogyr are listed in Appendix C.

4. Sterilisation

A. PREPARATION AND ASSEMBLY

Kits, containers, cassettes, and instruments should be assembled (according to the instructions provided with each device) prior to sterilisation.

Place the device by itself or the kit in the sealed sterilisation bag according to standard NF EN ISO11607 and adapted to autoclave sterilisation.

Follow the autoclave manufacturer's recommendations and instructions for use and maintenance.

B. STERILISATION VIA AUTOCLAVE

Anthogyr recommends class B autoclave sterilisation according to standard EN 13060 for all devices bearing the logo 

Devices should not be sterilised without first being cleaned.

The sterilisation device must be approved and in compliance with the applicable standards. The manufacturer's recommendations and instructions for use should be obeyed.

→ 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).

WARNING!

Zirconia prosthetic components should not be sterilised in the autoclave. They should be sterilised with dry heat at 160 °C (320 °F) for 4 hours.

5. Appendices

A. APPENDICES

AAMI TIR12 : 2010 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities : A guide for medical device manufacturers.

AAMI TIR30 : 2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.

ISO 11607-1 : 2006 : Packaging for terminally sterilized medical devices -- Part 1 : Requirements for materials, sterile barrier systems and packaging systems.

ISO 17664 : 2004 : Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices.

ISO 17665-1 : 2006 : Sterilization of health care products -- Moist heat -- Part 1 : Requirements for the development, validation and routine control of a sterilization process for medical devices.

ISO 14161 : 2009 : Sterilization of health care products -- Biological indicators -- Guidance for the selection, use and interpretation of results.

EN 13060 : 2004 : Small steam sterilizers.

B. WATER QUALITY

The water used for cleaning, dilution of detergents, and rinsing should be monitored. It is recommended that purified water be used (Ultra Pure Water or Highly Purified Water), according to the specifications of the local pharmacopoeia.

Example :

Properties:	European Pharmacopoeia (Eur.Ph) limit values
Conductivity	<1.3 μ S/cm à 25°C
Bacteria	<10CFU/100mL
Endotoxins	<0.25EU/mL

C. PRODUCTS AND DETERGENTS

Anthogyr used the following products and detergents to approve the various protocols. However, other products and detergents may be used according to local availability. Approval of these products is the responsibility of the user.

MANUAL CLEANING :

Cidezyme (Johnson&Johnson) for 3 minutes at a concentration of 8mL/L.

AUTOMATIC CLEANING :

Enzymatic detergent: Neodisher Mediclean Dental (DrWeigert) at a concentration of 2mL/L .

Neutraliser: Neodisher Z Dental (DrWeigert) at a concentration of 1mL/L.

Rinsing: Neodisher Mielclear (DrWeigert) at a concentration of 0.2mL/L.

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