

Instruction Manual Torque Wrench

ENGLISH

1 Product Description

The Torque Wrench is a stainless steel multi-component tool designed to attach to screwdrivers, insertion tools, adapters, and drivers. It is supplied with a dual direction wrench mechanism (for insertion and removal function). When the selected torque value is reached – a choice of 10, 20, or 30 Ncm – the Torque wrench snaps. This prevents use of an undefined torque value. The Torque Wrench can be dismantled into five components for cleaning and care. It is supplied non-sterile and must be cleaned, disinfected and sterilized before first use and every use.

2 Indications

Tool for manual thread cutting and manual insertion of implants into the bone as far as the definitive position and for the tightening of abutment screws and abutments with a defined torque in Ncm.

3 Contraindications

Any indication not listed here is contraindicated.

4 General Safety Instructions and Warnings

- An improper procedure in surgery or prosthetics can lead to implant damage or bone loss. The BioHorizons[®] implant system should be used only by dentists, doctors and surgeons trained in the use of the implant system. Use of the implant system requires specialized knowledge and skills in implantology. Every patient must be thoroughly examined and evaluated on radiographic, psychological and physical parameters, including the condition of the teeth and deficits in the related hard and soft tissue that might affect the final outcome. Close collaboration between surgeon, prosthodontist and dental technician is essential for success. The BioHorizons[®] implant system and the related procedures were developed and clinically tested by experts in the field. Detailed information on the choice of suitable implants, prosthetic components, treatment planning and the use of BioHorizons[®] implants is available in the user information and on the BioHorizons[®] website at www.biohorizons.com. BioHorizons[®] also regularly offers courses or technical consultations on the use of its products. Your local BioHorizons[®] representative is glad to advise you.
- Since their safe application requires specialized knowledge, the BioHorizons[®] products are sold only to doctors/dentists and dental laboratories or on their prescription. Not all parts are available in all countries.
- It may happen, because of the small sizes involved, that a product is swallowed or aspirated. Aspiration can lead to dyspnea and in the worst case to asphyxiation. For this reason the products should be secured to prevent them being swallowed or aspirated during intra-oral use.
- Where indications are listed for a particular product, it should be noted that any indications that are not listed are in fact contraindicated.
- We guarantee the high quality of our products as part of our sales and delivery conditions. Specifications on existing patents, trademarks, or other intellectual rights are not legally binding.

5 Use

5.1 Fixation of Prosthetic Components

For the final placement in the implant, all abutment and prosthetic screws, bar, ball and Locator® abutments must be tightened at the specified torque using the torque wrench. Information on the relevant final torques is given in the corresponding product instructions.

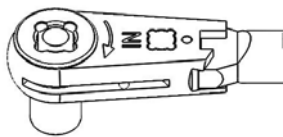
Caution:

- Only use NEW abutment screws to ensure optimal screw tension during final integration of the abutment.

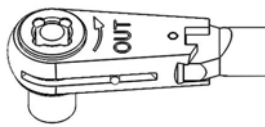
Tool Installation

The tools lock in during their insertion in the wrench wheel.

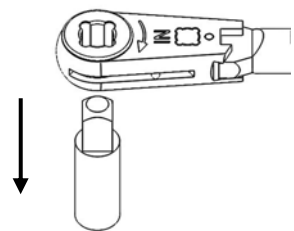
- For the insertion function: "IN" is visible on the wrench button
- For the removal function: "OUT" is visible on the wrench button.
- To remove, press on the tool button with the finger and remove downward. Do not use pliers!



Insertion function
"IN"



Removal function
"OUT"



Remove the tool
downward

Setting Torque Limits

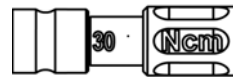
Screwing the torque adjustment screw in or out determines the release torque (10, 20 and 30 Newton centimeters).



10 Ncm

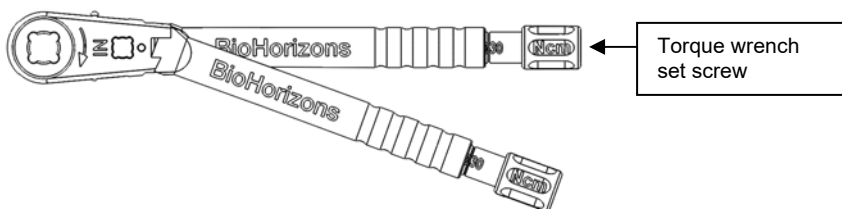


20 Ncm



30 Ncm

The torque wrench snaps when the release torque is reached. After that, do not tighten further!



5.2 Manual Thread Cutting and Implant Insertion

For these functions, the wrench is used in its locked position. The locked position is set as follows:

1. Loosen the torque wrench setscrew (counterclockwise).



2. Slide back the handle.



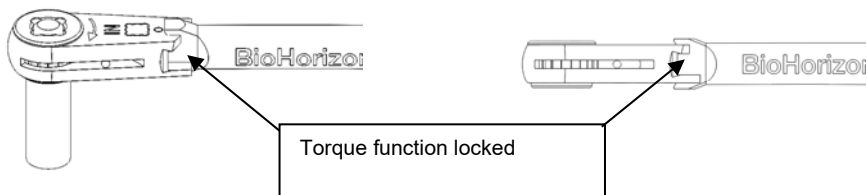
3. Rotate handle 90°.



4. Slide handle forward to the locking position in the wrench head.



5. Fasten the handle with the torque setscrew (clockwise).
The torque function is now locked.



6 Care and preparation

Note: Every deviation from the processes quoted here must be evaluated carefully by the processor for effectiveness and possible negative consequences. The operator is responsible for ensuring that actual reprocessing achieves the desired results with the equipment, materials and personnel used in the reprocessing plant. This requires validations and routine monitoring of the process.

For U.S.: The validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79:2006.

6.1 Disassembly

The torque wrench should be disassembled after use into its five components.

- To do this, completely unscrew the torque wrench setscrew (counterclockwise) and pull out the spring and handle.
- Pull back the fastening pin with your thumb and forefinger and remove the wrench wheel from the wrench head.

6.2 Cleaning and disinfection

General information for sterilizer and disinfectant

As part of your responsibility for the sterility of the products in application, please observe the following:

- A) In general, use only adequately validated methods specific to the equipment and product for cleaning/disinfection and sterilization.
- B) Regularly check and service the equipment used (thermal disinfectant, sterilizer).
- C) Observe the validated parameters in each cycle.
- D) Thorough cleaning and disinfection is indispensable for effective sterilization.
- E) When choosing a combined cleaning and disinfecting agent for initial disinfection and for manual cleaning and disinfection, one should make sure that:
 - ❖ it is suitable for cleaning and disinfecting dental instruments.
 - ❖ it is suitable for ultrasonic cleaning (no foam development).
 - ❖ it has a proven efficacy for disinfection (e. g. VAH/DGHM listed, CE marking for EU, or EPA registered and FDA compliant for U.S.).
 - ❖ it is compatible with the materials of the products to be cleaned and disinfected.
 - ❖ it does not contain aldehyde (otherwise blood, secretions, tissue remains, etc. may stick).
- F) The concentrations and application times as well as instructions for post-rinsing specified by the manufacturer must be observed.
- G) Two procedures are proposed in the following for cleaning and disinfection prior to sterilization: a mechanical procedure under point 6.2.1 and a manual procedure under point 6.2.2. Wherever possible, the mechanical procedure described under point 6.2.1 should be employed.

6.2.1 Mechanical cleaning and thermal disinfection

The worksteps are described as follows:

- 1) Initial disinfection: Immediately after use, immerse all instruments in a bath containing combined cleaning and disinfecting agent. This serves for user safety and prevents the contaminants from drying. The cleaning and disinfecting agent used for pre-treatment is only for personal protection and may not take the place of the disinfection step to be performed after cleaning.
- 2) Completely disassemble the torque wrench after use into its five components (see Section 6.1.).
- 3) Remove coarse contaminants from the torque wrench within a maximum of 2 hours after use.
- 4) Remove contaminants from the torque wrench under running water using a soft brush (no metal bristles or steel wool). The brush must be used exclusively for this purpose only. Brush until no visible contaminants remain.
- 5) Full rinse of the torque wrench for at least one minute under deionized water with a low bacterial count (maximum 10 bacteria/ml) and low endotoxin count (maximum 0.25 endotoxin units/ml).
- 6) **Disinfection of the pre-cleaned torque wrench in the thermal disinfectors:**

a. Thermal disinfectors (cleaning and disinfection device)

When choosing the thermal disinfectors (cleaning and disinfecting device), care should be taken that:

- In general, the thermal disinfectors has a proven efficacy (CE marking, compliant with EN ISO 15883 in Europe or FDA clearance in the U.S.) and is validated specifically for the equipment and product.
- A proven program for thermal disinfection is used (A0 value > 3000 or – for older devices – at least 5 min. at 90°C / 194°F).
- The program used is suitable for the instruments and includes sufficient rinsing cycles.
- Only deionized water with a low bacterial count (maximum 10 bacteria/ml) and low endotoxin count (maximum 0.25 endotoxin units/ml) is used for rinsing.
- The air used for drying is filtered.
- The thermal disinfectors (cleaning and disinfection device) is regularly checked and serviced.

Use only thermal disinfection that requires no disinfecting agent. Avoid using any rinse aids. There is a risk of disinfectant residues on the instruments when chemical disinfection is used.

b. Cleaning agents

When using cleaning agents, care should be taken that:

- In general, the cleaning agents are suitable for cleaning instruments made of metals and plastics.
- The chemicals used are compatible with the instruments.

We recommend the use of cleaning agents that require no neutralizing agents.

c. Worksteps

- Place the disassembled and pretreated torque wrench in the thermal disinfectors using a small parts basket. The torque wrench should not come into contact with other instruments.
- Start the program.
- Remove the torque wrench from the thermal disinfectors after program end.
- Dry the torque wrench if necessary. Use compressed dry air, free of oil and with a low bacterial count. We also recommend the use of a sterile filter.
- Inspect the torque wrench for signs of corrosion, surface damage, chipping or contamination. Remove damaged torque wrench from use. Re-clean and disinfect torque wrenches which are still contaminated.
- Assembly: Reassemble all disassembled torque wrenches (see Section 6.3)

- Packaging: Pack torque wrenches for sterilization promptly. We recommend using disposable sterilization packaging with CE marking in Europe or FDA clearance in the U.S. It must be ensured that the sterilization packaging is suitable for steam sterilization (constant temperature of at least 141°C / 286°F, sufficient vapor permeability) and that the products are adequately protected against mechanical damage.

General note

The proof of general suitability for effective mechanical cleaning and disinfection was provided by an independent accredited testing laboratory taking into account the above-described procedure. A thermal disinfectant (cleaning and disinfecting device) G 7836 CD (Manufacturer: Miele & Cie. GmbH & Co., Gütersloh) and neodisher medizym as the cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) were used. The procedure described above was taken into account.

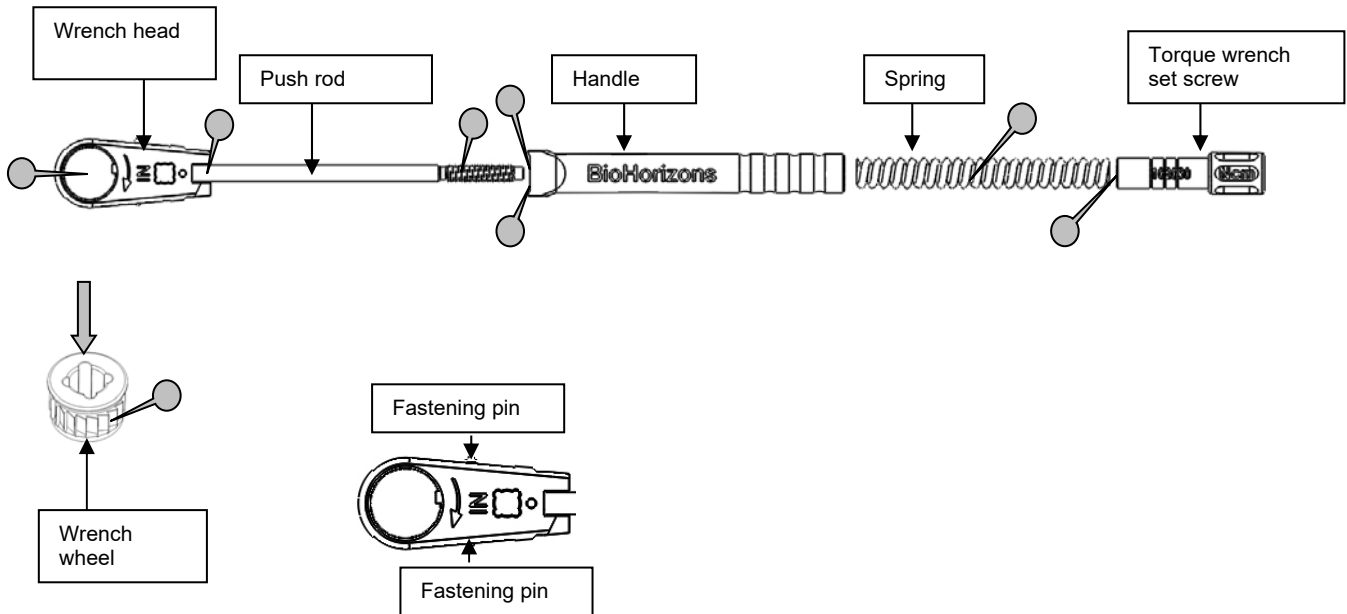
6.2.2 Manual cleaning and disinfection

The worksteps are described as follows:

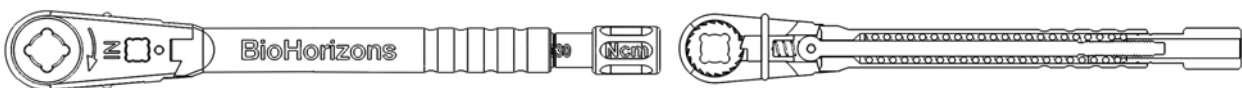
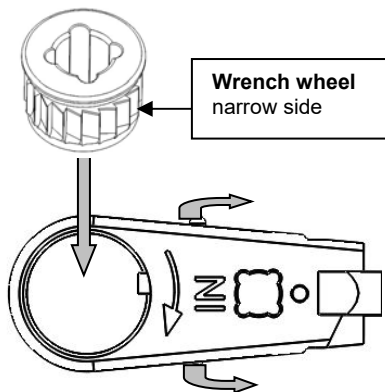
- 1) Initial disinfection: Immediately after use, immerse all instruments in a bath containing combined cleaning and disinfecting agent. This serves for user safety and prevents the contaminants from drying. The cleaning and disinfecting agent used for pre-treatment is only for personal protection and may not take the place of the disinfection step to be performed after cleaning.
- 2) Completely disassemble the torque wrench after use into its five components (see Section 6.1.).
- 3) Remove coarse contaminants from the torque wrench within a maximum of 2 hours after use. For this purpose use a disposable cloth, running water, and a soft brush (no metal bristles or steel wool). The brush must be used exclusively for this purpose only.
- 4) Place the torque wrench in a bath of freshly prepared combined cleaning and disinfecting solution for the scheduled application time, making sure it is completely covered. The torque wrench is not to come into contact with one another. In case of persistent contamination use an ultrasonic unit. To completely remove residue, brush off the instruments with a soft brush (no metal bristles or steel wool). The brush must be used exclusively for this purpose only.
- 5) Remove the torque wrench, rinse it completely for at least one minute under deionized water with a low bacterial count (maximum 10 bacteria/ml) and low endotoxin count (maximum 0.25 endotoxin units/ ml). Take particular care in rinsing the areas that have limited access.
- 6) Dry the torque wrench. Use a loose lint free disposable cloth and compressed dry air, free of oil and with a low bacterial count. We also recommend the use of a sterile filter.
- 7) Inspect the torque wrench for signs of corrosion, surface damage, chipping or contamination. Remove damaged torque wrench from use. Re-clean and disinfect torque wrenches which are still contaminated.
- 8) Assembly: Reassemble all disassembled torque wrenches (see Section 6.3)
- 9) Pack instruments for sterilization promptly. We recommend using disposable sterilization packaging with CE marking in Europe or FDA clearance in the U.S. It must be ensured that the sterilization packaging is suitable for steam sterilization (constant temperature of at least 141°C / 286°F, sufficient vapor permeability) and that the products are adequately protected against mechanical damage.

6.3 Assembly

Lubricate the indicated places (●) with contra-angle handpiece oil or spray and reassemble the torque wrench.



- First install the wrench wheel: with your thumb and forefinger, pull back the fastening pin on both sides and insert the wrench wheel narrow side in the wrench head ("IN" must show).
- Slide the handle back on, insert the spring in the handle, insert and tighten the torque setscrew (clockwise).



6.4 Sterilization

Permissible steam sterilization procedures are fractionated vacuum / dynamic air removal and gravity displacement procedures (with sufficient product drying). Other sterilization procedures are not allowed.

If using gravity displacement sterilization, note that the device must be packaged in a single-sterilization bag only (no double sterile packaging, no sterilization container).

Parameters:

- Fractionated vacuum / dynamic air removal:
4 minutes at 132°C / 270°F
- Gravity displacement:
15 minutes at 132°C / 270°F or
30 minutes at 121°C / 250°F

A minimum drying time of 30 minutes is recommended for each of the cycles described above.

Care should be taken that:

- The maximum steam sterilization temperature is 138°C / 280°F.
- The steam sterilizers used have CE marking and comply with the requirements of EN 13060 or EN 285 in Europe or have FDA clearance in the U.S.
- In general, use only adequately validated methods specific to the equipment and product for sterilization according to ISO 17665.
- Regularly check and service the sterilizers used.
- Observe the validated parameters in each cycle.

Attention: All non-sterile packed products must not be sterilized in the original packaging!

Important information: If not otherwise specified, torque wrenches may be reprocessed as long as they are maintained in working condition according to the instruction manuals and processing procedures.

7 Explanation of Symbols



Non-sterile



Consult instructions for use



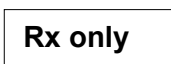
Article number



Lot number



Manufacturer



Caution: US Federal law restricts this device to sale by or on the order of a dentist or physician.

8 Contact

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