

Instructions for cleaning and disinfection of: instruments and boxes (surgical and prosthetic)

Protocol to be carried out by qualified personnel for the preparation of instruments and surgical/prosthetic boxes for use.

ATTENTION: the instruments and surgical/prosthetic boxes must be cleaned and disinfected after each use and sterilised before their next use. Pay attention to sharp elements, the use of gloves is recommended to avoid accidents during handling when following these instructions. Do not clean or disinfect instruments of different materials together.

Cleaning and disinfection of instruments

1- Disassembly

- Disassemble the instruments that require it such as manual ratchets (see diagram below), drills and drill stops...
- Disassemble the surgical/prosthetic boxes into their components for proper cleaning.
- Uncouple the micro-implants insertion key from the handle (see diagram below).

2- Cleaning

- Immerse the instruments in a solution of a cleaning agent suitable for dental instruments to facilitate the removal of adhering biological debris.
- Remove biological residue manually with a soft brush and pH-neutral detergent.
- Rinse with plenty of water.
- Perform a final rinse with deionised water.
- Always use pH-neutral detergents and non-abrasive tools to clean surgical/prosthetic boxes so as not to damage the surfaces of the box.

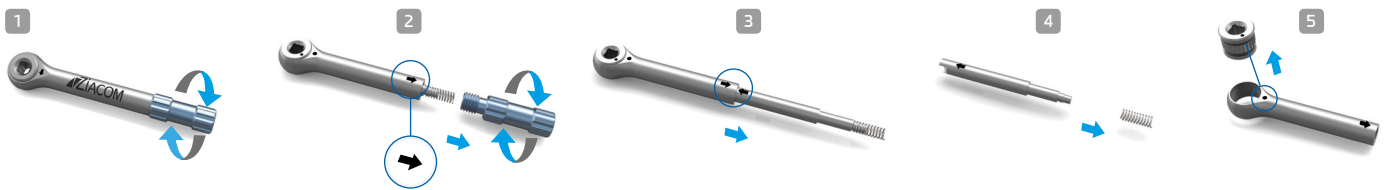
3- Disinfection

- Immerse the instruments in a disinfectant explicitly indicated for dental instruments.
 - For disinfection with ultrasonic equipment: immerse the material in the ultrasonic bath.
 - Rinse with plenty of deionised water to remove any residues of the disinfectant.
 - Dry the material with filtered compressed air.
- IMPORTANT:**
- Follow the instructions of the disinfectant manufacturer to determine concentrations and times.
 - Follow the instructions of the manufacturer of the ultrasound equipment to determine temperature, concentration and times.

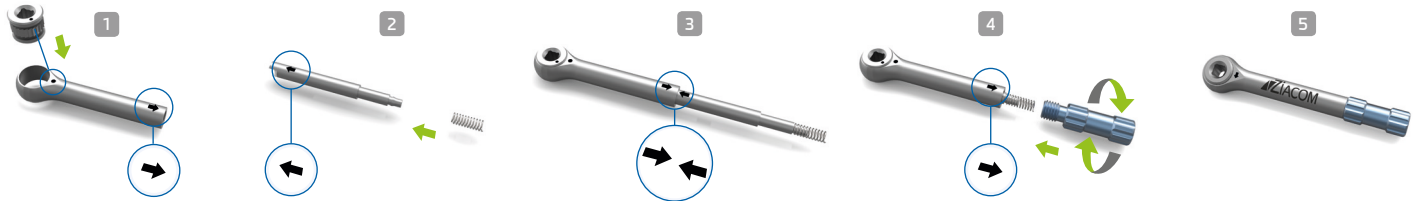
4- Inspection

- Check that the instruments are perfectly clean, otherwise repeat the above cleaning and disinfection steps.
- Discard instruments that show damage and replace them for the next surgery.
- Verify that the instruments and surgical/prosthetic boxes are perfectly dry before assembly and sterilisation.

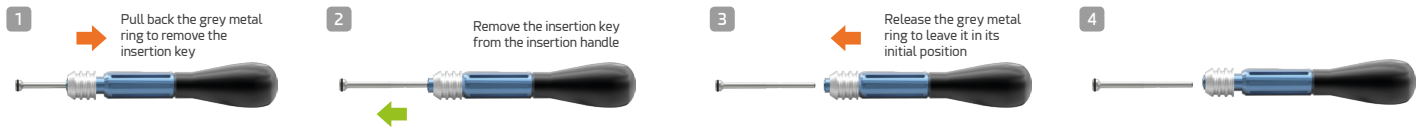
Disassembly of ZIACOM® ratchets



Assembly of ZIACOM® ratchets



Disassembly of DSQ® micro-implant insertion handle



Assembly of DSQ® micro-implant insertion handle



Sterilisation instructions for: orthodontic micro-implants, abutments, instruments and boxes (surgical and prosthetic)

Protocol to be carried out by qualified personnel for the sterilisation of micro-implants, abutments, instruments and surgical/prosthetic boxes for use.

ATTENTION: all micro-implants, abutments, instruments and surgical/prosthetic boxes are supplied NON-STERILE. They should be sterilised as directed before the first clinical use.

They must be removed from their original packaging for sterilisation prior to first clinical use. Surgical/prosthetic instruments and boxes should be cleaned and disinfected after each use and sterilised prior to use. Do not sterilise instruments of different materials together, unless the corresponding surgical/prosthetic box is used correctly.

Steam autoclave sterilisation: sterilisation of micro-implants, abutments, instruments and boxes

- Insert the material individually into sterilisation bags and seal the bags.
For joint sterilisation: assemble the instruments in their corresponding surgical box, insert the box in a sterilisation bag and seal the bag.

- Place the bags to be sterilised in the autoclave.

- Sterilise in steam autoclave at 134°C/273°F (max. 137°C/276°F), for 4 min (minimum) and 2 atm of pressure.

Only for USA: the validated and recommended sterilisation cycle is in a steam and gravity autoclave at 132°C/270°F, minimum 15 minutes and drying time 15-30 minutes.

IMPORTANT:

- Make sure that the drying phase is completed to prevent the products from coming out wet.
- Check the sterilisation equipment if the sterilisation material or bags are wet at the end of the sterilisation.
- Carry out the maintenance of the autoclave with the established periodicity and the necessary actions, following the manufacturer's instructions.

Conservation of ZIACOM® products (micro-implants, abutments, instruments and boxes)

- Keep the products in the original ZIACOM® packaging in a dry and clean environment until use.
- After sterilisation, keep the products (micro-implants, instruments, abutments and surgical boxes) in their sealed sterilisation bags and in a dry and clean environment.
- Never exceed the expiration dates determined by the manufacturer of the sterilisation bags.

IMPORTANT:

- Follow the instructions of the manufacturer of the sterilisation bags.

General recommendations

- Never use damaged or dirty material. Never reuse products indicated for a single use, the user is responsible for the correct follow up of the instructions described in this document.
- Always wear gloves when cleaning the material.
- Follow the safety instructions given by the manufacturer of the disinfection agent.
- Sterility cannot be guaranteed if the sterilisation bag is open, damaged or wet.
- Respect all phases of the steriliser. If the sterilisation material or bags have water or moisture residues, check the autoclave and dry the bags.
- Carry out the maintenance of the autoclave according to its manufacturer, with the established periodicity.
- The sterilisation, cleaning and disinfection processes progressively deteriorate the instruments. Inspect the instruments carefully for signs of deterioration.
- Ziacom Medical SLU recommends following these instructions to avoid impairing the purpose and safety of its products. If alternative procedures are used, it is the responsibility of the user to ensure that the chosen cleaning, disinfection and sterilisation procedure achieves the desired results without affecting the products.