

Screwdrivers

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



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

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.

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

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.

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 1 – Instruction For Use of Components

Clinical Screw, Abutment Screw, Prosthetic	IFU1057
Healing Abutment	IFU1026 and IFU1094
Manual Torque Wrenches Surgical and Prosthetic	IFU1047
Impression coping	IFU1086
Bone Mills and Bone Mill Guides	IFU1032, IFU1089
Abutment Retrieval Instrumentation	IFU1096
Drill Stop Kits for Guided and Freehand	IFU1036
Nobel Guided Surgery Tooling	IFU2004/2005/2006

Materials

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

Screwdrivers Omnigrip™, Omnigrip™ Mini (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

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/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).

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 IFU1058 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.

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.

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

Distributed in USA by

Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, CA, 92887 USA

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

Legal Statements

US All rights reserved.

Nobel Biocare, the Nobel Biocare logotype and all other trademarks used in this document are, if nothing else is stated or is evident from the context in a certain case, trademarks of Nobel Biocare. Product images in this folder are not necessarily to scale. All product images are for illustration purposes only and may not be an exact representation of the product.

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.