Screwdrivers
Instructions for use

Omnigrip™ Mini

Omnigrip™

Important – Disclaimer of Liability:

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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:

Screwdrivers are reusable instruments which are used in conjunction with Nobel Biocare clinical screws, abutment screws, cover screws, prosthetic screws, prosthetic components (e.g. laboratory screws, abutments, healing abutments, impression copings), rescue tools (bone mill guides, abutment retrieval tool), and drill stops.

The "machine" versions of the screwdrivers feature a fitting compatible to ISO 1797-1 in order to connect the driver (using a wrench adapter) to the Manual Torque Wrench Prosthetic, while the "manual" versions of the screwdrivers have an attached handle to hold and turn the driver by hand. See Nobel Biocare Instructions for Use (IFU) IFU1047 for information regarding the Manual Torque Wrench Prosthetic. This IFU is available for download at ifu.nobelbiocare.com.

Table 1: Compatible Interfaces, Connections, and Instruments

Screwdriver	Screw Interface	Handpiece connection	Instruments
Omnigrip Screwdriver Manual	Omnigrip	n/a	n/a
Omnigrip Screwdriver Machine	Omnigrip	Instruments with ISO 1797 fitting	– Handle for Machine Instruments – Torque Wrench adapters
Omnigrip Mini Screwdriver Manual	Onmigrip Mini	n/a	– Impression Coping TCC
Omnigrip Mini Screwdriver Machine	Onmigrip Mini	Instruments with ISO 1797 fitting	– Handle for Machine Instruments – Torque wrench adapters – Impression Coping TCC

Screwdrivers Omnigrip™ and Omnigrip™ Mini (Manual and Machine):
The Screwdrivers Omnigrip™ and Omnigrip™ Mini are used to tighten screws and prosthetic components where the interface allows an angulation between screw and screwdriver of up to 25°. These screwdrivers can be used to engage the respective screw or component in order to pick up and transfer it from outside the oral cavity to the implant site, and to subsequently loosen or tighten the screw or component.

The Screwdrivers Omnigrip™ and Omnigrip™ Mini are available in both manual and machine versions and in various lengths and are compatible with screws and prosthetic components which feature the Omnigrip™ or Omnigrip™ Mini interface, respectively.

Intended Use:

Screwdrivers Manual and Machine:
Intended for use to tighten and/or loosen screws used to connect dental implant system components.

Indications for Use:

Same as Intended Use / Intended Purpose.

Contraindications:

It is contraindicated to use Screwdrivers in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are contraindicated for treatment with Nobel Biocare implants or restorative components.
- Patients who are allergic or hypersensitive to stainless steel or titanium nitride (TiN).

For contraindications specific to the screws, abutment, or other components, refer to the Nobel Biocare Instructions for Use for the respective component:

Table 2: Instruction For Use of Components

Components	Instruction For Use references
Clinical Screw, Abutment Screw, Prosthetic	IFU1057
Healing Abutment	IFU1026
Manual Torque Wrenches Surgical and Prosthetic	IFU1047
Impression coping	IFU1086
Bone Mills and Bone Mill Guides	IFU1032
Abutment Retrieval Instrumentation	IFU1041
Drill Stop Kits for Guided and Freehand	IFU1036
Nobel Guided Surgery Tooling	IFU2004/2005/2006

Cautions:

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

The Screwdrivers must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with the Screwdrivers can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method 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 surgical and laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

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 sizes 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).

Handling Procedure:

Manual Screwdrivers:
Note: Prior to use, loop dental floss through the hole in the handle of the manual screwdriver to prevent dropping the instrument, potentially into the mouth of the patient where it may be aspirated or swallowed.

1. Engage the screwdriver to the screw or component with light pressure.
2. Tighten or loosen the screw/component by hand.

Machine Screwdrivers:
1. Connect the screwdriver to the Manual Torque Wrench Adapter Prosthetic.
2. Engage the screwdriver to the screw or component with light pressure.
3. Connect the Manual Torque Wrench Prosthetic to the screwdriver/wrench adapter assembly and tighten the screw/component to the recommended tightening torque. For the maximum tightening torque of the screws or components which are compatible with the screwdrivers refer to the IFU for the screw/component. The maximum allowed tightening torque of the screwdrivers is presented in Table 3.

Table 3: Maximum Tightening Torque for Machine and Manual Screwdrivers

Screwdriver	Maximum Tightening Torque
Omnigrip™	35 Ncm
Omnigrip™ Mini	20 Ncm

Caution: Never exceed recommended maximum tightening torque in applicable instructions for use of the surgical or prosthetic screw/component. Overtightening of the screw may lead to a screw fracture and/or damage of the component.

Caution: In case the Screwdriver Omnigrip™ or Omnigrip™ Mini is used at an angulation to the screw and slips out of the interface, increase the axial force applied on the screwdriver, or try reducing the angulation of the screwdriver to the screw.

Note: Machine screwdrivers can be connected to the Handle for Machine Instruments instead of the torque wrench, and can then be used manually. Refer to Nobel Biocare IFU1058 for more information regarding the Handle for Machine Instruments.

Materials:

Screwdrivers Omnigrip™, Omnigrip™ Mini (Manual and Machine): Stainless steel AISI 303 / AISI 304 / 420F Mod according to ASTM F899, with titanium nitride (TiN) coating.

Sterility and Reusability Information:

Sterility and Reusability Claims for Product Category II:
Screwdrivers 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.

The screwdrivers are reusable instruments which shall be inspected before each re-use to ensure that the integrity and performance continues to be maintained. Check if any wear, abrasion of the coating, deformations or corrosion is visible on the instrument. Screwdrivers showing those signs shall be discarded.

If with slight pressure the Screwdriver Omnigrip and Omnigrip Mini do not engage in the respective screw, the screwdriver is worn and shall be discarded.

Warning: Do not use device if the packaging has been damaged or previously opened.

Note: Screwdrivers can be processed as individual devices as described in the Cleaning and Sterilization Instructions below, or together with other devices in a PureSet tray following the cleaning and sterilization instructions in Nobel Biocare Instructions for Use (IFU) IFU1067. This IFU is available on ifu.nobelbiocare.com.

Cleaning and Sterilization Instructions:

Screwdrivers are delivered non-sterile by Nobel Biocare and are 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 Screwdrivers have been validated to withstand these cleaning and sterilization procedures.

Caution: Do not deviate from the following reprocessing instructions.

Caution: Keep dissimilar metals separated during sterilization to resist corrosion.

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. Use a dental probe to remove soil and debris from cavities, where applicable.
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. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
2. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
3. 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.
4. 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.
5. 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.
6. 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.

Note: FDA-cleared washer-disinfectors are to be used for the recommended cleaning parameters.

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. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cydezyme ASP; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
4. 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.
5. 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.
6. 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. Cydezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
9. 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 discard 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.

1. Seal each device in a suitable sterilization pouch. 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 4 presents examples of suitable sterilization pouches.

Table 4: 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:
   - Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure, followed by drying 15-30 minutes in chamber.
   - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by drying 20-30 minutes in chamber.

Note: FDA-cleared sterilization equipment and accessories are to be used for the recommended sterilization parameters.

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.

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:
Nobel Biocare AB
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411 17 Göteborg
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www.nobelbiocare.com

Distributed in USA by:
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Yorba Linda, CA, 92887
USA

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

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.

Batch code

Catalogue number

Date


Date of manufacture


Manufacturer

Serial number

Unique Device Identifier

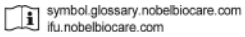

Health care centre or doctor


Patient identification


Patient number


Tooth number


Consult instructions for use



Link to Online Symbols Glossary and IFU Portal


Patient information website


Caution

Do not resterilize


Do not re-use


Do not use if package is damaged and consult instructions for use


Use-by date


Temperature limit


Upper limit of temperature


Keep away from sunlight


Keep dry

Contains biological material of animal origin


Contains hazardous substances

Contains or presence of DEHP phthalate

Contains or presence of natural rubber latex

Contains or presence of phthalate


Non-pyrogenic

Magnetic resonance conditional

Magnetic resonance safe

Non-sterile

Sterilized using Ethylene Oxide

Sterilized using irradiation

Sterilized using steam or dry heat


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside


Double sterile barrier system

Authorised Representative in Switzerland

Authorized representative in the European Community / European Union

UK Responsible Person

CE mark

CE mark with Notified Body number

EU Importer

Swiss Importer

UKCA mark

UKCA mark with Approved Body number

Medical device

Rx only

For prescription use only