

Upon publication, these instructions for use supersede all previous editions.

The manufacturer is not liable for any damages due to the user disregarding the instructions for use below.

Follow the instructions of use.

Not sterile.

Specifications

1. Use

This torque wrench is a dental instrument that provides a means of tightening and loosening screws, prosthesis elements and implants.

2. Cleaning

It is not advisable to use products with a high percentage of chlorine or containing oxalic acid.

3. Sterilisation

Do not use hot air sterilisers or ball sterilisers.

4. Grease

«Instrument Lubricant» agréé USDA H1

5. Precision of new devices

± 5 % (with total confidence of 95 %)

6. Nature of the material

All metallic parts except the springs: 1.4404+S+Cu (~316 L)
Springs: 1.4310
Plastic washer: PEEK

7. Recommendations

Check for corrosion after sterilisation, do not sterilise corroded instruments. Wrenches that are used in the laboratory must be used only in the laboratory. If wrenches are used in the mouth, they must be used only in the dental surgery. This device must not be used for other applications or with non-conforming components. Each constituent part is designed for each wrench. It is important not to mix parts from several wrenches.

This torque wrench is a dismantable instrument for multiple use sold non-sterilised. Before each use the instrument should be cleaned, disinfected and sterilised in accordance with the instructions for use of the wrench. The instrument must be used by trained staff who have read the instructions for use before handling.

1. Cleaning

- As soon as possible after use the instrument should be placed in a receptacle filled with a disinfectant / detergent solution and covered with a cloth. The aim of this phase is to prevent the drying of the contaminants originating from the patient and to dissolve them.
- Dismantle the wrench completely as shown in drawings A to C and U to Z, and mechanically clean all the outer and inner surfaces of the instrument with a soft brush under hot running water.
- Rinse the somewhat inaccessible holes in the head (1) and around the ratchet wheel (2) by injecting hot water with a syringe without a needle. If necessary, treat the interior of the shaft (7) and of the calibrator (10) in the same way.
- Clean the wrench ultrasonically with the appropriate disinfectant / detergent cleaning solution. Avoid contact between the components during this cycle.
- If in doubt, a supplementary wash in an autoclave can be performed, which will provide thermal disinfection.
- Rinse all the components in hot water.

Note: Residual blood or debris reduce the effectiveness of the disinfection and sterilisation process; this is why thorough cleaning is important. Avoid contact between this instrument and other nickel-plated instruments. During cleaning process avoid splashes of liquids and use appropriate protection.

2. Disinfection

There is a choice of two possibilities:

- Perform a thermal disinfection in an autoclave, ensuring contact with boiling water (above 90°C) during 3 to 10 minutes. Then rinse all the pieces in cold distilled water.
- Perform a chemical disinfection with an appropriate product (which does not damage the steel) which acts quickly and provides a broad spectrum (virucide and fungicide). The effectiveness of chemical disinfection depends on the concentration of the product, temperature, duration of contact, hardness of the water and the degree of contamination. Rinse all pieces afterwards in cold distilled water.



3. Preparation prior to sterilisation

- Dry the parts and moderately lubricate the functional areas (Σ) as in drawings A, C, V (excessive lubricant leaves traces on the instrument's surface during sterilisation). Use only the lubricant «Instrument Lubricant» which is delivered with the instrument.
- Reassemble the wrench following instructions in drawings U to Z and A to C. It is important to make the laser marking of the shaft (7) correspond to the laser marking on the head (1) (drawing A). Screw the calibrator (10) to position «0».
- While placing the rod (5) into the handle (1), side «IN», ensure that the two arrows are facing (drawing X). This procedure is important to preserve the torque wrench precision within the $\pm 5\%$ margin.
- Operate the torque and ratchet mechanisms to check their functioning.
- Remove any traces of the lubricant from the outer surface of the wrench.
- Wrap up the wrench in appropriate sterilisation foil prior to sterilisation in autoclave or chemclave.

4. Sterilisation

- In autoclave: follow sterilisation cycles recommended by the manufacturer of the autoclave. We recommend the use of devices equipped with a vacuum pump to minimise the risk of air pockets forming; this recommendation is particularly important with hollow instruments, and to ensure perfect drying. If corrosion traces appear, the components should be treated with a 0.1 % sodium nitride solution prior to sterilisation.
- With a chemclave: follow sterilisation cycles recommended by the manufacturer of the chemclave. The advantage of the chemclave is the less frequent occurrence of corrosion since the solution's humidity rate is below the critical 15 % level.

Note: Hot-air sterilisation is not advised as it can accelerate the aging of the spring and consequently lead to torque modification.

5. Use of the wrench

- After sterilisation the wrench is ready to use. During the preparation of the instruments, and before surgery, a test is needed to check the assembly and its functioning.
- Torque is adjusted by aligning the chosen torque marking (marked on calibrator 10), in the round opening on the handle (7).
- The «IN» arrow visible on the head (1) from underneath indicates wrench position which permits tightening. The «OUT» arrow visible on the head (1) from underneath indicates the unscrew position.
- The «infinite» torque position is obtained by setting the calibrator (10) to «0» and turning the handle (7) by $\frac{1}{4}$ of a circle; this places it between the guides and blocks its movement. Then retighten the calibrator (10). This position can be used in case of wrench torque failure, incorrect assembly of the wrench or in an exceptional case requiring «infinite» torque.
- Always set a torque position while screwing. If a torque under the one in use is needed, unscrew the calibrator (10) two turns under the new needed torque, and then screw the calibrator to the desired torque.

Note: Staff responsible for the use and maintenance of this dental instrument should monitor any deterioration of the tightening, ratchet and torque mechanisms. The components of this mechanism are not interchangeable; it is not possible to use a component from another wrench for replacement. If a component is lost, please return the whole instrument immediately to your retailer for repair. Components cannot be sold separately.

