

Manual Torque Wrench Prosthetic

Instructions for use



Important: Please read.

Disclaimer of liability:

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Description:

The Manual Torque Wrench Prosthetic is a manual reusable wrench used to ensure that correct torque is achieved during manual tightening of Nobel Biocare abutments and abutment screws. The Manual Torque Wrench Prosthetic can be connected to screw drivers via the Manual Torque Wrench Adapter Prosthetic that can be inserted in the wrench. Torque level is indicated on a scale when a lever arm is loaded with a certain load (force). The scale has markings for the recommended torque values when using Nobel Biocare products. The Manual Torque Wrench Prosthetic consists of a wrench body and a metal rod that is inserted in the body to set the direction of rotation.

Intended use:

The Manual Torque Wrench Prosthetic is intended to be used to tighten Nobel Biocare abutments and abutment screws and can be used as a controlled alternative to machine tightening.

Indication:

The Manual Torque Wrench Prosthetic is indicated to be used with Nobel Biocare abutments and abutment screws and to ensure that correct torque is achieved during manual tightening.

Contraindications:

In general, contraindications are applicable for implant surgery related procedures in patients:

- who are medically unfit for an oral surgical procedure.
- who are allergic or hypersensitive to commercially stainless steel.

Warnings:

Do not use the Manual Torque Wrench Prosthetic for any purpose other than the manual tightening of Nobel Biocare abutments and abutment screws.

Cautions:

Care and maintenance of instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components. Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

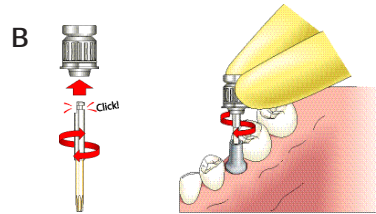
Handling procedure:

For tightening of abutments and abutment screws, always start with manual tightening (steps 1 and 2) before using the wrench (steps 3 and 4).

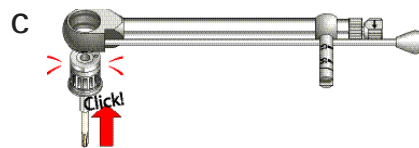
1. For manual tightening, remove the Manual Torque Wrench Adapter Prosthetic (Fig. A).



2. Insert the driver and tighten the prosthetic component in a clockwise direction (Fig. B). See drawing for proper instruction on the movement to connect the driver.



3. For tightening with the wrench, insert the Manual Torque Wrench Adapter Prosthetic into the Manual Torque Wrench Prosthetic. A click will indicate that the adapter is fitted correctly (Fig. C).

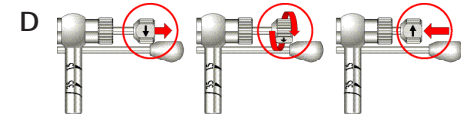


4. Secure that arrow is pointing in clockwise direction (Fig. D). Tighten the prosthetic component with the tightening torque specified in the procedures manual and/or Instructions for Use for the applicable product.

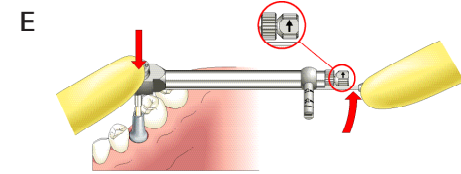
Warning: By applying force on the main body of the ratchet and not the lever arm, the applied torque cannot be measured, which could result in excessive torque which may lead to damage of the prosthetic component.

Caution: Never exceed recommended maximum prosthetic tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

5. If necessary, the prosthetic component can be backed out using the Manual Torque Wrench Prosthetic with the direction indicator in reverse mode / counter-clockwise direction (Fig. D).



6. Apply manual pressure to the lever arm to unscrew the prosthetic component (Fig. E).



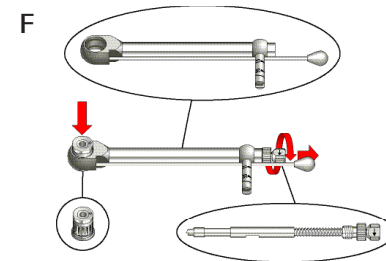
For additional information on surgical procedures please consult the procedures manual from the respective implant systems available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

Medical grade stainless steel.

Cleaning and sterilization instructions:

The devices are delivered non-sterile for re-use and must be cleaned and sterilized prior to use. After use, disassemble Manual Torque Wrench Prosthetic by removing the adapter and the rod from the wrench body as shown in Fig. F. Clean the parts thoroughly under lukewarm water. After visual inspection of the parts and allowing them to dry completely, reassemble the instrument and continue with sterilization according to cleaning and sterilization guidelines.



For USA: Seal single device in a pouch and steam sterilize at 270°F (132°C) for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132°C–135°C (270°F–275°F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134°C–135°C (273°F–275°F) for 3 minutes.

Full set of recommended parameters are provided in "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Warning: Use of non-sterile components may lead to infection of tissues or infectious diseases.

MR safety information:

Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

Storage and handling:

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

Manufacturer: Nobel Biocare AB, Box 5190, 402 26 Västra Hamngatan 1, 411 17 Göteborg, Sweden. Phone: +46 31 81 88 00. Fax: +46 31 16 31 52. www.nobelbiocare.com



Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription device: Rx only

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

Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.



Authorized representative in the European Community



Batch code



Catalogue number



Caution



CE marking



Consult instructions for use



Contains hazardous substances



Contains or presence of phthalate



Date



Date of manufacture



Do not resterilize



Do not re-use



Do not use if package is damaged



Double sterile barrier system

Rx Only

For prescription use only



Health care centre or doctor



Keep away from sunlight



Keep dry

symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com

Link to Online Symbols Glossary and IFU Portal



Magnetic resonance conditional



Manufacturer



Medical device



Non-pyrogenic



Non-sterile



Patient identification



Patient information website



Patient number



Serial number



Single sterile barrier system



Single sterile barrier system with protective packaging inside



Single sterile barrier system with protective packaging outside



Sterilized using ethylene oxide



Sterilized using irradiation



Temperature limit



Tooth number



Upper limit of temperature



Sterilized using steam or dry heat



Unique Device Identifier



Use-by date

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