

Screwdrivers

Omnigrip™ Mini, Omnigrip™, Unigrip™, Multi-unit, Cover Screw Brånemark System® Hexagon



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) IFU1098 for information regarding the Manual Torque Wrench Prosthetic. This IFU is available for download at ifu.nobelbiocare.com.

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

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.

Screwdrivers Unigrip™ (Manual and Machine)

The Screwdrivers Unigrip™ are available in both manual and machine versions and in various lengths and are used to tighten and loosen screws, prosthetic components and abutment retrieval instruments which feature the Unigrip™ interface.

Screwdrivers Multi-unit (Manual and Machine) and Screwdriver Multi-unit Brånemark System® WP (Machine and Manual)

The Screwdrivers Multi-unit are available in both manual and machine versions and are used to tighten and loosen the screws of the Multi-unit Abutments, as well as screws for abutment retrieval instruments, that feature the external hex interface.

The Screwdriver Multi-unit Brånemark System® WP are available in both manual and machine versions and feature a larger external hex interface which is used with Multi-unit Abutment Brånemark System® WP.

Screwdriver Cover Screw Brånemark System® Hexagon

The Screwdriver Cover Screw Brånemark System® Hex is used to tighten and loosen Cover Screws Brånemark System®.

Intended Use/Intended Purpose

Screwdrivers Manual and Machine

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

Indications

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 component:

Table 1 – Instruction For Use of Components

Clinical Screw, Abutment Screw, Prosthetic	IFU1057
Healing Abutment	IFU1026 and IFU1094
Manual Torque Wrenches Surgical and Prosthetic	IFU1098
Impression coping	IFU1086
Bone Mills and Bone Mill Guides	IFU1089
Abutment Retrieval Instrumentation	IFU1096
Drill Stop Kits for Guided and Freehand	IFU1092
Nobel Guided Surgery Tooling	IFU2011

Materials

Screwdrivers Omnigrip™, Omnigrip™ Mini and Unigrip™ (Manual and Machine)

Stainless steel AISI 303/AISI 304/420F Mod according to ASTM F899, with titanium nitride (TiN) coating.

Screwdrivers Multi-unit (Manual and Machine) and Cover Screw Brånemark System® Hexagon

Stainless steel AISI 303/AISI 304/420F Mod according to ASTM F899.

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 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 the clinical and/or 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).

Intended Users and Patient Groups

Screwdrivers are to be used by dental health care professionals.

Screwdrivers are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Devices in the IFU

Screwdrivers 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 Screwdrivers

The use of this device is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, swelling. Depending on location it may also lead in rare cases to fenestration or fracture of bone, perforation of neighboring structures/restorations, sinusitis, or sensory/motor disturbances. During use of this device 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
www.nobelbiocare.com/complaint-form

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 2.

Table 2 – Maximum Tightening Torque for Machine and Manual Screwdrivers

Screwdriver	Maximum Tightening Torque
Omnigrip™	35 Ncm
Omnigrip™ Mini	20 Ncm
Unigrip™	35 Ncm
Multi-unit	35 Ncm
Cover Screw Brånemark System® Hexagon	Hand-tighten

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 IFU1090 for more information regarding the Handle for Machine Instruments.

Sterility and Reusability Information

Screwdrivers 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.

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 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

These products are intended to be cleaned and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices 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 the devices, 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. For more information 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 	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
UK Responsible Person UK RP	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
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Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class IIa Devices	
UKCA Mark for Class IIa Devices	

Note Refer to the product label to determine the applicable conformity marking for each device.

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

Basic UDI-DI Information

Product	Basic UDI-DI Number
Omnigrip™ Screwdrivers Manual	73327470000001787L
Screwdrivers Manual Omnigrip™ Mini	73327470000001787L
Screwdrivers Manual Unigrip™	73327470000001787L
Screwdrivers Manual Multi-unit	73327470000001787L
Screwdriver Manual Multi-unit Brånemark System® WP	73327470000001787L
Cover Screw Driver Brånemark System® Hexagon	73327470000001787L
Omnigrip™ Screwdrivers Machine	73327470000001797N
Screwdrivers Machine Omnigrip™ Mini	73327470000001797N
Screwdrivers Machine Unigrip™	73327470000001797N
Screwdriver Machine Multi-unit	73327470000001797N
Screwdriver Machine Multi-unit Brånemark System® WP	73327470000001797N

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Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.