

Manual Torque Wrench Surgical

Instructions for use



Important: Please read.

Disclaimer of liability:

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Description:

The Manual Torque Wrench Surgical is a manual re-usable wrench used to ensure that correct torque is achieved during manual insertion of implants. The instrument can be connected to implant drivers via the Manual Torque Wrench Adapter Surgical 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 Surgical consists of a wrench body and a metal rod that is inserted in the body to set the direction of rotation. Two different models of the Manual Torque Wrench Surgical exist, one for NobelActive® and one for the remaining Nobel Biocare implant systems. The different connections are handled by different adapters that are inserted into the wrench.

Intended use:

The Manual Torque Wrench Surgical is intended to be used to insert Nobel Biocare implants and obtain correct insertion torque.

Indications:

The Manual Torque Wrench Surgical is indicated to be used with Nobel Biocare implants to ensure that correct torque is achieved during manual insertion. The device is available in different versions depending on the implant system used.

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 Surgical for any purpose other than the manual insertion of Nobel Biocare implants with internal conical connection, tri-channel connection or external hex connection.

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.

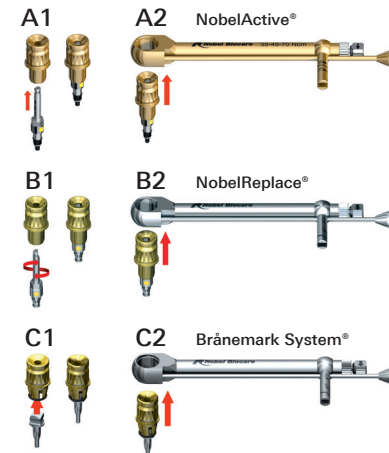
It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

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:

1. Depending on the implant system used, select the corresponding Manual Torque Wrench Adapter Surgical and insert the corresponding Implant Driver into the adapter (Fig. A1-C1). See figures for proper instruction on the movement to connect the driver.
2. Depending on the implant system used, insert the Manual Torque Wrench Adapter Surgical into the Manual Torque Wrench Surgical (Fig. A2-C2). A click will indicate that the adapter is fitted correctly.

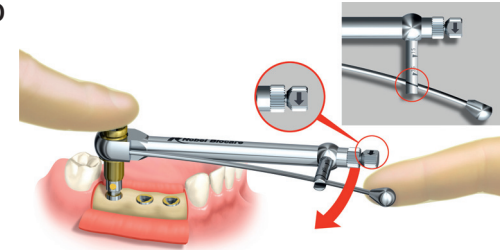
Note: The Manual Torque Wrench Surgical cannot be used with manual screwdrivers.



3. Secure that the arrow is pointing in clockwise direction before use. For correct insertion torque, see the procedures manual and/or Instructions for Use for the applicable implant. The maximum insertion torque is indicated with a line on the scale.
4. Connect the Implant Driver to the implant. Put your finger on top of the adapter and apply gentle pressure to the lever arm of the wrench not exceeding the maximum insertion torque (Fig. D). Move as far as possible and release handle in counterclockwise direction (indicated by noise of ratchet). Repeat procedure until desired insertion depth is achieved.

Caution: Overtightening of implant may lead to damage of the implant, fracture or necrosis of the bone site. If a Surgical Driver is used to insert the implant, special care needs to be taken to avoid overtightening.

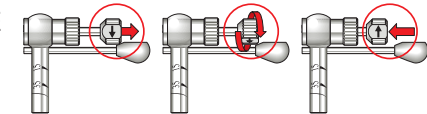
D



Warning: By applying force on the main body of the ratchet and not the lever arm, the applied torque cannot be measured. High forces may cause over compression of the bone leading to bone resorption, especially in case of a thin buccal / lingual marginal bone crest.

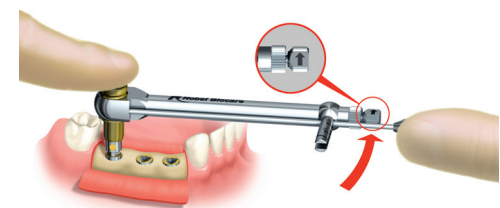
5. If necessary, the implant can be backed out using the Manual Torque Wrench Surgical with the direction indicator in reverse mode / counter-clockwise direction (Fig. E).

E



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

F



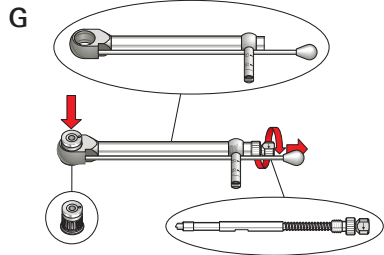
For additional information on surgical procedures please consult the procedures manual from the respective implant systems available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

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 Surgical by removing the adapter and the rod from the wrench body as shown in Fig. G. 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

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Prescription device: Rx only

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

CE 0086

Rx Only



Non-sterile



Caution



Consult instructions
for use



Use-by date



Batch code

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