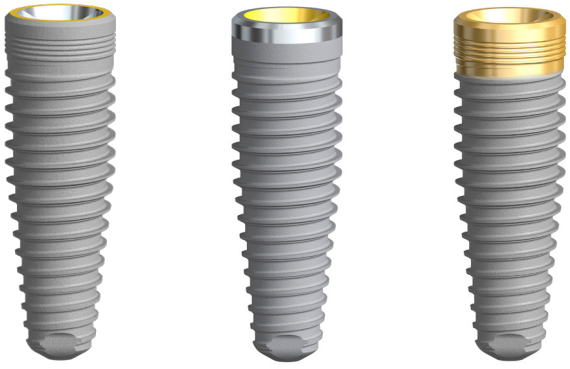
NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC, NobelReplace® Conical Connection TiUltra™



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

NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC (Partially Machined Collar) and NobelReplace® Conical Connection TiUltra™ dental implants are made from commercially pure titanium (grade 4).

- Implant macroshape: tapered body
- Implant connection: conical connection
- Implant surface:
  - NobelReplace® Conical Connection: TiUnite® anodized implant surface
  - NobelReplace® Conical Connection PMC: TiUnite® anodized implant surface and 0.75 mm machined collar

  - NobelReplace® Conical Connection TiUltra™: TiUltra™ anodized implant surface

- Color-coding:
  - NobelReplace® Conical Connection and NobelReplace® Conical Connection PMC: the implant platform is anodized with the color-coding of the prosthetic platform
  - NobelReplace® Conical Connection TiUltra™: no color-coding – the implant platform color is yellow for all implant sizes

NobelReplace® Conical Connection PMC includes a co-packed Cover Screw made of titanium alloy Ti-6Al-4V. For information specific to the Cover Screws, refer to the Nobel Biocare Instructions for Use for the component (IFU1016).

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

Intended Use/Intended Purpose

NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC and NobelReplace® Conical Connection TiUltra™ implants

Intended for use as an endosseous dental implant in the maxilla or mandible for anchoring or supporting dental prostheses to restore chewing function.

Indications

NobelReplace® Conical Connection and NobelReplace® Conical Connection PMC implants

NobelReplace® Conical Connection and NobelReplace® Conical Connection PMC implant restorations range from single tooth to fixed-removable full dental arch overdenture applications to restore chewing function. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

NobelReplace® CC TiUltra™ implants

NobelReplace® CC TiUltra™ implants are endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function.

The NobelReplace® CC TiUltra™ implants are indicated for single or multiple unit restorations. The NobelReplace® CC TiUltra™ implants can be used in splinted or non-splinted applications. The NobelReplace® CC TiUltra™ implant may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

Contraindications

It is contraindicated to use NobelReplace® Conical Connection and NobelReplace® Conical Connection PMC implants in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients with inadequate bone volume unless an augmentation procedure can be considered.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially pure titanium (grade 4) or titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium).

It is contraindicated to use NobelReplace® Conical Connection TiUltra™ implants in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients with inadequate bone volume unless an augmentation procedure can be considered.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially pure titanium (grade 4), sodium dihydrogen phosphate (NaH_2PO_4) or magnesium chloride ($MgCl_2$).

For contraindications specific to the Cover Screws, refer to the Nobel Biocare Instructions for Use for the component (IFU1016).

For contraindications specific to the Tapered Drills and Screw Taps Reusable, refer to the Nobel Biocare Instructions for Use for the component (IFU1048).

For contraindications specific to the Manual Torque Wrenches Surgical and Prosthetic, refer to the Nobel Biocare Instructions for Use for the component (IFU1098).

For contraindications specific to the Screwdrivers, refer to the Nobel Biocare Instructions for Use for the component (IFU1085).

For contraindications specific to the Nobel Biocare Reusable Instruments and Components, refer to the Nobel Biocare Instructions for Use for the component (IFU1090).

For contraindications specific to the PureSet™ Trays, refer to the Nobel Biocare Instructions for Use for the component (IFU1067).

Materials

NobelReplace® Conical Connection PMC

Implant: Commercially pure Titanium grade 4. Detailed chemical composition is Titanium balanced with max. 0.50 wt.% Iron, max. 0.40 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, and max. 0.015 wt.% Hydrogen (max.-maximum value).

Screw: Titanium alloy: Titanium-6Aluminium-4Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen (max.-maximum value).

NobelReplace® Conical Connection Implant

Implant: Commercially pure Titanium grade 4. Detailed chemical composition is Titanium balanced with max. 0.50 wt.% Iron, max. 0.40 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, and max. 0.015 wt.% Hydrogen (max. – maximum value).

NobelReplace® Conical Connection TiUltra™ Implant

Implant: Commercially pure Titanium grade 4. Detailed chemical composition is Titanium balanced with max. 0.50 wt.% Iron, max. 0.40 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, and max. 0.015 wt.% Hydrogen (max.-maximum value). Implant is layered with water soluble salt mixture of Sodium dihydrogen phosphate and Magnesium chloride.

Warnings

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mouth.

Besides the mandatory precautions for any surgery such as asepsis, during drilling in the jaw bone, one must avoid damage to nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

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.

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.

NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC and NobelReplace® Conical Connection TiUltra™ implants must only be used with compatible Nobel Biocare instruments and components and prosthetic components. Use of instruments or components or prosthetic components that are not intended to be used in combination with NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC and NobelReplace® Conical Connection TiUltra™ implants can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

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

Small diameter implants and angled abutments are not recommended for the posterior region.

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. dental dam, gauze or throat shield).

The implants may be tilted up to 45° relative to the occlusal plane. When used with angulations between 30° and 45°, the following applies: The tilted implant must be splinted; a minimum of 4 implants must be used when supporting a fixed prosthesis in a fully edentulous arch.

After the implant installation, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

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 about appropriate oral hygiene.

Intended Users and Patient Groups

NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC and NobelReplace® Conical Connection TiUltra™ implants are to be used by dental health care professionals.

NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC and NobelReplace® Conical Connection TiUltra™ implants are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Devices in the IFU

NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC and NobelReplace® Conical Connection TiUltra™ implants are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC and NobelReplace® Conical Connection TiUltra™

The placement of a dental implant constitutes an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, and swelling. Depending on the location, placement of the implant may also lead (in rare cases) to bone fracture, damage/perforation of neighboring structures/restorations, sinusitis, or sensory/motor disturbances. During placement of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Dental implants are the substructure of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to those associated with teeth, such as mucositis, calculus, peri-implantitis, fistulas, ulcers, soft tissue hyperplasia, soft and/or hard tissue recession/loss. Some patients may experience discoloration in the mucosal area such as graying.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC and NobelReplace® Conical Connection TiUltra™ implants. The SSCP can be obtained at the following website: ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED)

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

Surgical Procedure

The minimum margin height on conical connection abutments is 1.5 mm from the implant platform (Figure A). Implant placement depth relative to available soft tissue must be planned with this in mind for esthetic considerations.

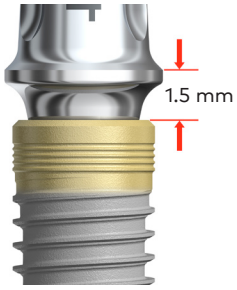


Figure A – Minimum margin height

1. Drilling must proceed at high speed (maximum 800 rpm for Tapered Drills) under constant and profuse irrigation by sterile saline at room temperature. Tapered Drills are internally-irrigated and require a specific technique to prevent irrigation holes becoming plugged with bone debris. During drilling use an in-and-out motion and drill in bone for 1–2 seconds. Move the drill up without stopping the handpiece motor which allows the irrigation to flush away bone debris.

Caution Tapered Drills extend up to 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures.

Figure B shows protocol steps and "Product Reference line" for tapered implants, 13 mm long with regular platform.

Figure B – Protocol steps

When using a flapless approach add on soft tissue height to drill depth.

In situations where adjacent structures (natural teeth) would interfere with the angle head and prevent the drill from reaching the desired depth, a drill extension shaft may be used.

2. Prepare implant site using Drill with Tip Tapered 2 mm (Figure C) and respective Tapered Drills depending on the implant to be installed, length and platform (Figure D).

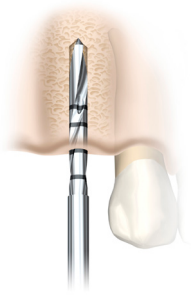


Figure C – Drill with Tip Tapered 2 mm

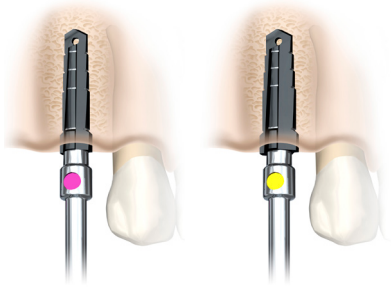


Figure D – Tapered Drills

3. Open the implant package and pick up the implant from the inner casing with the implant driver (Figure E). For conical connection implants it is recommended to applying light pressure on the implant driver and carefully turn the implant sleeve counter clockwise until the implant driver is fully seated (Figure E). The implants are ideally installed with low speed (maximum 25 rpm) using a drilling device or the Manual Torque Wrench Surgical.

Figure E – Fully seated implant driver

Figure F – max 45 Ncm

Place and tighten the implant using max 45 Ncm installation torque (Figure F).

To ensure ideal prosthetic abutment orientation for internal conical connection implants position one of the internal hexagon flat surfaces in the implant towards buccal/facial. To facilitate proper orientation, refer to the markings on the implant driver (Figure F).

Caution Never exceed insertion torque of 45 Ncm. Overtightening an 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.

If the implant gets stuck during implant installation or 45 Ncm of insertion torque is achieved before fully seated, rotate the implant counter clockwise using the drilling device (reverse mode) or manual torque wrench and remove the implant from site. Replace the implant back into the inner casing before proceeding further.

4. Dense bone protocol – as indicated:
    a. Dense Bone Drill Tapered (Figure G) is only needed for 13 mm and 16 mm implants. If shorter implants are used, go directly to step c. Select the Dense Bone Drill matching the diameter and length (13 or 16 mm) of the final Tapered Drill.
    b. Drill one pass into the prepared site with high speed (800 rpm) using the Dense Bone Drill.
    c. For product reference line Screw Tap vs implant length see (Figure H). Select the Screw Tap Tapered matching the diameter of the final Tapered Drill. Place into prepared implant site using low speed (25 rpm).
    d. Apply firm pressure and begin rotating the Screw Tap slowly. When the threads engage, allow the Screw Tap to feed without pressure to appropriate depth (Figure I).
    e. Switch the handpiece to reverse mode and back the Screw Tap out.

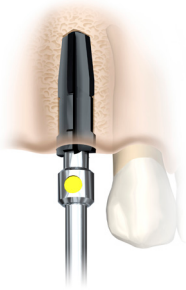


Figure G – Dense Bone Drill

Figure H – Reference lines for implant length

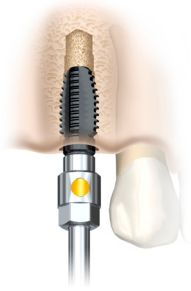


Figure I – Screw Tap inserted

Continue with the implant installation until the desired position is achieved using max 45 Ncm installation torque.

5. For Immediate Function, the implant should be able to withstand a final torque of 35–45 Ncm.

6. Depending on surgical protocol of choice, place a cover screw or abutment and suture (Figure J, Figure K).

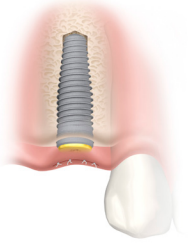


Figure J – Cover screw

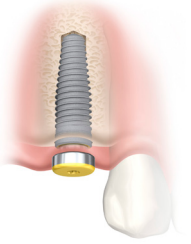


Figure K – Healing abutment

See Table 1 for implant specifications.

Table 1 – Implant specifications

Platform	Platform diameter	Implant diameter	Abutment interface	Bridge interface	Lengths
NP	Ø 3.5 mm	Ø 3.5 mm	Ø 3.0 mm	Ø 3.5 mm	8 mm, 10 mm, 11.5 mm, 13 mm, 16 mm
RP	Ø 3.9 mm	Ø 4.3 mm	Ø 3.4 mm	Ø 3.9 mm	8 mm, 10 mm, 11.5 mm, 13 mm, 16 mm
RP	Ø 3.9 mm	Ø 5.0 mm	Ø 3.4 mm	Ø 3.9 mm	8 mm, 10 mm, 11.5 mm, 13 mm, 16 mm

Caution Please note the NobelReplace® Conical Connection TiUltra™ implant platform color is yellow for all implant sizes and does not reflect Nobel Biocare's platform color-coding.

For information specific to the Cover Screws, refer to the Nobel Biocare Instructions for Use for the component (IFU1016).

Sterility and Reusability Information

NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC and NobelReplace® Conical Connection TiUltra™ implants been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

Warning Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

Caution NobelReplace® Conical Connection, NobelReplace® Conical Connection PMC and NobelReplace® Conical Connection TiUltra™ implants are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Magnetic Resonance (MR) Safety Information

These products are fabricated from a metal material which can be affected by MR energy. For further information refer to Nobel Biocare publication **Magnetic Resonance (MR) Safety Information** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with the devices, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

Storage, Handling and Transportation

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information

Manufacturer	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
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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 IIb Devices	CE 2797
UKCA Mark for Class IIb Devices	UK CA 0086

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

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

Basic UDI-DI Information

Product	Basic UDI-DI Number
NobelReplace® Conical Connection	733274700000012875
NobelReplace® Conical Connection PMC	
NobelReplace® Conical Connection TiUltra™	

Legal Statements

Symbols Glossary

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