NobelReplace® Conical Connection TiUltra™

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.

Description:

NobelReplace® Conical Connection (CC) TiUltra™ are endosseous tapered implants which give a higher initial stability compared with a parallel implant. The implants are made from biocompatible commercially pure grade 4 titanium with TiUltra® surface.

Intended Use:

NobelReplace® CC TiUltra™ implants are threaded, root-form dental implants intended for use in the upper and lower jaw arches to support prosthetic devices, such as an artificial tooth, in order to restore esthetics and chewing function to partially or fully edentulous patients.

Indications for Use:

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® CC 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 ($MgCl_2$).

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.

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

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.

It is strongly recommended that Nobel Biocare implants are used only with compatible Nobel Biocare surgical instruments and prosthetic components Use of surgical instruments and prosthetic components that are not intended to be used in combination with Nobel Biocare implants 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.

It is especially important to achieve proper stress distribution through adaptation and fitting of the crown or bridge, by adjusting the occlusion to the opposing jaw. In addition, avoid excessive transverse loading forces, particularly in immediate loading cases.

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 procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At surgery:

Particular caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.

Care and maintenance of 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).

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 placement, 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.

Bending moments: Forces that cause bending moments are known to be the most unfavorable, as they can potentially jeopardize the long-term stability of an implant-supported restoration. In order to decrease bending moments, the distribution of forces should be optimized by cross-arch stabilization, minimizing distal cantilevers, having a balanced occlusion as well as decreased cuspal inclination of the prosthetic teeth.

If modifying the restoration, use copious irrigation and appropriate protection equipment. Avoid inhalation of dust.

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.

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.

A

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.

Refer to (**Figure B**) for the protocol steps and "Product Reference line" for NobelReplace® CC TiUltra™, 13 mm long with regular platform.

B

Figure B: Protocol steps and "Product Reference line" NobelReplace® CC TiUltra™, 13 mm long with regular platform

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 implant to be installed, length and platform (**Figure D**).

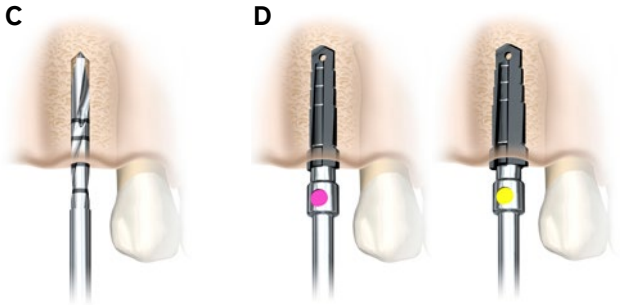

Figure C: Preparation of Implant Site with Drill with Tip Tapered 2 mm

Figure D: Preparation of Implant Site with Tapered Drill

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

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

To ensure ideal prosthetic abutment orientation, position one of the implant's internal hexagon flat surfaces in alignment with the buccal/vestibular side. To facilitate proper orientation, refer to the black markings on the implant drivers (**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 drilling device (reverse mode) or manual torque wrench and remove implant from site. Replace the implant back into inner casing before proceeding further.

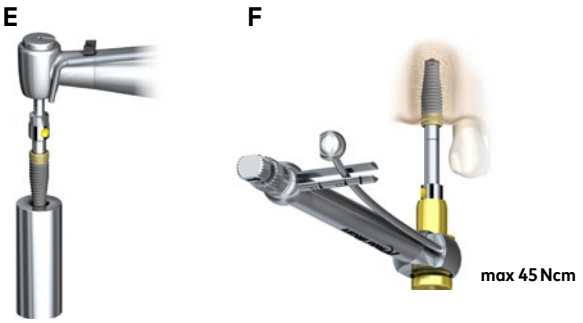

Figure E: Seating the Implant Driver

Figure F: Placement and Tightening of Implant

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 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:1**). Select the Screw Tap tapered matching the diameter of 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 Screw Tap to feed without pressure to appropriate depth (**Figure H:2**).

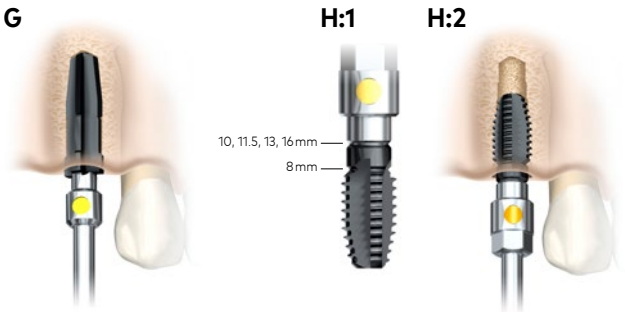

Figure G: Preparation of Implant Site with Dense Bone Drill

Figure H: Screw Tap Reference Line (H:1) and Preparation of Implant Site with Screw Tap (H:2)

e. Switch the handpiece to reverse mode and back the Screw Tap out. Continue with implant installation until 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 (**Figure I:1**) or abutment (**Figure I:2**) and suture.

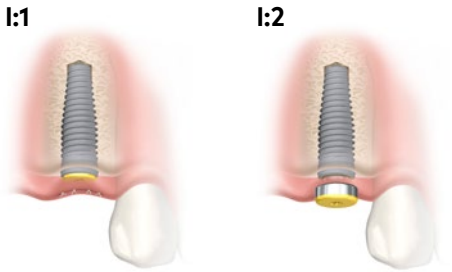

Figure I: Placement of a Cover Screw (I:1) or Healing Abutment (I:2)

Table 1 summarizes the NobelReplace® CC TiUltra™ implant specifications.

Table 1: NobelReplace® CC TiUltra™ 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® CC TiUltra™implant platform color is yellow for all implant sizes and does not reflect Nobel Biocare's platform color-coding.

For additional information on surgical procedures please consult the "NobelReplace® CC TiUltra Surgical Procedures" manual available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

NobelActive® TiUltra™ implant: commercially pure titanium grade 4, sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).

Sterility and reusability information:

NobelReplace® CC TiUltra™ has been sterilized using irradiation and is 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.

Caution: NobelActive® TiUltra™ is a single use product 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:

The NobelReplace® CC TiUltra™ implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of NobelReplace® CC TiUltra™ implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 compromise the integrity of the sterile barrier or the legibility of the labelling.

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:
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411 17 Göteborg
Sweden
www.nobelbiocare.com

Distributed in USA by:
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, CA, 92887 USA

Caution: Federal (United States) law restricts this device to sale by or on the order of a dentist or a physician.

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 Union

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 re-sterilize


Do not re-use


Do not use if package is damaged


Double sterile barrier system

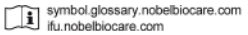
Rx Only

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