Manual Torque Wrenches Surgical and Prosthetic

Instructions for use

Important – Disclaimer of Liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

Manual Torque Wrenches are reusable manual wrenches used for manual insertion and tightening or loosening of Nobel Biocare implants, abutments and abutment screws with a specific amount of torque. It can also be used with Implant Retrieval Instruments and Abutment Screw Retrieval Instruments. Manual Torque Wrenches consist of a wrench body and a metal rod that is inserted in the wrench body to set the direction of rotation. The applied torque 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. For the recommended torque values refer to the Instruction For Use of the implant system and prosthetic component in use.

The following models of Manual Torque Wrench are available:

- NobelActive Manual Torque Wrench Surgical (for use with NobelActive implant system).
- NobelReplace Manual Torque Wrench Surgical (for use with NobelReplace and NobelParallel CC implant systems).
- Brånemark System® Manual Torque Wrench Surgical (for use with Brånemark System® and Nobel Speedy implant systems).
- Manual Torque Wrench Surgical Nobel Biocare N1™ (for use with Nobel Biocare N1™ implant system).
- Manual Torque Wrench Prosthetic Nobel Biocare N1™ (for use with Nobel Biocare N1™ compatible prosthetic screwdrivers as shown in Table 1).
- Manual Torque Wrench Prosthetic (for use with compatible prosthetic screwdrivers as shown in Table 1).

The NobelReplace Manual Torque Wrench Surgical, Brånemark System® Manual Torque Wrench Surgical, and the Manual Torque Wrench Prosthetic must be connected to implant drivers and screw drivers via dedicated Manual Torque Wrench Adapters that are inserted in the wrenches. The Manual Torque Wrench Adapters contain O-rings which are used to secure retention of the instruments inserted into the wrench. Adapters and O-rings are also available separately as spare parts.

Table 1 summarizes the available torque wrenches and torque wrench adapters, and the compatible implant drivers and/or screw drivers.

Table 1: Manual Torque Wrenches, Wrench Adapters, and Compatible Drivers

Wrench	Wrench Adapter	Instruments
NobelActive Manual Torque Wrench Surgical	NOBELREPLACE® Manual Torque Wrench Adapter Surgical	Implant Driver CC 3.0 28mm (IFU1090) Implant Driver CC 3.0 for Slim Abutment (IFU1090) Implant Driver CC NP (IFU1090) Implant Driver CC NP for Slim Abutment (IFU1090) Implant Driver CC RP (IFU1090) Implant Driver CC RP for Slim Abutment (IFU1090) Implant Driver CC WP (IFU1090) Implant Retrieval Instruments (IFU1097) Abutment Screw Retrieval Instrument (IFU1043)
NOBELREPLACE® Manual Torque Wrench Surgical	NOBELREPLACE® Manual Torque Wrench Adapter Surgical	
Brånemark System® Manual Torque Wrench Surgical	Brånemark System® Manual Torque Wrench Adapt Surgical	Implant Driver Bmk Syst NP (IFU1090) Implant Driver Bmk Syst RP (IFU1090) Implant Driver Bmk Syst WP (IFU1090)
Manual Torque Wrench Surgical Nobel Biocare N1™	NOBELREPLACE® Manual Torque Wrench Adapter Surgical	Implant Driver Nobel Biocare N1™ TCC NP (IFU1087) Implant Driver Nobel Biocare N1™ TCC RP (IFU1087) Implant Retrieval Instruments (IFU1097) Abutment Screw Retrieval Instrument (IFU1043)
Manual Torque Wrench Prosthetic	Manual Torque Wrench Adapter Prosthetic	Screwdriver Machine Unigrip (IFU1085) Screwdriver Machine Multi-Unit (IFU1085) Omnigrip Screwdriver Machine (IFU1085) On1 Base Screwdriver Machine (IFU1074) Screwdriver Machine Multi-unit Branemark System (IFU1085) Screwdriver Machine Ball Abutment (IFU1085)
Manual Torque Wrench Prosthetic Nobel Biocare N1™	Manual Torque Wrench Adapter Prosthetic	Screwdriver Machine Omnigrip Mini (IFU1085) Screwdriver Machine Multi-Unit (IFU1085)

Intended Use/Intended Purpose:

Manual Torque Wrenches Surgical and Prosthetic:
Intended for use to tighten and/or loosen dental implant system components with a measurable amount of torque.

Manual Torque Wrench Adapters:
Intended for use as an interface between a wrench and the instrument used to tighten or loosen dental implant system components.

Indications:

Manual Torque Wrenches Surgical:
Manual Torque Wrenches Surgical are indicated for use with Nobel Biocare dental implant drivers to ensure that the desired torque is achieved during implant placement. They are also indicated to be used with implant retrieval instruments and abutment screw retrieval instruments. Manual Torque Wrenches Surgical can be used as an alternative to machine torque wrenches.

Manual Torque Wrenches Prosthetic:
Manual Torque Wrenches Prosthetic are indicated for use with Nobel Biocare abutments and abutment screws to ensure that the desired torque is achieved during placement or removal of the abutment or screw. Manual Torque Wrenches Prosthetic can be used as an alternative to machine torque wrenches.

Manual Torque Wrench Adapters:
Manual Torque Wrench Adapters are indicated for use to connect implant drivers, screwdrivers, implant retrieval instruments and abutment screw retrieval instruments to the Manual Torque Wrenches Surgical and Prosthetic.

Contraindications:

It is contraindicated to use Manual Torque Wrenches in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are allergic or hypersensitive to medical grade stainless steel, fluoroelastomer-PAI-Compound-9844 or Elastomer Klarez Compound 6230.

It is contraindicated to use the Manual Torque Wrench Prosthetic Nobel Biocare N1™ with components that requires a maximum torque higher than 20 Ncm.

Cautions:

General:
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Manual Torque Wrenches Surgical and Prosthetic must only be used with compatible Nobel Biocare instruments and components. Use of instruments and components that are not intended to be used in combination with the Manual Torque Wrenches Surgical and Prosthetic can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment for the first time, working with a colleague who is experienced with the new device/treatment may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

Before Surgery:
All components, instruments and tooling used during the clinical and laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

The device has not been evaluated in pediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jaw bone growth phase has been properly documented.

At Surgery:
Care and maintenance of sterile 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.

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. gauze, dental dam, or throat shield).

Overtightening an implant may lead to damage of the implant, fracture or necrosis of the bone site.

Intended Users and Patient Groups:

Manual Torque Wrenches Surgical and Prosthetic are to be used by dental health care professionals.

Manual Torque Wrenches Surgical and Prosthetic are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Manual Torque Wrenches Surgical and Prosthetic:
Manual Torque Wrenches Surgical and Prosthetic are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with Manual Torque Wrenches Surgical and Prosthetic:
During use of these devices the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Notice regarding serious incidents:
For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB

https://www.nobelbiocare.com/complaint-form

Handling Procedure:

Manual Torque Wrenches Surgical:

1. Depending on the implant system used, select the corresponding Manual Torque Wrench Adapter Surgical and insert the corresponding Implant Driver into the adapter.
2. Depending on the implant system used, insert the Manual Torque Wrench Adapter Surgical into the Manual Torque Wrench Surgical. A click will indicate that the adapter is fitted correctly.
3. Manual Torque Wrench Nobel Biocare N1™ must be used only with Nobel Biocare N1™ components.

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

4. The arrow on the knob at the end of the wrench indicates which direction the torque is applied (clockwise or counterclockwise). Twist the knob to ensure that the arrow is pointing in clockwise direction before tightening. The maximum insertion torque is indicated by a line on the scale. Refer to the Nobel Biocare Instructions for Use (IFU) for the applicable implant for the maximum insertion torque to be applied.
5. 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 (**Figure A**). Tighten the implant by rotating the wrench clockwise as far as possible, and then release the handle in counterclockwise direction (indicated by noise of ratchet). Repeat this procedure until the desired insertion depth or the maximum insertion torque has been achieved.

A

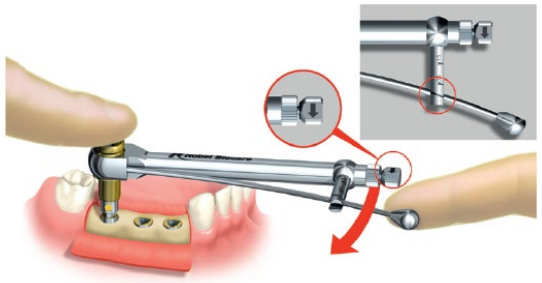

Figure A: Applying Torque to the Manual Torque Wrench Surgical

Warning: If force is applied to the main body of the Manual Torque Wrenches Surgical and not to 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.

6. If necessary, the implant can be backed out using the Manual Torque Wrench Surgical with the direction indicator in the reverse (counter clockwise) direction (**Figure B**). Pull the knob and simultaneously rotate it so that the arrow is pointing counter clockwise direction (**Figure G**).

B

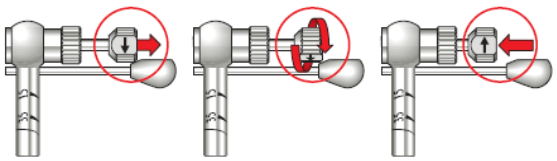

Figure B: Setting the Manual Torque Wrench Surgical to Reverse Mode

Apply manual pressure to the lever arm to unscrew the implant (**Figure C**).

C

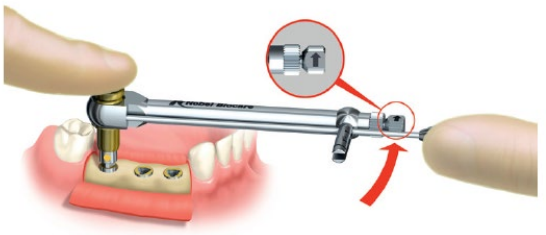

Figure C: Unscrewing Implant with Manual Torque Wrench Surgical in Reverse Mode

Manual Torque Wrenches Prosthetic:

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 (**Figure D**).

D

Figure D: Removal of Manual Torque Wrench Adapter

2. Insert the screwdriver into the adapter and tighten the prosthetic component in a clockwise direction (**Figure E**).

E

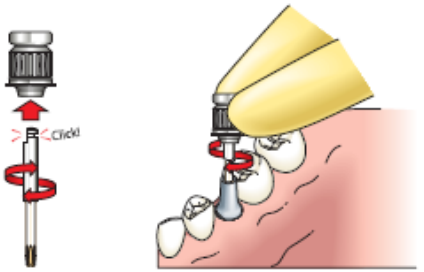

Figure E: Engagement of screwdriver with Manual Torque Wrench Adapter

3. For tightening with the wrench, insert the Manual Torque Wrench Adapter Prosthetic with the screwdriver into the Manual Torque Wrench Prosthetic. A click will indicate that the adapter is fit correctly (**Figure F**).

F

Figure F: Engagement of Adapter with Manual Torque Wrench

4. Secure that arrow is pointing clockwise direction (**Figure G**). 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. Tighten the prosthetic component with the tightening torque specified in the Instructions For Use for the applicable product.

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

G

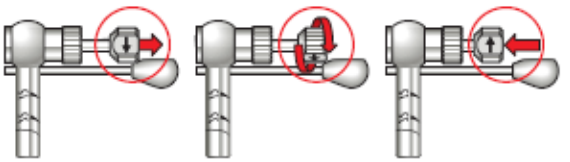

Figure G: Reverse of direction indicator

5. If necessary, the prosthetic component can be backed out using the Manual Torque Wrench Prosthetic and the screwdriver with the direction indicator in reverse mode/counter-clockwise direction (**Figure G**).
6. Apply manual pressure to the lever arm to unscrew the prosthetic component (**Figure H**).

H

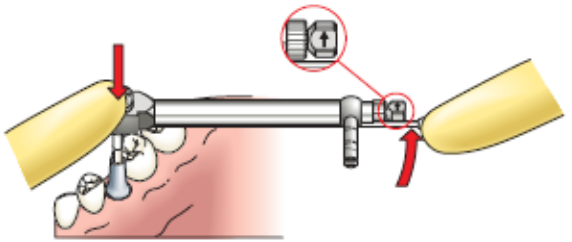

Figure H: Unscrew prosthetic component

Materials:

- Manual Torque Wrenches Surgical and Prosthetic: Stainless steel (ASTMF899).
- Manual Torque Wrench Adapters (main body): Stainless steel (ASTMF899).
- O-ring (NobelActive Manual Torque Wrench Surgical, NobelReplace Manual Torque Wrench Surgical, Manual Torque Wrench Surgical Nobel Biocare N1™): fluroelastomer-PAI-Compound-9844 (USP VI).
- O-ring (Brånemark System® Manual Torque Wrench Surgical): Elastomer Klarez Compound 6230 (USP Class VI).

Sterility and Reusability Information:

Manual Torque Wrenches Surgical and Prosthetic are delivered non-sterile and are intended for reuse. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Manual Torque Wrenches Surgical and Prosthetic are reusable instruments which must be inspected before each reuse to ensure that the integrity and performance of the instrument is maintained. Before each use, inspect the devices for signs of degradation that may limit the useful life of the device, such as the following:

- Inspect for the bending of torque arm in its home position.
- Inspect for visible corrosion.
- Ensure that the components engage the adapter.
- Ensure that the direction indicator and screw are fully seated in home position.
- Ensure that laser marking of device is clearly legible.

The degree of accuracy of Manual Torque Wrenches Surgical and Prosthetic is claimed within the following tolerances:

- NobelActive Manual Torque Wrench Surgical: ± 5 Ncm (measured at 35 Ncm, 45 Ncm and 70 Ncm) over 10 years of use.
- Branemark System Manual Torque Wrench Surgical and NobelReplace Manual Torque Wrench Surgical: ± 2 Ncm, at 15 Ncm, 35 Ncm and 45 Ncm, over 8 years of use.

- Manual Torque Wrench Surgical Nobel Biocare N1™: ± 5 Ncm at 70 Ncm over 10 years.
- Manual Torque Wrench Prosthetic Nobel Biocare N1™: ± 2 Ncm at 20 Ncm over 10 years.
- Manual Torque Wrench Prosthetic: ± 2 Ncm at 45 Ncm for 10 years.

Cleaning and Sterilization Instructions:

Manual Torque Wrenches are delivered non-sterile by Nobel Biocare and is intended for reuse. Prior to each use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12.
- Sterilization: AAMI ST79 and ISO 17665-1.

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note: The manufacturer's instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note: The Manual Torque Wrenches Surgical have been validated to withstand these cleaning and sterilization procedures.

Caution: Do not deviate from the following reprocessing instructions.

Initial Treatment at Point of Use Prior to Reprocessing:

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.
3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Note: Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning):

Pre-cleaning:

1. Disassemble the Manual Torque Wrenches prior to cleaning by removing the adapter and the rod from the wrench body as shown in **Figure I**.

I

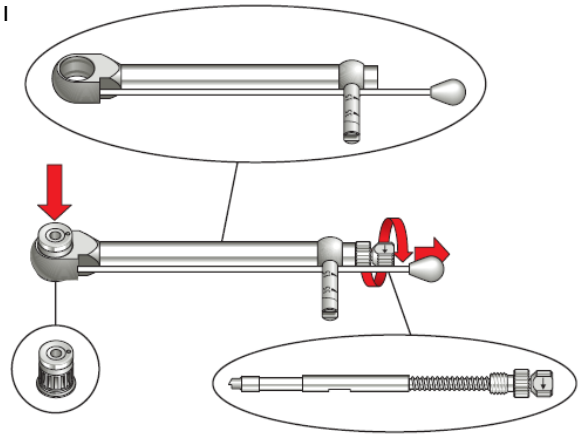

Figure I: Disassembly of the Manual Torque Wrench

2. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.
5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 20 seconds until all visible soil is removed.
6. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying:

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note: It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying:

1. Disassemble the Manual Torque Wrenches prior to cleaning by removing the adapter and the rod from the wrench body as shown in Figure I.
2. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
5. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/maximum 45°C (113°F).
8. Flush the inner surfaces, lumina and cavities of the Manual Torque Wrenches for a minimum of 15 seconds using a water jet pistol
9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
10. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly dispose any devices that fail the inspection.

Sterilization:

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 (pre-vacuum cycle); Amsco Century Sterilizer (gravity cycle).

Note: It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

Caution: Keep dissimilar metals separated during sterilization to resist corrosion

1. Reassemble the Manual Torque Wrench and seal each device in a suitable sterilization pouch.

Note: Make sure that the rod is properly screwed inside the Manual Torque Wrench main body.

The sterilization pouch should fulfill the following requirements:

- EN ISO 11607 and/or DIN 58953-7.
- Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
- Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 2 presents examples of suitable sterilization containers, pouches, and wraps.

Table 2: Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch
Pre-vacuum Cycle	SteriCLIN® pouch

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (**Table 3**):

Table 3: Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar[4]
Pre-Vacuum Cycle[1]	132°C (270°F)	4 minutes		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

[1] Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

[2] Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

[3] Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.

[4] Saturated steam pressure at 132°C as per required by EN ISO 17665-2.

[5] Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note: Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance:

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/Shipping to Point of Use:

The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Performance Requirements and Limitations:

To achieve the desired performance, Nobel Biocare Guided Surgery Tooling must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with Nobel Biocare Guided Surgery Tooling, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training:

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

Storage, Handling and Transportation:

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

Disposal:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information:

Manufacturer:
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411 17 Göteborg
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www.nobelbiocare.com

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Macquarie Park, NSW 2113 Australia
Phone: +61 1800 804 597

Distributed in New Zealand by:
Nobel Biocare New Zealand Ltd
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Phone: +64 0800 441 657

CE Mark for Class I Devices

CE 2797 CE Mark for Class Ir Devices

Note: Refer to the product label to determine the applicable CE mark for each device.

Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Product	Basic UDI-DI Number
NobelActive Manual Torque Wrench Surgical	73327470000001887P
NOBELREPLACE® Manual Torque Wrench Surgical	
Brånemark System® Manual Torque Wrench Surgical	
Manual Torque Wrench Surgical Nobel Biocare N1™	
Manual Torque Wrench Prosthetic	
Manual Torque Wrench Prosthetic Nobel Biocare N1™	
NOBELREPLACE® Manual Torque Wrench Adapter Surgical	73327470000001907A
Brånemark System® Manual Torque Wrench Adapt Surgical	
Manual Torque Wrench Adapter Prosthetic	

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 mark

CE mark with Notified Body number


Consult instructions for use


Contains hazardous substances

Contains or presence of DEHP phthalate

Contains or presence of natural rubber latex

Contains or presence of phthalate

Date


Date of manufacture

Do not resterilize

Do not re-use


Do not use if package is damaged

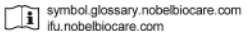

Double sterile barrier system

Rx only
For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional

Magnetic resonance safe


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

Sterilized using steam or dry heat


Temperature limit

Tooth number

Unique Device Identifier

Upper limit of temperature

Use-by date