

PROTOCOL

STERILIZATION INSTRUCTIONS FOR TBR® INSTRUMENTATION TO BE STERILIZED BEFORE USE OR BETWEEN EACH USE

Warning :

- 1) Information regarding the need to sterilize before use (symbol: «Not Sterile») and the possible sterilization between each use (absence of the symbol: ⊗ single use) are indicated on the labeling.
- 2) Please respect the legal provisions and regulations applicable in your country regarding hygiene at the dentist office or at the hospital and specially the instructions for an effective inactivation of prions.
- 3) In case of using a disinfection, cleaning or sterilization method different from the one that is recommended, the practitioner will take full responsibility.
- 4) For medical devices not manufactured by Sudimplant, please follow the particular instructions contained in the user's instructions regarding the preparation or the reuse.

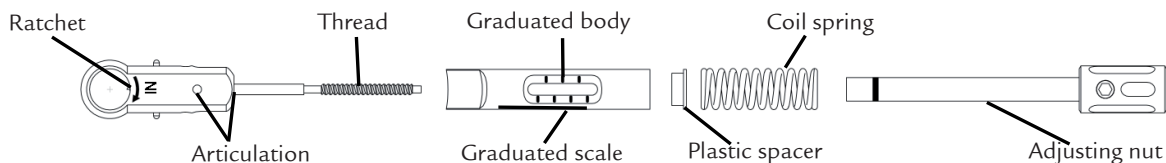
1 Maintenance and lifetime

Parts that are not disposable have an «indefinite» lifetime (except for drills that can be use for a maximum of 10 drillings; screwtools, angulation kits and transfers Swissclip rings for 50 uses and ancillary joints for 30 uses). This lifetime will depend on the respect of these instructions, the use and the handling of those instruments. We advise you to check the state and the availability of every instrument before any intervention, and to always have an extra set of sterile instrumentations. Never use a defective or rusty instrument.

2 Assembly and dismantling

Kits Box: Completely dismantle the box before any disinfection and cleaning. Before assembly, thoroughly dry the box and the instruments. All the instruments can be packaged in the box (placed in a sterilization pouch) and sterilized in the sterilizer.

Torque wrench:



It is possible to dismantle, without any tool, the different parts of the torque wrench by entirely unscrewing the adjusting nut. Be careful not to lose the plastic spacer, it could alter the instrument precision. It is not generally necessary to remove the plastic spacer. Replace the spacer after cleaning.

Swissclip rings and joints: Leave the rings and the joints before the disinfection stage of the sterilization chain. See the instructions or the specific protocol delivered with the purchase.

3 Warnings and recommendations for disinfection, cleaning and sterilization

Before each intervention (including the first use), surgical equipment must be disinfected, cleaned and sterilized by trained and qualified staff.

Check for the presence, the cleanliness, the operational state and the qualification (calibration, maintenance, etc.) of all the necessary material before starting the cleaning and sterilization cycle. The handling of contaminated devices must be done by using personal protective equipment (gloves, gowns, glasses, mask, etc. ...). The drying, packaging and sterilization process must be performed in a clean, orderly and clear environment.

Caution: All the parts to be sterilized require some recommendations for the preservation of their quality. The non respect of these instructions can alter the lifetime of the devices (corrosion, colouring, deterioration of the marking, premature wear, etc.) and the users and patients safety (contamination):

Point A: Use cleaning / disinfection products adapted to surgical instrumentation and materials they are made of. Do not use products containing chlorine, iodine, phenols, strong acids or alkaline (do not use sodium hypochlorite (bleach), oxalic acid, sodium hydroxide or hydrogen peroxide, or normal saline, beware of the too strongly chlorinated tap water). Avoid any product containing aldehyde because of their ability to bind proteins.

Point B: For the washer-disinfector: Only use agents recommended by the manufacturer and prefer the use of slightly alkaline products (pH between 7 and 10.5).

Point C: For all products and materials (for cleaning / disinfection, washer-disinfector, ultrasound vat, sterilization pouch, autoclave etc ...), follow carefully all manufacturer's instructions (dosage, soaking time, temperature etc ...) and expiration dates.

Point D: Avoid as far as possible shocks and contacts with other instruments (deterioration of the surface state, the marking laser and/or the cutting power).

Point E: Please clean products made from the same material in the same container.

Point F: Do not leave contaminated instruments to dry before the cleaning / sterilization cycle.

4 Disinfection, cleaning and sterilization protocol

Before each intervention:

① As soon as possible after their use (if more than 30 minutes, do not forget to wrap them in a damp cloth to prevent the soiling from drying), the dirty instruments are carried in a suitable container, avoiding shocks, to the area dedicated for the cleaning. They are arranged in a clean and adapted packaging, dismantled if necessary (in the case of the torque wrench) and completely soaked in a freshly prepared disinfecting solution, without any bubble (the use of a system with ultrasounds is also appropriate) (see points A, C, D & E). Rinse thoroughly under running water until the absence of chemical residues on the device.

② Remove carefully all the post-operative residues (blood, bones ...) on the instruments (use a nylon brush), or inside for products with an internal irrigation or hollow products (thanks to a syringe, e.g. drills, cannula, etc ...) by using an alkaline detergent (but not a strong one) or neutral one (see points A, C & E). Rinse thoroughly (preferably use using deionized water for the final rinse).

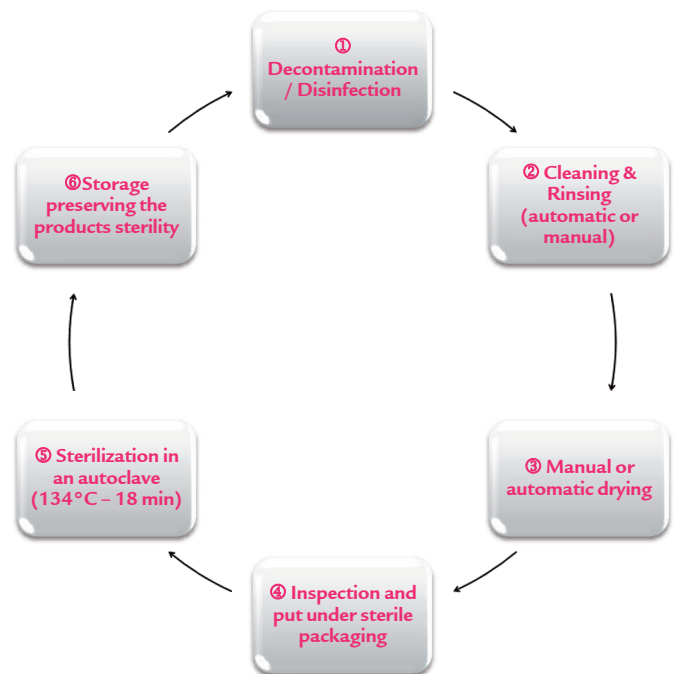
③ **In case of a manual cleaning:** Immediately after cleaning, dry all the instruments surfaces with a lint-free clean absorbing paper by scrubbing carefully or with compressed air for medical use (see points C).

In case of a washer-disinfector : Immediately after cleaning, put the instruments in the washer-disinfector avoiding contacts between the devices and start the cycle following the manufacturer's instructions (see points B, C & D).

④ Visually inspect the cleanliness and the absence of humidity or stains on the components and make sure that no deterioration may affect their safety, integrity or functioning. If necessary, repeat the cleaning cycle from the point 2. Reassemble the instruments when needed. Put one or several products in a sterilization pouch, big enough so that no tension is applied on the closure (see point C).

⑤ Make sure that there are no corroded elements inside the type B pressurized steam sterilizer. Sterilize in the autoclave at 134 °C, 18 minutes (see points C & E).

⑥ Verify the good progress of the cycle, the integrity of the pouches as well as the physico-chemical indicator of sterilization (if necessary, start again the operation from the point 4). Indicate the sterilization date on every pouch (and any information necessary for the traceability) which will then be stored in conditions preserving the products safety and sterility (a clean, dry, safe and stress-free place, at room temperature and out of direct sunshine).



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to prevent periprosthetic