Nobel Biocare Reusable Instruments, Components

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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® NobelActive® TiUltra™ (IFU1001)	Unigrip™ Screwdrivers Twist Drill Ø 2.0 mm Drill with Tip Tapered 2.0 mm
NobelParallel™ Conical Connection NobelParallel™ Conical Connection TiUltra™ (IFU1002)	
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	
Brånemark System® (IFU1007)	
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.

Multi-unit Aligning Instrument can be connected to internal conical and tri-channel connection implant drivers, see table below for details on related implant families.

Table 2 – Multi-unit Aligning Instrument Compatibility

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

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.

Table 3 – Combined Open-End Wrench Compatibility

Implant Family	Compatible Implant Mounts
Brånemark System®	Guided Implant Mount Brånemark System® NP, RP 3.75, RP 4.0, WP
NobelSpeedy®	
NobelParallel™	Guided Implant Mount NobelParallel™ NP 3.75, RP 4.3, RP 5.0, WP 5.5
Trefoil™ System	Trefoil™ Implant Mount
NobelActive®	Guided Implant Mount NobelActive® NP 3.5, RP 4.3, RP 5.0, WP 5.5
NobelReplace® CC	Guided Implant Mount NobelReplace® CC NP 3.5, RP 4.3, RP 5.0
NobelReplace® Tapered	Guided Implant Mount NobelReplace® Tapered NP 3.5, RP 4.0, WP 5.0, 6.0

Connection to Handpiece

Connections to handpiece are used to connect an implant/implant mount assembly to an ISO 1797-compatible dental handpiece/contra angle.

Table 4 – Connection to Handpiece Compatibility

Connection to Handpiece	Compatible Devices	Implant Family
Connection to Handpiece	Guided Implant Mount Brånemark System® NP, RP 3.75, RP 4.0, WP Zygoma Implant Mount	Brånemark System® NobelSpeedy® Zygoma RP
NOBELREPLACE® Connection to Handpiece	Guided Implant Mount NobelActive® NP, RP 4.3, RP 5.0, WP 5.5 Guided Implant Mount NobelParallel™ NP 3.75, RP 4.3, RP 5.0, WP 5.5 Guided Implant Mount NobelReplace® NP 3.5, RP 4.3, WP 5.0, 6.0 Guided Implant Mount NobelReplace® CC NP 3.5, RP 4.3, RP 5.0 Implant Mount Ø5mm	NobelActive® NobelParallel™ NobelReplace® Tapered NobelReplace® CC Trefoil™ System

Depth Probe 7-18 mm Z-shaped and NobelSpeedy® Depth Probe 18-25 mm

The depth probes are used to verify the depth of an osteotomy. The markings on the instruments correspond to the desired implant length.

Depth probes are not connected to any other devices.

Direction Indicator Ø2/Ø 2.4-2.8 mm and Direction Indicators Tapered NP/RP/WP/6.0

The 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.

Direction indicators are not connected to any other devices.

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.

The Handle for Implant Rescue Collar and Rescue Drill Guides can be connected to the Implant Rescue Collars and Rescue Drill Guides.

Handle for Machine Instruments

The 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.

The Handle for Machine Instruments can be connected to Screwdrivers Machine Unigrip™, Omnigrip™ Screwdrivers Machine, Screwdrivers Machine Multi-unit, Omnigrip™ Mini Screwdrivers, Abutment Screw Removers, Abutment Screw Retrieval Instruments, Screw Tap Repairs Tools.

Implant Drivers

The implant drivers are attached to a dental handpiece and to the internal or external connection of a dental implant and allow for the application of insertion torque to thread the implants into the bone.

Implant drivers are attached to an ISO 1797- compatible dental handpiece/contra angle and to the internal or external connection of the following dental implants.

Table 5 – Implant Driver Compatibility

Implant Driver	Implant Family
Implant Drivers CC 3.0 (28/37mm)	NobelActive® TiUnite®
Implant Drivers CC NP (28/37mm)	NobelActive® TiUltra™
Implant Drivers CC RP (28/37mm)	NobelParallel™ Conical Connection
Implant Drivers CC WP (28/37mm)	NobelParallel™ Conical Connection TiUltra™
Implant Drivers CC Slim Abutment 3.0/NP/RP	
Implant Drivers NobelReplace® NP (Long/Short)	NobelReplace® Conical Connection
Implant Drivers NobelReplace® RP (Long/Short)	NobelReplace® Conical Connection PMC
Implant Drivers NobelReplace® WP (Long/Short)	NobelReplace® Tapered Groovy
Implant Drivers NobelReplace® 6.0 (Long/Short)	Replace Select™ Tapered TiUnite®
	Replace Select™ Tapered PMC
Implant Drivers Brånemark System® NP (26/34mm)	Brånemark System®
Implant Drivers Brånemark System® RP (21/26/34mm)	
Implant Drivers Brånemark System® WP (21/26mm)	

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

The implant driver wrench adapters are used to connect Brånemark System® or NobelSpeedy® implants to the Brånemark System® Manual Torque Wrench. See Nobel Biocare IFU1098 for information regarding the Brånemark System® Manual Torque Wrench.

Table 6 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 6 – Implant Driver Wrench Adapters Brånemark System® Compatibility

Implant	IFU	Torque Wrench
Brånemark System®	IFU1007	Brånemark 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 7 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 7 – Surgical Driver NobelReplace® Compatibility

Implant Family	IFU	Implant Driver
NobelActive® TiUnite® NobelActive® TiUltra™	IFU1001	Implant Drivers Conical Connection
NobelParallel™ Conical Connection NobelParallel™ Conical Connection TiUltra™	IFU1002	
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	Implant Drivers NobelReplace® and Replace Select™ Tapered
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.

Tissue Punches

The tissue punches are designed to match the diameter of the various Nobel Biocare dental implants and are used to remove a circular area of soft tissue to allow access to a site for drilling and placement of the implant.

Tissue punches are attached to an ISO 1797 compatible dental handpiece/contra angle.

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.

Connection to Handpiece

Intended for use to insert or remove dental implants during dental implant surgery.

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 Drivers

Intended for use to insert or remove dental implants during dental implant surgery.

Implant Driver Wrench Adapters Brånemark 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.

Tissue Punch

Intended for use to remove a circular area of soft tissue prior to preparation of an osteotomy.

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.

Connection to Handpieces

The Connection to Handpiece is indicated for use during dental implant surgery to connect an implant mount/implant assembly to a dental handpiece.

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, NobelSpeedy® and Brånemark System® implants in the maxilla or mandible.

Direction Indicators Tapered NP/RP/WP/6.0

The 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

The 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 Drivers

Implant Drivers are indicated for use during dental implant surgery in the maxilla or mandible.

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

The Implant Drivers Wrench Adapter Brånemark System® are indicated to be used during dental implant surgery for the insertion and removal of Brånemark 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.

Tissue Punches

The tissue punches are indicated for use to remove soft tissue in the maxilla or mandible.

Contraindications

It is contraindicated to use 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 Brånemark 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, NOBELREPLACE® Connection to handpiece, Connection to handpiece, and Tissue Punches: Stainless steel.
  - Implant drivers Brånemark System® and CC 3.0: Stainless steel and TiN coating.
  - Implant drivers CC NP, RP, and WP: Stainless steel, DLC coating, silicone, and PEEK.
  - Implant drivers NobelReplace® NP: Stainless steel, TiN coating, silicone, and PEEK.
  - Implant drivers NobelReplace® RP, WP, and 6.0: Stainless steel, silicone, and PEEK.
  - Direction Indicators: Alloyed titanium Ti-6Al-4V.
  - O-ring for Surgical Driver NobelReplace® and NOBELREPLACE® Connection to handpiece: Fluoroelastomer PAI Compound 9844.
- There are no contraindications for the Irrigation Needle.

For contraindications specific to the implant or implant system component, refer to the Nobel Biocare Instructions for Use for the component (refer to tables 1-4).

Materials

- All-on-4® Guide: Stainless steel according to EN 10088-3/ASTM F899.
- Multi-unit Aligning Instrument: Stainless steel according to EN 10088-3/ASTM F899.
- Combined Open-end Wrench: Stainless steel according to EN 10088-3/ASTM F899.
- Connection to Handpiece: Stainless steel 420F Mod according to ASTM F899.
- NOBELREPLACE® Connection to handpiece:
  - Tool: Stainless steel according to ASTM F899
  - O-ring: Fluoroelastomer PAI Compound 9844
- Direction Indicator Ø 2/2.4-2.8 mm: Titanium alloy Ti-6Al-4V according to ASTM F136.
- Implant Driver Bmk Syst: Stainless steel UNS S46910 according to ASTM F899 with titanium nitride (TiN) coating.
- Implant Driver CC NP:
  - Tool: Stainless steel UNS S46910 according to ASTM F899 with diamond-like carbon (DLC) coating.
  - Insert: Silicone GE 50S5289 50 Duro Color Magenta Pantone 228U.
  - Clip: PEEK Polymer (Glass Fiber Reinforced), natural.
- Implant Driver CC RP:
  - Tool: Stainless steel UNS S46910 according to ASTM F899 with diamond-like carbon (DLC) coating.
  - Insert: Silicone GE 50S5288 50 Duro Color YELLOW Pantone 102U.
  - Clip: PEEK Polymer (Glass Fiber Reinforced), natural.
- Implant Driver CC 3.0: Stainless steel UNS S46910 according to ASTM F899 with titanium nitride (TiN) coating.
- Implant Driver CC NP for Slim Abutment
  - Tool: Stainless steel UNS S46910 according to ASTM F899 with diamond-like carbon (DLC) coating.
  - Insert: Silicone GE 50S5289 50 Duro Color Magenta Pantone 228U.
  - Clip: PEEK Polymer (Glass Fiber Reinforced), natural.
- Implant Driver CC RP for Slim Abutment:
  - Tool: Stainless steel UNS S46910 according to ASTM F899 with diamond-like carbon (DLC) coating.
  - Insert: Silicone GE 50S5288 50 Duro Color YELLOW Pantone 102U.
  - Clip: PEEK Polymer (Glass Fiber Reinforced), natural.
- Implant Driver CC 3.0 for Slim Abutment: Stainless steel UNS S46910 according to ASTM F899 with titanium nitride (TiN) coating.
- Implant Driver NobelReplace® RP:
  - Tool: Stainless steel UNS S46910 according to ASTM F899.
  - Insert: Silicone GE 50S5288 50 Duro Color Yellow Pantone 102U.
  - Spring Clip: PEEK Polymer (Glass Fiber Reinforced), natural.
- Implant Driver NobelReplace® WP:
  - Tool: Stainless steel UNS S46910 according to ASTM F899.
  - Insert: Silicone GE 50S5286 50 Duro Color BLUE Pantone 208C.
  - Spring Clip: PEEK Polymer (Glass Fiber Reinforced), natural.
- Implant Driver NobelReplace® 6.0:
  - Tool: Stainless steel UNS S46910 according to ASTM F899.
  - Insert: Silicone GE 50S5285 50 Duro Color GREEN Pantone 364C.
  - Spring Clip: PEEK Polymer (Glass Fiber Reinforced), natural.
- Implant Driver Wrench Adapters Brånemark System® NP/RP/WP: Stainless steel according to EN 10088-3/ASTM F899.
- Depth Probe 7-18 mm Z-shaped, NobelSpeedy® Depth Probe 18-25 mm:
- Surgical Driver NobelReplace®:
  - Tool: Stainless steel according to EN 10088-3/ASTM F899.
  - O-ring: Fluoroelastomer PAI Compound 9844.
- Handle for Machine Instruments: Stainless steel according to EN 10088-3/ASTM F899.
- Handle for Implant Rescue Collars and Drill Guides: Stainless steel according to EN 10088-3/ASTM F899.
- Irrigation Needle:
  - Tube: Stainless steel according to EN 10088-3/ASTM F899.
  - Hub: Brass alloy and nickel plated.
- Tissue Punch: Stainless Steel 1.4542/UNS S17400 according to ASTM F899.

Cautions

General Cautions

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.

Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.

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

Nobel Biocare reusable instruments 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 Nobel Biocare reusable instruments can lead to product failure, damage to tissue, or unsatisfactory esthetic results. The storage and organization of non-Nobel Biocare instruments and components can lead to mechanical, cleaning, sterilization and/or instrumental failures.

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 has to 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.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

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 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).

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 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:

Nobel Biocare reusable instruments and components 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 Nobel Biocare reusable instruments and components:

The use of these devices 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, damage/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.

There are no side effects associated with the Irrigation Needle.

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

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-in-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 ø2 mm Twist Drill.

3. Place the All-on-4® Guide in the osteotomy (Figure A) and ensure the guide is properly seated.

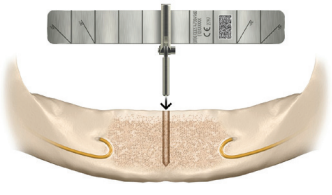

Figure A – Placement of All-on-4® Guide in the First (ø2 mm) Osteotomy

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

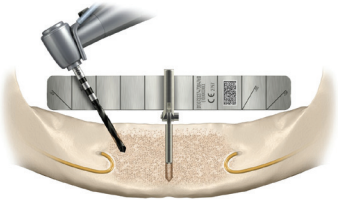

Figure B – Preparation of Second Osteotomy

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 osteotomy, 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.

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 C)

Figure C – 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.

Connection to Handpiece and NOBELREPLACE® Connection to Handpiece

Connection to Handpiece:

The Connection to Handpiece (Figure D) is used during guided surgery with Brånemark System® or NobelSpeedy® implants, to connect guided implant mounts to an ISO 1797-compatible handpiece. It can also be used with the Zygoma handpiece to facilitate handling and implantation of Nobel Biocare Zygoma RP dental implants.

Figure D – Connection to Handpiece

Refer to IFU2011 for detailed information regarding use of the Connection to Handpiece in a guided surgical application. Refer to IFU1095 for information regarding use of the Connection to Handpiece with the Zygoma handpiece during Zygomatic implant procedures.

NOBELREPLACE® Connection to Handpiece:

The NOBELREPLACE® Connection to Handpiece (Figure E) is used during guided surgery with NobelActive®, NobelParallel™ CC, NobelReplace® CC, NobelReplace®, Replace Select™, or Trefoil™ implants to connect guided implant mounts to an ISO 1797-compatible handpiece.

Figure E – NOBELREPLACE® Connection to Handpiece

Refer to IFU2011 for detailed information regarding use of the NOBELREPLACE® Connection to Handpiece in a guided surgical application.

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 (18-25mm).

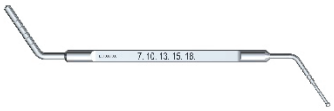

Figure F – Depth Probe 7-18mm Z-shaped

Caution Use of wrong depth probe results in incorrect osteotomy depth.

Direction Indicator Ø2/Ø2.4-2.8 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 G).

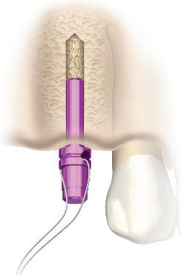

Figure G – Securing the Direction Indicator with Dental Floss

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 Ø2/Ø2.4-2.8 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 H.

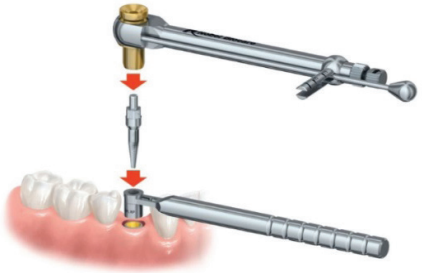

Figure H – Connecting the Handle for Implant Rescue Collar and Drill Guides to Implant Rescue Collar

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 I.

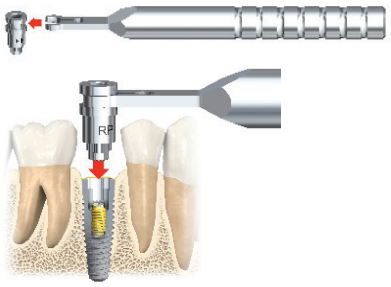

Figure I – Connection of Handle for Implant Rescue Collar & Drill Guide to Rescue Drill Guide and Insertion of Rescue Drill Guide into Implant Connection Interface

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 (Figure J) 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.

Figure J – Handle for Machine Instruments

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 Drivers Brånemark System®/ Conical Connection/NobelReplace®

Implant drivers are attached to a dental handpiece, surgical driver, or manual torque wrench and to the internal or external connection of a dental implant, and is used to handle the implant and to apply the insertion torque necessary to thread the implant into the bone.

Pick up/Handle Implant

1. Connect the appropriate Implant Driver to the dental handpiece, surgical driver, or manual torque wrench.

2. Insert the implant driver into the implant. Apply light pressure on the implant driver and carefully turn the casing counterclockwise until the implant driver is fully seated. The implant drivers have markings to facilitate insertion of the driver into the implant (Figure K). Ensure that the driver is fully seated on the o-ring (Figure L).

Internal tri-channel connection Internal conical connection

Figure K – Example Markings on Implant Driver to Facilitate Insertion into Implant

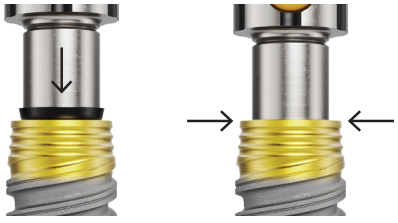

Figure L – Ensure Implant Driver is Fully Seated on O-ring

3. Pick up the implant from the inner casing (Figure M).

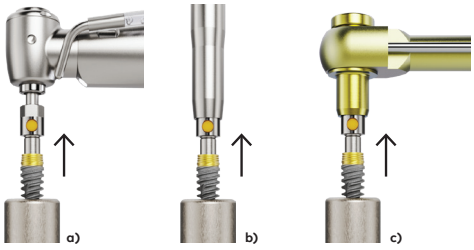

Figure M – Picking Up the Implant using Implant Driver and Dental Handpiece (a), Surgical Driver (b), or Manual Torque Wrench (c)

Placing an Implant

Machine Implant Placement:

1. Connect the implant driver to the dental handpiece.

2. Insert the implant driver into the implant and place the implant to final depth using low speed (maximum 25 rpm) (see Figure N). Refer to the IFU for the implant system for specific instructions and torque values.

Figure N – Machine Placement of Implant

Caution Never exceed the maximum insertion torque indicated for the implant. Overtightening an implant may lead to damage of the implant, fracture, or necrosis of the bone site.

3. Remove the implant driver with a gentle upward motion.

Manual Implant Placement with Torque Wrench:

1. Connect the implant driver to a manual torque wrench adapter and to the appropriate manual torque wrench (Figure O). See Nobel Biocare IFU1098 for more information regarding manual torque wrenches and wrench adapters.

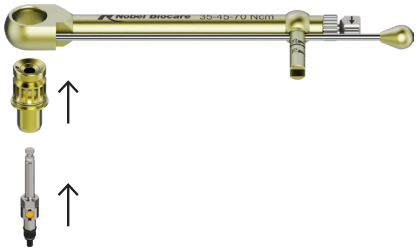

Figure O – Implant Driver with Manual Torque Wrench and Torque Wrench Adapter

2. Insert the implant driver into the implant and place the implant to final depth (see Figure P). Refer to the IFU for the implant system for specific instructions and torque values.

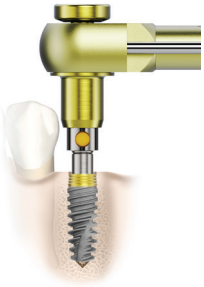

Figure P – Manual Placement of Implant with Torque Wrench

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.

3. Remove the implant driver with a gentle upward motion.

Manual Implant Placement with Surgical Driver:

1. A surgical driver may be used to insert or to adjust the final position of the implant (Figure Q). If a surgical driver is used to insert the implant, special attention is required to avoid overtightening. Refer to the IFU for the implant system for specific instructions and torque values.

Figure Q – Manual Placement or Adjustment of Implant with Surgical Driver

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.

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 Brånemark System® Manual Torque Wrench. See Nobel Biocare IFU1015 for information regarding Brånemark System® implants, and to IFU1007 for NobelSpeedy® implants.

Caution It is mandatory to use a contra-angle with a hexagon clamping connection (DIN EN ISO 17509).

1. Connect the Implant Driver Wrench Adapter Brånemark System® to the Manual Torque Wrench Brånemark System® as shown in Figure R.

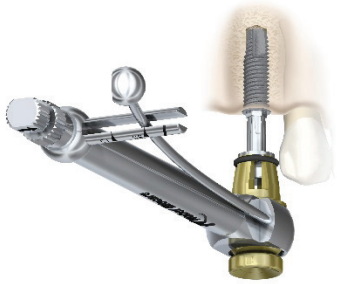

Figure R – Connecting the Implant Driver Wrench Adapter Brånemark System® to Manual Torque Wrench Brånemark System®

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

Irrigation Needle

The irrigation needle (Figure S) 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.

Figure S – Irrigation Needle

1. Connect the irrigation needle to a 20ml 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.

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 T.

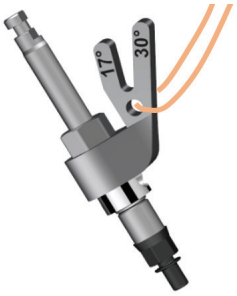

Figure T – Assembling the Multi-unit Aligning Instrument on Implant Driver

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 U.

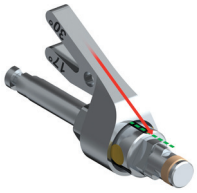

Figure U – Alignment of Multi-unit Aligning Instrument on Implant Driver with Tri-channel Connection

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

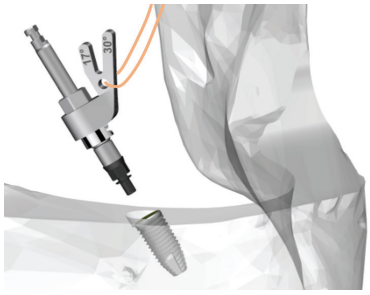

Figure V – Inserting Multi-unit Aligning Instrument into Implant

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 W illustrates the 30° option.

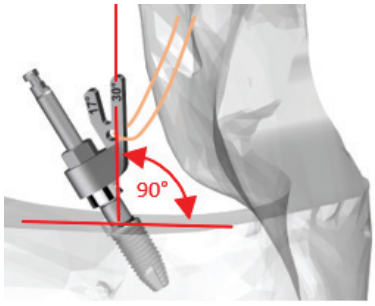

Figure W – Angulation Indicator Identifies Recommended Multi-unit Abutment (Example: 30°)

4. Rotate the implant into its final position as necessary using the Manual Torque Wrench Surgical (see Figure X). 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.

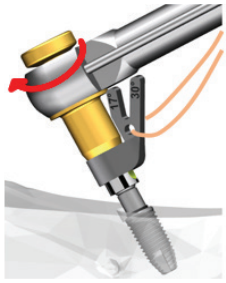

Figure X – Adjusting Rotational Position of Implant with Manual Torque Wrench Surgical

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

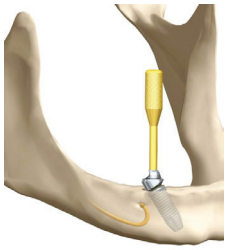

Figure Y – 30° Multi-unit Abutment (Including the Insertion Handle)

Surgical Driver NobelReplace®

The Surgical Driver NobelReplace® (Figure Z) 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.

Figure Z – Surgical Driver NobelReplace®

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.

Tissue Punches

Tissue punches (Figure AA) are used after drilling a pilot hole to remove a circular area of soft tissue at the osteotomy site, in order to facilitate drilling and placement of the implant.

Figure AA – Tissue Punch

Note This technique is recommended only if there is a sufficient amount of attached mucosa. After punching, there should be at least 1 mm of attached mucosa available around the surgical entrance and later around the abutment.

1. Connect the tissue punch to the contra-angle head.

2. Using high speed (maximum 800 rpm), cut through soft tissue down to the crest.

Using a scalpel, cut around the tissue plug perpendicular to the alveolar crest to release the tissue plug from the alveolar crest.

Sterility and Reusability Information

The 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

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 as the device sterility and/or integrity may be compromised.

Note Articles that are included in a PureSet tray can be processed as individual devices as described in the Cleaning and Sterilization Instructions below, or together with other devices in a PureSet tray (not applicable for article 2042 irrigation needle) 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

The Nobel Biocare reusable instruments and components are delivered non-sterile 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 All-on-4® Guide, Multi-unit Aligning Instrument, Combined Open-end Wrench, Connection to Handpieces, Depth Probe 7-18 mm Z-shaped, NobelSpeedy® Depth Probe 18-25 mm, Direction Indicator Ø 2/Ø 2.4-2.8 mm, Direction Indicators Tapered NP/RP/WP/6.0, Handle for Implant Rescue Collar and Drill Guides, Handle for Machine Instruments, Implant Drivers, Implant Driver Wrench Adapters Brånemark System® NP/RP/WP, Surgical Driver NobelReplace®, Irrigation Needle, and Tissue Punches have been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

Initial Treatment at Point of Use Prior to Reprocessing

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. 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. Repeat this step until the lumens are free of any visually datable soil.
3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 1 minute 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 1 minute 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 1 minute 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 of 2 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5 % mildly alkaline detergent (e.g. Neodisher Mediclean)

- Draining
- Minimum of 3 minutes neutralization with cold desalinated water
- Draining
- Minimum of 2 minutes rinsing with cold desalinated water
- Draining

4. Run drying cycle at a minimum of 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 the 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 1 minute until all visible soil is removed.

3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm enzymatic cleaning solution (e.g. Cydezyme ASP; maximum of 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 an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 1 minute 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 1 minute to remove all cleaning solution.

6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F)/maximum 45°C (113°F).

7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml 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 1 minute 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 8 – Presents examples of suitable sterilization pouches.

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

2. Label the sterilization pouch with the information necessary to identify the device (e.g., 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 9):

Table 9 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time	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 EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

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

Containment and Transportation/ Shipping to Point of Use

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

Performance Requirements and Limitations

To achieve the desired performance, Nobel Biocare reusable instruments and components must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with Nobel Biocare reusable instruments and components, 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
UK Responsible Person 	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113, 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 Mark for Class I Devices	CE
CE Mark for Class Ir/IIa/IIb Devices	CE 2797
UKCA Mark for Class I Devices	UK CA
UKCA for Class Im/Is/IIa/IIb Devices	UK CA 0086

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

Basic UDI-DI Information

Product	Basic UDI-DI Number
All-on-4® Guide	733274700000002006L
Multi-unit Aligning Instrument	733274700000021877
Combined Open-end Wrench	73327470000001927E
Connection to Handpiece NOBELREPLACE® Connection to handpiece	73327470000001577C
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	733274700000016377
Implant Drivers Brånemark System® Implant Drivers NobelReplace® Implant Drivers Conical Connection	73327470000001597G
Implant Driver Wrench Adapters Brånemark System® NP/RP/WP Surgical Driver NobelReplace®	73327470000001587E
Irrigation Needle	733274700000016479
Handle for Machine Instruments	73327470000001787L
Handle for Rescue Collars and Drill Guides	73327470000001747C
Connection to Handpiece NobelReplace® Connection to handpiece	73327470000001577C
Tissue Punches	733274700000001867K

Legal Statements

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 / European Union	UK Responsible Person	Authorised Representative in Switzerland	Sterilized using Ethylene Oxide	Sterilized using irradiation	Sterilized using steam or dry heat		
							
Batch code	Catalogue number	Unique Device Identifier	Serial number	Medical device	Magnetic resonance safe		
							
Caution	Magnetic resonance conditional	Non-sterile	Contains hazardous substances	Contains or presence of DEHP phthalate	Contains or presence of natural rubber latex	Contains or presence of phthalate	Contains biological material of animal origin
					Rx only	 symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com	
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	Link to Online Symbols Glossary and IFU Portal	
							
Date of manufacture	Manufacturer	Use-by date	Upper limit of temperature	Temperature limit	Do not resterilize	Do not re-use	Non-pyrogenic
							
Date	Tooth number	Patient number	Patient identification	Health care centre or doctor	Patient information website	EU Importer	Swiss Importer
Double sterile barrier system	Single sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside	Do not use if package is damaged and consult instructions for use	Keep away from sunlight	Keep dry	