OMEGA Torque Wrench

English

Instruction for use

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Description of the torque Wrench

Torque wrench kit consisting of:
1x Torque wrench
1x Tube of grease

Option: adjustment wrench

The torque wrench, with torque adjustment, is a dental device which allows the tightening and loosening of screws, prosthetic elements, and implants; it is a precision, easy to disassemble instrument, delivered unsterilized. In order to guarantee its proper operation, the torque wrench must be 1) disassembled, 2) cleaned, 3) disinfected 4) assembled/greased, and 5) sterilised before the first use and after each use by following the instructions described below;

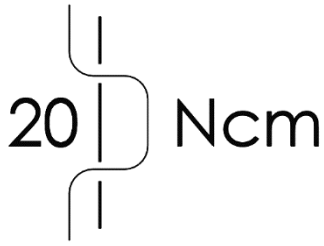
The handling and use of the product are carried out without direct control on our part and remain the responsibility of the user. No responsibility may be attributed to us for damages resulting from improper use.

This instrument is not a device with a measurement function

Use

By turning the tightening torque adjustment screw, the torque wrench can be adjusted to the desired torque. To correctly adjust the torque, just turn the adjusting torque nut (no. 7) clockwiset o achieve the desired tightening torque. This by positioning the marker located on the handle (no. 4) so that it forms a line with the marks positioned on the adjustment torque nut (no. 7). To return to a tightening torque lower than that used, unscrew two turns below the desired torque and then screw back to the value desired.

Fig. 1
Alignment of marks for torque adjustment



The word “IN”, legible on the cover (no. 3) indicates the wrench position allowing tightening; by turning the device over, the word “OUT” allows loosening.

The interface of the end caps used with the wrench must correspond to the interface of the socket (no. 1).

Grease

« Instrument Lubricant » NSF H1 and FDA 21 CFR § 178.3570 certified

Recommendations

This instrument must not be used for applications other than those mentioned in the paragraph “Description of wrench” or with equipment that affects the expected performance of the device.

The set torque must comply with the requirements defined by the manufacturer of the screwed element.
In the event of deterioration of the screwing or ratcheting mechanisms, the medical device must be inspected by the person responsible for use and maintenance of the device. In the event of a defect or change in device performance, return the wrench to the supplier or distributor.

During assembly, it is essential to not mix different components belonging to different intruments as the parts are not interchangeable.

If any part is misplaced, please return the instrument in question immediately to your approved dealer. No part may be sold separately.

Do not store the wrench with the spring compressed, but adjusted to the minimum torque.

This device must not be sterilised in its original packaging.

Storage / Packing

Wrenches must be kept in a dry place at room temperature and kept in a dry place.

No packaging for sterilisation is provided with the wrench. The person responsible for maintaining this medical device must provide a rack corresponding to the dimensions of the wrench.

The different parts of the torque wrench

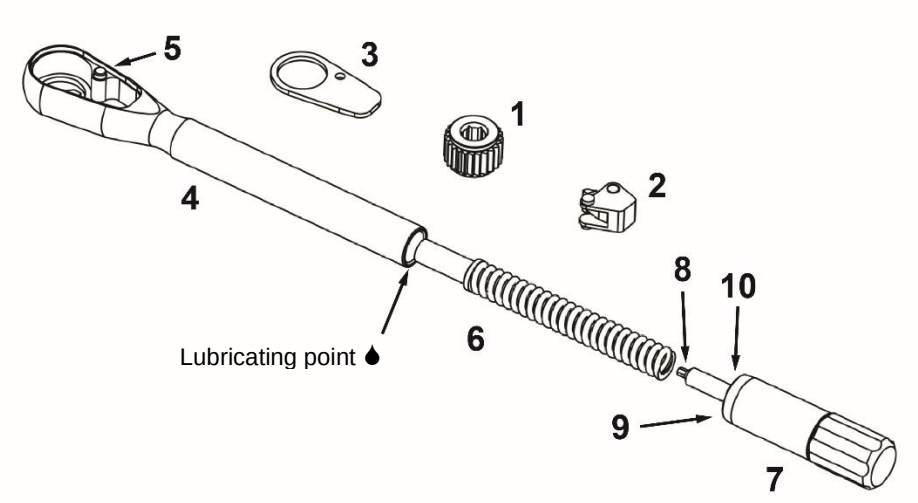


Fig. 2 The wrench is composed of the following elements :

1. socket
2. ratchet
3. cover
4. head / handle
5. screw
6. spring / stop
7. torque adjustement screw
8. hex socket
9. washers (PPS)
10. brake (PTFE)

Wrench handling process :

1) Disassembly
2) Cleaning
3) Disinfection
4) Assembly / lubrication
5) Sterilisation

1. Disassembly of the torque wrench

Fig. 3
Completely loosen the torque adjustment screw (7) and extract the spring/ stop assembly (6).
Use the end of the torque adjustment screw, if necessary, to extract the spring; this operation must be done carefully so as not to damage the hex socket (8).
Don't disassemble the stop and the spring (6)

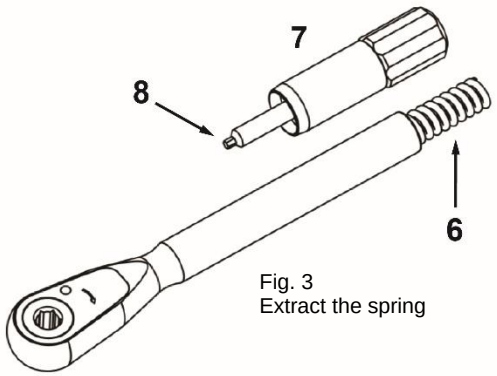


Fig. 3
Extract the spring

Fig. 4
Using a hex socket (8), loosen the screw (5) while maintaining a light pressure which will allow the cover (3) to release from the head (4).

Fig. 4
Loosen the screw using a hex socket

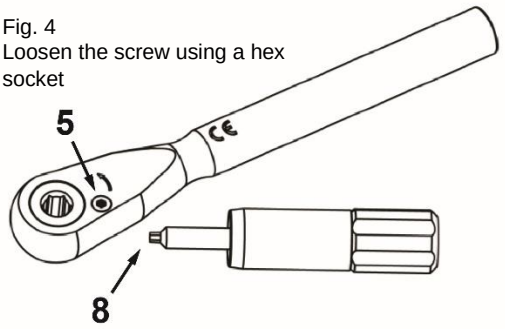


Fig. 5
The head (4) contains two elements which are to be extracted: the ratchet (2) and the socket (1).

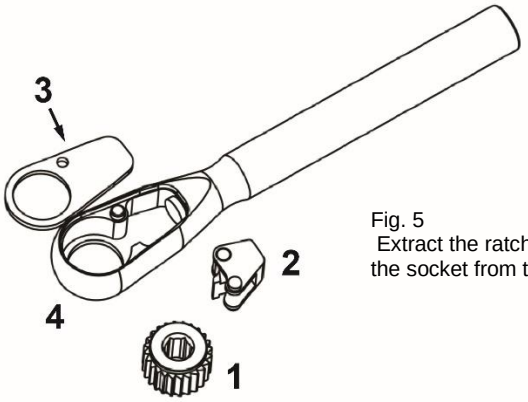


Fig. 5
Extract the ratchet and the socket from the head

2. Cleaning the torque wrench

Prior to the first use and after each use, the torque wrench must be completely disassembled (Fig. 3 to 5), passed under water and brushed with a soft bristle brush in order to remove all residue.

3. Disinfecting the torque wrench

In a bath containing a disinfectant product (Helvemed Disinfection Instrument Forte+) diluted to 1.5% in room temperature water. Let the elements soak for 5 minutes in an ultrasonic bath. Rinse the parts in distilled water.

Visually inspect if the Wrench parts are residue-free.

4. Assembling the torque wrench

Fig. 6

To assemble the torque wrench, it is necessary to insert the following two elements in the indicated order: the socket (1) and the ratchet (2).

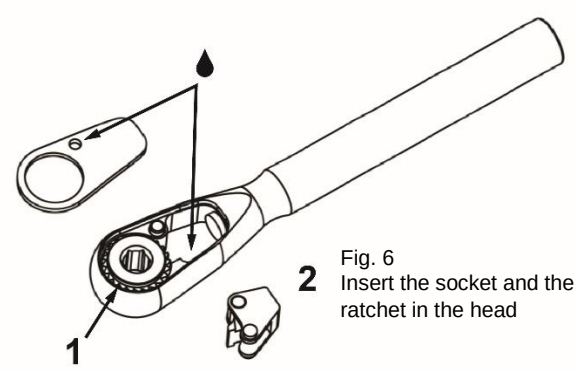


Fig. 6
Insert the socket and the ratchet in the head

Fig. 7

Moderately lubricate the contact area between the teeth of the socket (1) and the ratchet pivot point (2) (S) as shown in Figure 7.
Remove traces of lubricant from the external surface as an excess of lubricant cause drippings on the tool surface during sterilisation.
Only use the “Instrument Lubricant” lubrication delivered with the torque wrench.

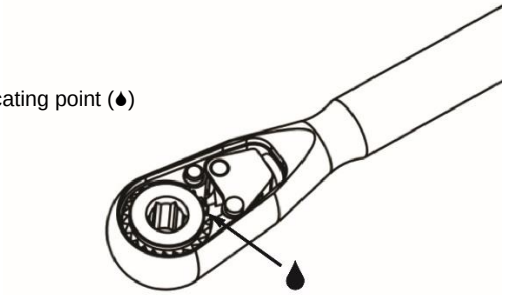


Fig. 7
Lubricating point (♦)

Fig. 8

With the elements (1) and (2) in place, replace the cover (3) by adjusting it on the head (4).
Firmly tighten the screw (5) using the tool inserted into the torque adjustment screw (7).

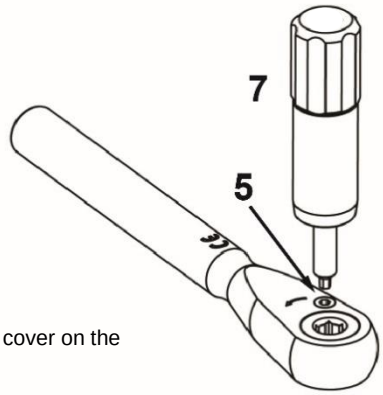


Fig. 8
Tighten the cover on the head

Fig. 9

Assembly of the wrench is finished when the spring/stop assembly (6) is introduced into the handle (4) and the torque adjustment screw (7) screws into the latter.
Once the assembly has been completed, a functional check must be performed; simply activate the socket and the tool works properly if the wrench emits a regular clicking noise.
You can now sterilize the previously cleaned, greased and reassembled wrench.

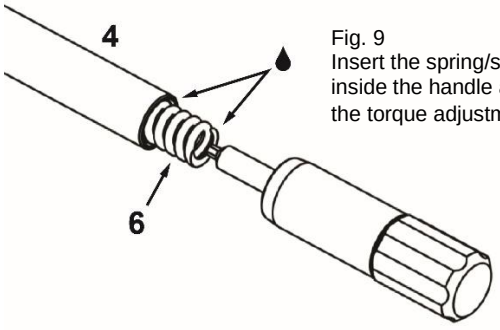


Fig. 9
Insert the spring/stop assembly inside the handle and tighten the torque adjustment screw.

5. Sterilisation

Before sterilisation, the wrench must be fully assembled and adjusted to its minimum torque (Fig 6 to 9).
The medical device must undergo steam sterilisation.

Recommended cycle: 3 (4 for the US market) pre-vacuums, 18 minutes at 134°C / 273°F at 2 bars and drying for 20 minutes.

We recommend the use of devices fitted with vacuum pumps (type B) to reduce the risk of air pockets forming. This recommendation is particularly important for hollow tools and to guarantee perfect drying. The hot air steriliser is not recommended as it can accelerate the ageing of the spring and consequently cause modification of the torque.

Inspection, maintenance and test

No inspection, calibration, or test is necessary for the torque wrench.

The wrench is delivered with a tolerance of ±7Ncm for a lifespan of 3 years, 300 sterilisations or 6,000 clicks. At the end of one of these lifespans, the devices must be returned to the supplier or distributor after a final cleaning process.

Fig. 10
Using the adjustment wrench makes it easier to reach upper torque values (wrench optional)