

EN - ENGLISH

## INSTRUCTIONS FOR USE TORQUE WRENCH

### LIMITATION OF LIABILITY

Before using the instrument, read the following instructions for use. It is the responsibility of all the operators handling the products in the context of their respective field of activity to have adequate knowledge about the product on the basis of the most recent technological standards. This allows a correct use of the products and avoids health and safety risks to the patient, the user and other stakeholders. The authorized dentist or surgeon must determine the suitability of the patient for oral surgery interventions and the appropriate surgical technique; they must also determine the suitability of the product chosen for the programmed use, therefore taking on every form of risk and responsibility in relation to such. The processing, manipulation and application steps of the product held in the surgery or dental laboratory are outside the control of the manufacturer and therefore fall under the responsibility of the user. Any use other than that described in the IESS Group informative material is considered "misuse" and frees the manufacturer from any obligation or responsibility.

### PRODUCT DESCRIPTION AND INDICATIONS

The torque wrench is a reusable medical device in stainless steel to be used with the proper insert in order to tighten and loose the screws and restorative components, and to get in position the implants, in two ways:

- torque mode: for restorative components (according to indications given in IESS Group informative material) and for dental implant positioning (according to instructions for use supplied with the implants);
- ratchet mode (no torque limit).

### LIMITATION OF USE

The complete torque wrench with Geass adapter should only be used together with other components and/or devices belonging to Geass implant prosthetic system. This instrument is not a measuring device.

### PACKAGING

The torque wrench is supplied non-sterile. The package comes with adhesive labels which show the traceability data. Do not use the medical device, should the packaging be damaged or open.

### INSTRUCTION FOR USE

Always use the torque wrench with the Geass adapter, this allows to use all Geass inserts. Place the torque wrench adapter below the hole and insert until it is flush and the click of the retentive ring is heard. Now the device is firmly with the torque wrench.



### TIGHTENING WITH CALIBRATED TORQUE

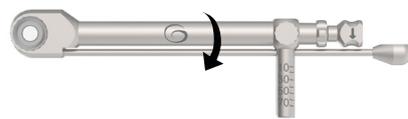
Application by using the knob on the bending rod. The torque will be read by means of the bending rod on the scale. The requested value will be achieved when the middle of the bending rod will be covered with the appropriate scale graduation mark.



**Attention:** reading should always be done directly from the top. When the desired torque has been achieved, please relieve the bending rod again. Then, the bending rod will spring back into the starting position.

### TIGHTENING IN BLOCKED FUNCTION (RATCHET MODE)

Use the torque without the bending rod, directly from the central body.

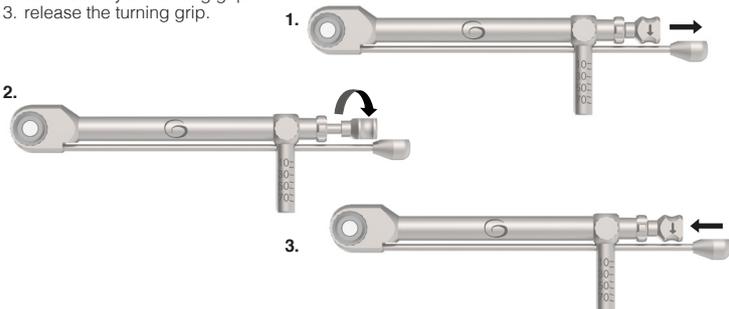


**Attention:** in the blocked function it is not possible to measure the applied torque value and therefore there is a risk of exceeding the limits indicated in the informative material.

### SWITCHING OVER OF THE DIRECTION OF ROTATION

The torque wrench can be used for tighten or loosen, the direction of rotation is indicated by the arrow on the knob. To reverse the direction of rotation:

1. pull the turning grip
2. turn half way the turning grip
3. release the turning grip.



### WARNINGS

Before use, always check the assembly and the correct function of the torque wrench. The torque wrench must be used with the proper insert; always check that the coupling with the insert has been correctly performed. Pay attention to the position of the torque wrench while using, so that the rotation axis of the instrument coincides with the axis of the handled device. Respect the torque values indicated on the instructions of the devices to be handled. Tightening by the blocked function can lead to excessive torques which damage the components that are being handled. If force is applied to the central body and not the bending rod, the applied

torque cannot be measured. High forces can lead to excessive compression of the cortical bone and cause its resorption. Excessive tightening of the implant can lead to damage to it, fracture or necrosis of the bone site. The people in charge for the use and maintenance of this dental instrument should monitor any deterioration of the tightening, ratchet and torque mechanism of the device and, in the event of a defect, return the wrench to the supplier. During assembly, it is essential not to mix the various components belonging to different torque wrenches because the components are not interchangeable. If a component is lost, please return the whole instrument immediately to your retailer for repair. Components cannot be sold separately. The torque wrench can be disassembled. To ensure that it functions perfectly all the time, the torque wrench must be disassembled, disinfected, cleaned, greased and sterilized before first use and after each use.

### PREPARATION

#### TREATMENT INSTRUCTIONS

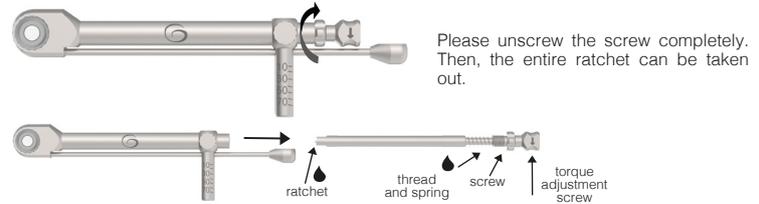
To avoid damage, do not use metal brushes or cleaning sponges. Only use cleaning and disinfectant solutions with a pH value of between 4.5 and 10. Follow the manufacturer's instructions (e.g., intended purpose, dosage, exposure period and replacement of the solution). The torque wrench is not sterile when delivered and must be cleaned and sterilized before it is used. When using several torque wrenches, do not interchange the individual parts. Each individual part belongs to the respective instrument.

#### RESTRICTION REGARDING REPREPARATION

The end of the product's service life is normally determined by wear and damage caused during use and by incorrect handling.

#### PREPARATIONS FOR CLEANING

For cleaning the torque wrench can be disassembled without any tool. Pull out the torque wrench Adapter downwards.



Please unscrew the screw completely. Then, the entire ratchet can be taken out.

Clean the parts under cold running water using a soft brush to remove all visible soiling. Ensure that all openings and cavities are thoroughly rinsed. Do not allow blood and other soiling to dry on.

#### CLEANING AND DISINFECTION: MANUAL

Ultrasonic cleaning bath: Place the parts into a wire basket and ensure that the parts do not touch, in order to avoid acoustic shadows. Clean for 3 minutes in an ultrasonic cleaning bath (35-40 kHz) at a temperature of 40°-50°C with an enzymatic cleaning solution. Ensure that the parts are completely immersed in the water, without the formation of any bubbles. Rinse with clear, cold water; if possible, use deionised water. Dry the parts with a lint-free cloth and blow dry with compressed air.

#### CLEANING AND DISINFECTION: AUTOMATIC, CLEANING AND DISINFECTION DEVICE

Securely apply the cleaned torque wrench parts to the carrier. Do not overload the carrier. Start the program. After rinsing, chemical cleaning starts at 40°-60°C. Residues from the cleaning process must be reliably removed in the subsequent rinsing phase. Avoid damage to the material from neutralising reagents. Thermal disinfection is achieved at 90°-95°C. The subsequent treatment with deionised water is followed by adequate drying. Remove the torque wrench parts from the device immediately after the program ends.

#### MAINTENANCE AND INSPECTION

Allow the parts to cool to room temperature and visually inspect them for residues of proteins and other soiling. If necessary, repeat the preparation steps.

#### ASSEMBLY AND TESTING

Moderately lubricate the pawl, the thread and the spring using contra-angle handpiece oil. Insert the shaft into the central body and tighten the screw until it is in flush. Insert the torque wrench adapter in the seat. Check the function by activating the ratchet wheel: if there is a regular ratchet noise, the instrument operates correctly.

#### STERILIZATION PACKAGING

Place the torque wrench into packaging suitable for sterilisation according to ISO 11607 and EN 868. The bag must be large enough for the instrument. Closures must not be under tension.

#### STERILIZATION

Method: Fractionated pre-vacuum process in accordance with ISO 17665

Temperature: heating to 134°C, max. 137°C

Pressure: 3 pre-vacuum phases with a minimum pressure of 60 millibars

Holding period: 5 minutes

Drying time: at least 10 minutes

After sterilisation, inspect the sterile packaging for damage and check sterilisation indicators

#### STORAGE

Place the cleaned and sterilized torque wrench in a dry place at room temperature, away from dust and light. Indicate on the medical envelopes the date of sterilization and expiry calculated on the basis of the timing provided by the current regulations.

#### ECOLOGICAL INFORMATION AND ON DISPOSAL

The torque wrench is not biodegradable. If they are used correctly, they do not give rise to any ecological damage. The medical devices must be treated according to current regulations. The material must be disposed of by authorized companies.

#### DOCUMENTATION

The brochures and detailed instructions for use for the implantological Geass systems must be requested from our commercial representatives, area dealers or directly from the head office. Customer service: telephone: +39 0432 669191 - fax +39 0432 665323 e-mail: [servizioclienti@iess.dental](mailto:servizioclienti@iess.dental) website: [www.geass.it](http://www.geass.it). Information herein contained shows the state of the art at the moment of commercialization of the product. This does not exonerate the user from the responsibility of personally verifying that the product is suitable for the purposes and procedures foreseen.

**BASIC UDI-DI INFORMATION** The following table contains basic UDI-DI information for devices described in these instructions for use.

PRODUCT	Torque wrench	BASIC UDI-DI CODE	805299004INSERTJV
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#### SYMBOL LEGEND



Manufacturer



Catalogue Number



Batch code



Non-sterile



Caution



Conformity of medical devices with the Medical Devices Regulation (EU) 2017/745. For Class I devices