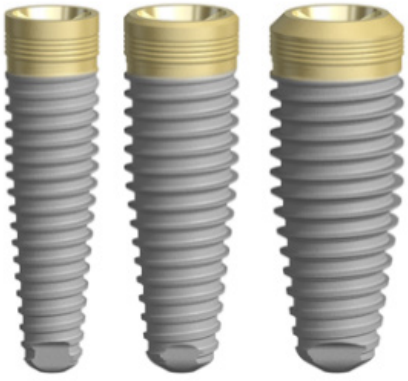
NobelReplace® Conical Connection TiUltra™



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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.

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

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 ($MgCl_2$).

Materials

NobelReplace® CC 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.

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

Cautions

General

One hundred percent implant success cannot be guaranteed. In particular, non-observance of the products 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 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 TiUltra™ 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. NobelÂ 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 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 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 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.

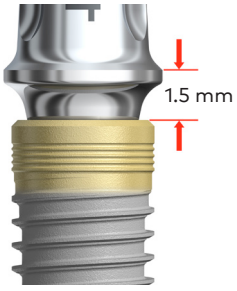

Figure A – Minimum Margin Height

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.

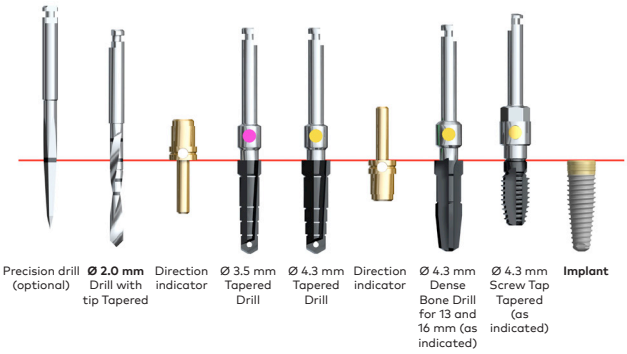

Figure B – Protocol steps and "Product Reference line" NobelReplace® CC TiUltra™, 13 mm long with regular platform

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

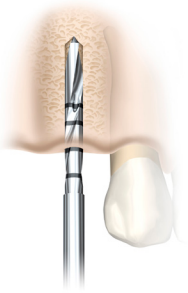

Figure C – Preparation of Implant Site with Drill with Tip Tapered 2 mm

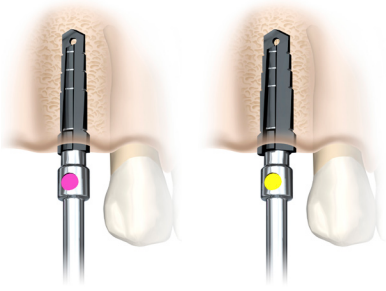

Figure D – Preparation of Implant Site with Tapered Drills

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 – Seating the Implant Driver

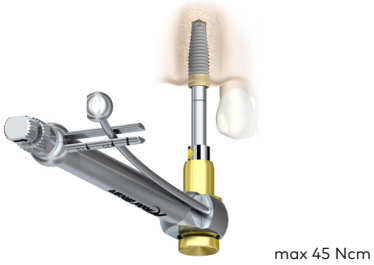

Figure F – Placement and Tightening of Implant

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).

Figure G – Preparation of Implant Site with Dense Bone Drill

Figure H – Reference lines for implant length

Figure I – Screw Tap inserted

    e. Switch the handpiece to reverse mode and back the Screw Tap out. 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).

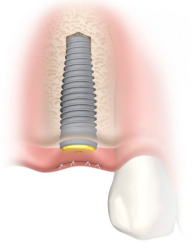

Figure J – Placement of a Cover screw

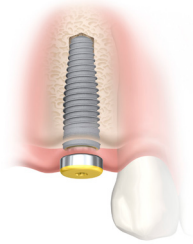

Figure K – Placement of a Healing abutment

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

Sterility and Reusability Information

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 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.

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	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA

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

Legal Statements

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.