Nobel Biocare Reusable Instruments and Components

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:

This Instructions for Use (IFU) encompasses assorted Nobel Biocare reusable instruments for implant site preparation, implant placement, implant retrieval, and device cleaning, processing/reprocessing.

- **All-on-4 Guide:** The All-on-4 Guide is an assembly that consists of a guide plate, pin, and screw which features a Unigrip screwdriver interface. It is used during the All-on-4 procedure to facilitate the preparation of the osteotomy by providing references lines (in 7 mm increments) to guide the angulation of the drill.

Table 1 summarizes the implant families and drills, which are compatible with the All-on-4 Guide; see the referenced IFU for more information regarding the respective product. These IFUs are available for download at www.nobelbiocare.com.

Table 1: All-on-4 Guide Compatibility

Implant Family	Drills
NobelActive (IFU1001) NobelActive TiUltra (IFU1076)	Unigrip Screwdrivers Twist Drill Ø 2.0 mm Drill with Tip Tapered 2.0 mm
NobelParallel Conical Connection (IFU1002) NobelParallel Conical Connection TiUltra (IFU1078)	
NobelReplace Conical Connection NobelReplace Conical Connection Partially Machined Collar (PMC) (IFU1010)	
NobelReplace Tapered Groovy Replace Select Tapered TiUnite Replace Select Tapered Partially Machined Collar (PMC) (IFU1012)	
NobelSpeedy Groovy (IFU1007)	
Branemark System (IFU1015)	
Nobel Zygoma 0° and 45° (IFU1050 and IFU1051)	

- **Multi-unit Aligning Instrument:** The Multi-unit Aligning Instrument can be attached to Nobel Biocare implant drivers featuring the internal conical connection or tri-channel connection and is used to determine the angulation of a dental implant, in order to identify the appropriate angled Multi-Unit Abutment. The instrument is also used to determine the implant's rotational position which in turn defines the location of the abutment screw access hole. Table 2 summarizes the implant families and related implant drivers which are compatible with the Multi-unit Aligning Instrument; see the referenced IFU for more information regarding the implants and implant drivers.

Table 2: Multi-unit Aligning Instrument Compatibility

Implant Family	IFU	Connection Type	Implant Driver
NobelActive TiUnite NobelActive TiUltra	IFU1001 IFU1076	Internal Conical Connection	Implant Drivers Conical Connection
NobelParallel Conical Connection NobelParallel Conical Connection TiUltra	IFU1002 IFU1078		
NobelReplace Conical Connection NobelReplace Conical Connection Partially Machined Collar (PMC)	IFU1010		
NobelReplace Tapered Groovy Replace Select Tapered TiUnite Replace Select Tapered Partially Machined Collar (PMC)	IFU1012	Tri-channel Connection	Implant Drivers NobelReplace

- **Combined Open-end Wrench:** The Combined Open-End Wrench is used in conjunction with a Unigrip screwdriver when mounting and removing fixture mounts from implants, before or after implant placement. The wrench has two heads, one for use with the Brånemark System implant mounts, the other for the internal conical connection, tri-channel and Trefoil implant mounts. The heads have two "teeth" which are placed over the square-shaped head of the fixture mount and are used to engage the mount. See Nobel Biocare IFU2011 for information regarding implant mounts, and IFU1099 for the Trefoil procedure.
- **Depth Probe 7-18 mm Z-shaped** and **NobelSpeedy Depth Probe 18-25 mm:** Depth probes are used to verify the depth of an osteotomy. The markings on the instruments correspond to the desired implant length.
- **Direction Indicator Ø 2/Ø 2.4-2.8 mm** and **Direction Indicators Tapered NP/RP/WP/6.0:** Direction indicators are used to verify the orientation of the osteotomy. The markings on the instruments convey the depth of the osteotomy relative to drilling.
- **Handle for Implant Rescue Collar and Drill Guides:** The Handle for Implant Rescue Collar and Drill Guides is designed to facilitate handling of Implant Rescue Collars and Rescue Drill Guides in the patient's mouth. See Nobel Biocare IFU1097 for information regarding implant rescue collars, and IFU1043 for information regarding rescue drill guides.
- **Handle for Machine Instruments:** is designed to be connected to Screwdrivers Machine Unigrip, Omnigrip Screwdrivers Machine and Omnigrip Mini Screwdrivers to tighten/loosen screws. It can be used also with Abutment Screw Removers, Abutment Screw Retrieval Instruments, Screw Tap Repairs to allow for manual removal of screws. See Nobel Biocare IFU1085 for information regarding the screwdrivers. See Nobel Biocare IFU1043 for information regarding the abutment screw retrieval instrumentation.
- **Implant Driver Wrench Adapters Brånemark System NP/RP/WP:** These wrench adapters are used to connect Brånemark System or NobelSpeedy implants to the Branemark System Manual Torque Wrench. See Nobel Biocare IFU1098 for information regarding the Branemark System Manual Torque Wrench.

Table 3 summarizes the implants and torque wrench which are compatible with the Implant Driver Wrench Adapters Brånemark System; see the referenced IFU for more information regarding the respective implant.

Table 3: Implant Driver Wrench Adapters Brånemark System Compatibility

Implant	IFU	Torque Wrench
Brånemark System	IFU1015	Branemark System Manual Torque Wrench
NobelSpeedy	IFU1007	

- **Surgical Driver NobelReplace:** The Surgical Driver NobelReplace is connected to a NobelReplace implant driver, Nobel Biocare N1™ Implant Driver or Implant Driver Conical Connection and is used for the manual insertion/removal of internal conical connection, tri-oval conical connection and tri-channel implant systems. See Nobel Biocare IFU1058 and IFU1087 for information regarding the implant drivers.

The Surgical Driver NobelReplace includes an O-ring, to increase the tool retention.

Table 4 summarizes the implant families and the corresponding implant drivers which are compatible with the Surgical Driver NobelReplace; see the referenced IFU for more information regarding the respective implant.

Table 4: Surgical Driver NobelReplace Compatibility

Implant Family	IFU	Implant Driver
NobelActive TiUnite NobelActive TiUltra	IFU1001 IFU1076	Implant Drivers Conical Connection
NobelParallel Conical Connection NobelParallel Conical Connection TiUltra	IFU1002 IFU1078	
NobelReplace Conical Connection NobelReplace Conical Connection Partially Machined Collar (PMC)	IFU1010	Implant Drivers NobelReplace
NobelReplace Tapered Groovy Replace Select Tapered TiUnite Replace Select Tapered Partially Machined Collar (PMC)	FU1012	
Nobel Biocare N1™ TCC TiUltra	IFU1087	Nobel Biocare N1™ Implant Driver

- **Irrigation Needle:** The Irrigation Needle is connected to a syringe containing cleaning solution and is used to flush the internal channels/lumina of cannulated drills and taps during processing/reprocessing.

Intended Use/Intended Purpose:

All-on-4 Guide:
Intended for use to guide drilling instruments during preparation of an osteotomy.

Multi-unit Aligning Instrument:
Intended to be used to identify the angulation of the best suitable Multi-Unit Abutment as well as the implant rotational position, that defines the abutment screw access hole.

Combined Open-end Wrench:
Intended for use to tighten and/or loosen dental implant system components.

Depth Probe 7-18 mm Z-shaped and NobelSpeedy Depth Probe 18-25 mm:
Intended for use to verify the depth of an osteotomy during dental implant surgery.

Direction Indicator Ø 2/Ø 2.4-2.8 mm and Direction Indicators Tapered NP/RP/WP/6.0:
Intended for use to verify the orientation of an osteotomy during dental implant surgery.

Handle for Implant Rescue Collar and Drill Guides:
Intended for use to facilitate the removal of dental implant system components.

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

Implant Driver Wrench Adapters Branemark System NP/RP/WP:
Intended for use to insert or remove dental implants during dental implant surgery.

Surgical Driver NobelReplace:
Intended for use to insert or remove dental implants during dental implant surgery.

Irrigation Needle:
Intended for use to flush the internal channels/lumina of cannulated drills and taps during cleaning.

Indications:

All-on-4 Guide:
The All-on-4- Guide is indicated for use when preparing an osteotomy during All-on-4 procedures in the maxilla or mandible, to guide the location and angle of the osteotomy and to protect the surrounding tissue.

Multi-unit Aligning Instrument:
The Multi-unit Aligning Instrument is indicated for use with Nobel Biocare implant drivers featuring the internal conical connection or tri-channel connection to determine the angulation of the dental implant in order to select the proper angulated Multi-unit abutment.

Combined Open-end Wrench:
The Combined Open-end Wrench is indicated for use in conjunction with a Unigrip screwdriver when mounting and removing fixture mounts from dental implants, before or after implant placement.

Depth Probe 7-18 mm Z-shaped:
The Depth Probe 7-18 mm Z-shaped is indicated for use when preparing an osteotomy for the placement of Nobel Biocare implants in the maxilla or mandible.

NobelSpeedy Depth Probe 18-25 mm:
The NobelSpeedy Depth Probe 18-25 mm is indicated for use when preparing an osteotomy for the placement of NobelSpeedy 18, 20, 22, 25 mm long implants in the maxilla or mandible.

Direction Indicator Ø 2/Ø 2.4-2.8 mm:
The Direction Indicator Ø 2/Ø 2.4-2.8 mm is indicated for use when preparing an osteotomy for the placement of NobelActive, NobelParallel CC, Nobel Speedy and Branemark System implants in the maxilla or mandible.

Direction Indicators Tapered NP/RP/WP/6.0:
Direction Indicators Tapered NP/RP/WP/6.0 are indicated for use when preparing an osteotomy for the placement of tapered implants in the maxilla or mandible.

Handle for Implant Rescue Collar and Drill Guides:
Same as Intended Use/Intended Purpose.

Handle for Machine Instruments:
Is intended to be connected to Screwdrivers Machine Unigrip, Omnigrip Screwdrivers Machine and Omnigrip Mini Screwdrivers to tighten/loosen screws. It can be used also with Abutment Screw Removers, Abutment Screw Retrieval Instruments, Screw Tap Repairs to allow for manual removal of screws.

Implant Driver Wrench Adapters Branemark System NP/RP/WP:
The Implant Drivers Wrench Adapter Branemark System are indicated to be used during dental implant surgery for the insertion and removal of Branemark System and NobelSpeedy dental implants from an osteotomy in the maxilla or mandible.

Surgical Driver NobelReplace:
The Surgical Driver NobelReplace is indicated for use with NobelReplace implant drivers, Nobel Biocare N1™ Implant Drivers and Implant Drivers Conical Connection to insert or remove dental implants placed in the maxilla or mandible.

Irrigation Needle:
Same as Intended Use/Intended Purpose.

Contraindications:

It is contraindicated using Nobel Biocare reusable instruments and components in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are allergic or hypersensitive to the following materials:
  - All-on-4 Guide, Multi-unit Aligning Instrument, Combined Open-end Wrench, Direction Indicator Ø 2/Ø 2.4-2.8 mm, Implant Driver Wrench Adapters Branemark System NP/RP/WP, Depth Probe 7-18 mm Z-shaped, NobelSpeedy Depth Probe 18-25 mm, and Surgical Driver NobelReplace (main body), Handle for Machine Instruments, Handle for Implant Rescue Collar and Drill Guides: Stainless steel.
  - Direction Indicators Tapered NP/RP/WP/6.0: Alloyed titanium Ti-6Al-4V.
  - O-ring for Surgical Driver NobelReplace: Fluoroelastomer PAI Compound 9844.

There are no contraindications for the Irrigation Needle.

Refer to the IFU for the implant or implant system component for contraindications specific to those products.

Cautions:

General:
One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) may result in failure.

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

It is strongly recommended that Nobel Biocare reusable instruments and components are only used other compatible Nobel Biocare instruments and components. Use of instruments and/or components that are not intended to be used in combination with Nobel Biocare reusable instruments and components 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:
Careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

Special attention must be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

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.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

All components, instruments and tooling used during the clinical 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. a throat shield).

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 over tightening.

After Surgery:
To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform the patient about appropriate oral hygiene.

Intended Users and Patient Groups:

Nobel Biocare reusable instruments and components are to be used by dental health care professionals.

Nobel Biocare reusable instruments and components (with the exception of the Irrigation Needle) are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:
Clinical Benefits Associated with Nobel Biocare Reusable Instruments and Components:
The devices described in this Instructions for Use are components 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 Nobel Biocare Reusable Instruments and Components:
The devices described in this Instructions for Use are 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, sinusitis, or sensory/motor disturbances.

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 Procedures:

All-on-4 Guide:
The All-on-4 Guide is used during the All-on-4 procedure to facilitate the preparation of the osteotomy by providing references lines to guide the angulation of the drill.

1. Refer to Table 1 in this IFU for information regarding the implants and drills, which are compatible with the All-on-4 Guide, and to the referenced IFU for those components, for further information related to the implant site preparation and placement of the implants.
2. After completing the flap elevation, prepare an osteotomy of approximately 8 mm depth in the midline using a Ø 2 mm Twist Drill.
3. Place the All-On-4 Guide in the osteotomy (**Figure A**) and ensure the guide is properly seated.

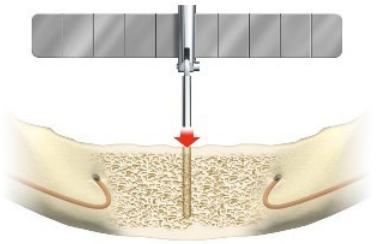


Figure A: Placement of All-On-4 Guide in the First (Ø 2 mm) Osteotomy

4. Proceed with drilling the two posterior sites using the guide to verify the correct angulation (**Figure B**).

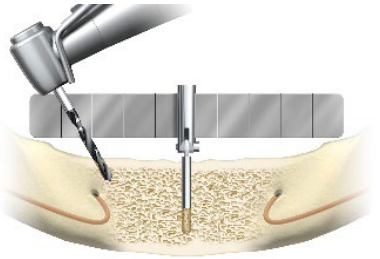


Figure B: Preparation of Second Osteotomy

5. Place the implants in the posterior sites together with the angulated Multi-unit abutment.
6. Proceed with drilling of the anterior osteotomies in the same way as the posterior osteotomies, using the guide to verify the correct angulation.
7. Remove the All-on-4 Guide from the surgical site.
8. Proceed with placement of the desired implants in the anterior osteotomies, following the Surgical/Handling Procedure in the IFU for the respective implant.

Multi-unit Aligning Instrument:
The Multi-unit Aligning Instrument is used to determine the angulation of a dental implant, in order to identify the appropriate Multi-Unit Abutment.

1. Assemble the Multi-unit Aligning Instrument on the implant driver and secure the instrument with dental floss as shown on **Figure C**.

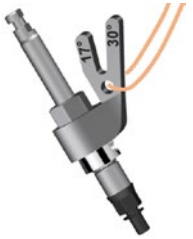


Figure C: Assembling the Multi-unit Aligning Instrument on Implant Driver

Note: For implant drivers featuring a tri-channel connection, furthermore ensure the laser marking on the implant driver (red arrow) is aligned with the Multi-Unit Aligning Instrument as shown in **Figure D**.

Figure D: Alignment of Multi-unit Aligning Instrument on Implant Driver with Tri-channel Connection

2. Insert the implant driver and Multi-unit Aligning Instrument assembly into the implant (see **Figure E**).

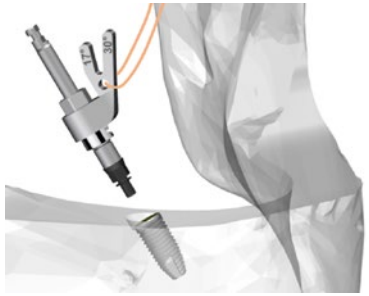


Figure E: Inserting Multi-unit Aligning Instrument into Implant

3. The angulation indicator of the Multi-Unit Aligning Instrument indicates the position of the prosthetic screw hole when placing a 17° or a 30° Multi-Unit Abutment. The arm of the angulation indicator which is perpendicular to the bone after placement indicates the recommended Multi-unit Abutment to use (17° or 30°). The red line in **Figure F** illustrates the 30° option.

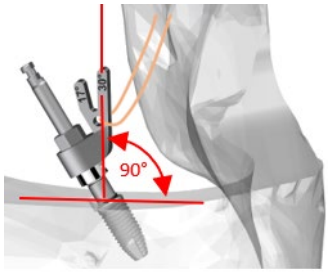


Figure F: Angulation Indicator Identifies Recommended Multi-unit Abutment (Example: 30°)

4. Rotate the implant into its final position as necessary using the Manual Torque Wrench Surgical (see **Figure G**). Refer to IFU1098 for information regarding the Manual Torque Wrench Surgical.

Caution: Never exceed tightening torque detailed in the IFU for the implant. Overtightening of implant may lead to damage of the implant or fracture or necrosis of the bone site. If a Surgical Driver is used to insert the implant, special care must be taken to avoid over tightening.

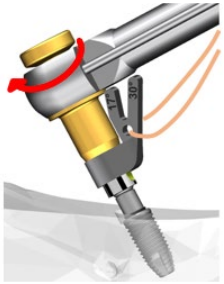


Figure G: Adjusting Rotational Position of Implant with Manual Torque Wrench Surgical

5. Remove the implant driver and Multi-unit Aligning Instrument assembly and insert the appropriate Multi-unit Abutment. **Figure H** illustrates a 30° Multi-unit Abutment including the insertion handle.

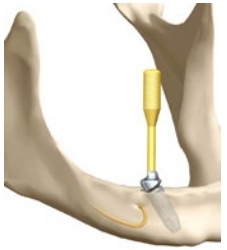


Figure H: 30° Multi-unit Abutment (Including the Insertion Handle)

Combined Open-end Wrench:
When applicable the Combined Open-end Wrench can be used to support the connection or removal of a Guided Implant Mount or Trefoil Implant Mount. Refer to IFU2011 for more information regarding the Guided Implant Mount, and to IFU1099 for information regarding the Trefoil Implant Mount).

1. Place the Guided Implant Mount or Implant Mount on the implant, and use the Combined Open-end Wrench to hold the implant mount in position as the screw is tightened using the Unigrip™ Screwdriver (**Figure I**).

Figure I: Using the Combined Open-end Wrench to Hold the Implant Mount

2. To remove the implant mount, use the wrench to hold the implant mount in position while unscrewing the screw using the Unigrip screwdriver.

Depth Probe 7-18 mm Z-shaped and NobelSpeedy Depth Probe 18-25 mm:
Depth probes can be used during the preparation of an osteotomy to verify the depth.

1. After the osteotomy has been created, insert the depth probe into the osteotomy until the probe is seated at the bottom of the osteotomy.
2. The depth markings on each side of the instrument corresponds to the desired implant length. The length in millimeters is marked on the shaft of the probe.

Note: The NobelSpeedy Depth Probe has just one side as it is specifically designed to be used with the long NobelSpeedy implants (18-25 mm).

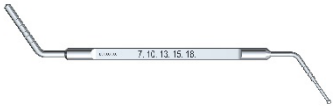


Figure J: Depth Probe 7-18 mm Z-shaped

Direction Indicator Ø 2/Ø 2.4-2.8 mm and Direction Indicators Tapered NP/RP/WP/6.0:
Direction indicators are used to verify the osteotomy orientation before moving to next step in the drilling protocol.

1. Loop a piece of dental floss through the hole of the direction indicator to prevent the instrument from being aspirated or swallowed (see **Figure K**).

Figure K: Securing the Direction Indicator with Dental Floss

2. After the osteotomy has been created, insert the instrument into the osteotomy to verify the appropriate orientation. The depth markings on the Direction Indicator Ø 2/Ø 2.4-2.8 mm correspond to the implant length.

Handle for Implant Rescue Collar and Drill Guides:
The Handle for Implant Rescue Collar and Drill Guides is used to facilitate handling of implant rescue collars and rescue drill guides in the patient's mouth.

Use with Implant Rescue Collars:
Implant rescue collars are used to facilitate the removal implants with internal tri channel connection, where the implant connection interface is damaged or has collapsed. They are placed around the implant collar to prevent expansion of the collar when removing the implant. Refer to Nobel Biocare IFU1097 for more detailed information regarding implant rescue collars.

1. Connect the Handle for Implant Rescue Collar and Drill Guides to the implant rescue collar and then connect it to the interface of the implant as shown in **Figure L**.

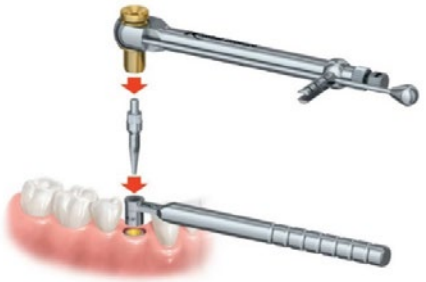


Figure L: Connecting the Handle for Implant Rescue Collar and Drill Guides to Implant Rescue Collar

2. Proceed with removal of the implant using the appropriate implant retrieval instrument as described in Nobel Biocare IFU1097.

Use with Rescue Drill Guides:
Rescue drill guides are used to protect the implant interface and to guide the abutment screw retrieval reverse drill when drilling a hole into the screw fragment. Refer to Nobel Biocare IFU1043 for more detailed information regarding rescue drill guides.

1. Connect the Handle for Implant Rescue Collar and Drill Guides to the rescue drill guide and then insert it into the implant connection interface as shown in **Figure M**.

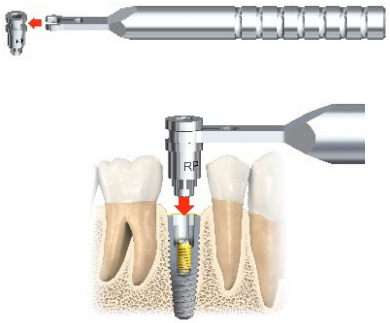


Figure M: Connection of Handle for Implant Rescue Collar & Drill Guide to Rescue Drill Guide and Insertion of Rescue Drill Guide into Implant Connection Interface

2. Proceed with removal of the screw using the abutment screw retrieval reverse drill as described in Nobel Biocare IFU1043.

Handle for Machine Instruments

The Handle for Machine Instruments can be connected to various Nobel Biocare machine screwdrivers to enable them to be used to manually tighten or loosen screws. It can be used also with abutment screw retrieval instrumentation. Refer to Nobel Biocare IFU1085 for information regarding the screwdrivers. Refer to Nobel Biocare IFU1043 for information regarding the abutment screw retrieval instrumentation.

Use with Screwdrivers:

1. Connect the Handle for Machine Instruments to the desired machine screwdriver.
2. Hold the screwdriver by the handle, and engage the screw with the screwdriver, using light pressure.
3. Tighten or loosen the screw by hand.

Use with Abutment Screw Retrieval Instrumentation:

1. Connect the Handle for Machine Instruments to the desired abutment screw retrieval instrument (Abutment Screw Remover, Abutment Screw Retrieval Instrument, or Screw Tap Repair).
2. Hold the screwdriver by the handle, and engage the screw/screw fragment with the instrument.
3. Proceed to remove the screw by hand as described in Nobel Biocare IFU1043. If required, the handle can also be used with the Screw Tap Repair tool to subsequently remove debris from the implant thread.

Implant Driver Wrench Adapters Brånemark System NP/RP/WP:

Implant Driver Wrench Adapters Brånemark System are used to connect Brånemark System or NobelSpeedy implants to the Branemark System Manual Torque Wrench. See Nobel Biocare IFU1015 for information regarding Brånemark System implants, and to IFU1007 for NobelSpeedy implants.

1. Connect the Implant Driver Wrench Adapter Branemark System to the Manual Torque Wrench Branemark System as shown in **Figure N**.

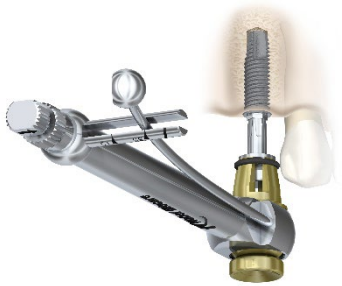


Figure N: Connecting the Implant Driver Wrench Adapter Branemark System to Manual Torque Wrench Branemark System

Insert the implant driver into the Brånemark System or NobelSpeedy implant connection interface and proceed to tighten the implant using the Manual Torque Wrench Branemark System to the desired tightening torque.

Surgical Driver NobelReplace:

The Surgical Driver NobelReplace can be connected to an implant driver featuring the internal conical connection, tri-oval conical connection or tri-channel connection, and is used for the manual insertion of implants. Surgical drivers provide enhanced tactile feel and control during implant insertion, which is particularly desirable when placing implants in the anterior region.

1. Connect the desired implant driver to the Surgical Driver NobelReplace.
2. While holding the implant driver using the Surgical Driver NobelReplace, connect the implant driver to the implant, place the implant into the osteotomy, and hand-tighten the implant as described in the referenced IFUs.

Irrigation Needle:

The irrigation needle is connected to a syringe containing cleaning solution and is used to flush the internal channels/lumina of cannulated drills and taps during processing/reprocessing.

1. Connect the irrigation needle to a 20 ml syringe.
2. Flush the internal channels/lumina of the drill/tap with cleaning solution using the irrigation needle.
3. Inspect the channels/lumina for residual soil and/or debris, and repeat the flushing as necessary to remove all visible debris.

Materials:

- All-on-4 Guide, Multi-unit Aligning Instrument, Combined Open-end Wrench, Direction Indicator Ø 2/Ø 2.4-2.8 mm, Implant Driver Wrench Adapters Branemark System NP/RP/WP, Depth Probe 7-18 mm Z-shaped, NobelSpeedy Depth Probe 18-25 mm, Surgical Driver NobelReplace (main body), Irrigation Needle, Handle for Machine Instruments, Handle for Implant Rescue Collars and Drill Guides: Stainless steel according to EN 10088-3/ ASTM F899.
- Direction Indicator Tapered: Titanium alloy Ti-6Al-4V according to ASTM F136.
- O-ring (Surgical Driver): Fluoroelastomer PAI Compound 9844.

Sterility and Reusability Information:

Nobel Biocare reusable instruments and components 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.

Prior to each use, Nobel Biocare reusable instruments and components must be inspected for signs of degradation that may limit the useful life or performance of the device, such as the following:

- Visible corrosion.
- Mechanical wear, abrasion, damage, or deformation.
- O-ring still in place (applicable for the Surgical Driver).

Discard the device if any of these signs of degradation are evident.

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

Note: The Direction Indicator Ø 2/Ø 2.4-2.8 mm, Direction Indicators Tapered NP/RP/WP/6.0, Depth Probe 7-18 mm Z-shaped, and NobelSpeedy Depth Probe 18-25 mm 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:

Nobel Biocare reusable instruments and components 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.

Caution: Do not deviate from the described reprocessing instructions.

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

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 All-on-4 Guide, Multi Unit Alignment, Combined Open End Wrench, Direction Indicators, Implant Driver Wrench Adapter, Depth Probe, Irrigation Needle, Surgical Driver, Handle for Machine Instruments and Handle for Rescue Collars and Drill Guides have been validated to withstand these cleaning and sterilization procedures.

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. 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.

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. Cidezyme 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. Cidezyme 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 devices 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 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.

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 5 presents examples of suitable sterilization containers, pouches, and wraps.

Table 5: 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 6):

Table 6: 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.

Performance Requirements and Limitations:

To achieve the desired performance, the devices described in this IFU 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 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
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

Distributed in Australia by:
Nobel Biocare Australia Pty Ltd
Level 4/7 Eden Park Drive
Macquarie Park, NSW 2114 Australia
Phone: +61 1800 804 597

Distributed in New Zealand by:
Nobel Biocare New Zealand Ltd
33 Spartan Road
Takanini, Auckland, 2105 New Zealand
Phone: +64 0800 441 657

CE 2797
CE Mark for
Class Ir Devices

Notice Regarding Canadian Device Licensure: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

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
All-on-4 Guide	73327470000002006L
Multi-unit Aligning Instrument	73327470000021877
Combined Open-end Wrench	7332747000001927E
Depth Probe 7-18 mm Z-shaped and NobelSpeedy Depth Probe 18-25 mm	73327470000001606Z
Direction Indicator Ø 2/Ø 2.4-2.8 mm and Direction Indicators Tapered NP/RP/WP/6.0	73327470000016377
Implant Driver Wrench Adapters Branemark System NP/RP/WP Surgical Driver NobelReplace	7332747000001587E
Irrigation Needle	73327470000016479
Handle for Machine Instruments	7332747000001787L
Handle for Rescue Collars and Drill Guides	7332747000001747C

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 marking


Consult instructions for use


Contains hazardous substances

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

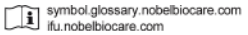
Rx Only

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


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


Temperature limit


Tooth number


Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier


Use-by date