NobelReplace® Conical Connection,
NobelReplace® Conical Connection Partially Machined Collar (CC PMC)
Instructions for use

Important: Please read.

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:

Implant:
NobelReplace® Conical Connection (CC) and NobelReplace® Conical Connection Partially Machined Collar (CC PMC) 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 TiUnite® surface. The implants are anodized with the color-coding of the prosthetic platform and the implant packages are color coded by the diameter of the implants. NobelReplace® CC PMC has a 0.75 mm machined collar and comes with a co-packed Cover Screw made of titanium alloy Ti-6Al-4V.

Tooling:
Nobel Biocare Drill with Tip Tapered, Tapered Drills, Dense Bone Drills and Screw Taps should be used in conjunction with NobelReplace® CC and CC PMC implants. Tapered Drills are internally-irrigated and require a specific technique to prevent irrigation holes becoming plugged with bone. Reusable Tapered Drills and Screw Taps are made of stainless steel with DLC (Diamond Like Carbon) coating and should be replaced after 20–30 uses, or when cutting efficiency declines. Tapered drills are unique for each implant length.

Intended use:

NobelReplace® CC and CC PMC implants are intended to be used in the upper or lower jaw bone (osseointegration) and used for anchoring or supporting tooth replacements to restore chewing function.

Indications:

NobelReplace® CC and CC 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.

Contraindications:

It is contraindicated placing NobelReplace® CC and CC PMC implants in patients:

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

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 from 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 the nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

Cautions:

General:
One hundred percent implant success cannot be guaranteed. Especially, non-observance of the indicated limitations of use and working steps 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 NobelReplace® CC and CC PMC implants are used only with Nobel Biocare surgical instruments and prosthetic components, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory esthetic results.

It is strongly recommended that clinicians, new as well as experienced implant users, 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 info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Before surgery:
Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient.

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 or unfavorable jaw relationships reappraisal of the treatment option may be considered.

With respect to pediatric patients, routine treatment is not recommended until the end of the 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 angulation.

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

After the implant installation, the surgeon's evaluation of bone quality and initial 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.

All 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.

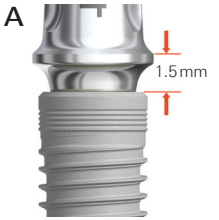
Because of the small size of components, care must be taken that they are not swallowed or aspirated by the patient.

NobelReplace® CC and CC PMC 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 surgery:
To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Surgical procedure:

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



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 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.

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

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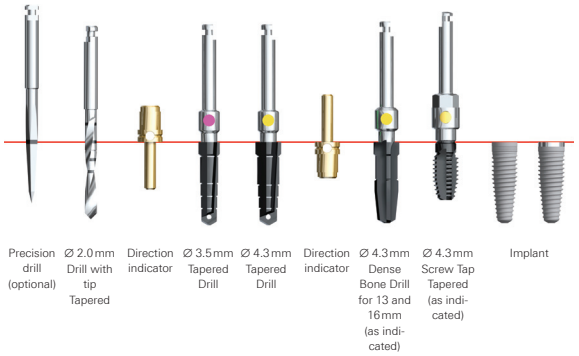
B

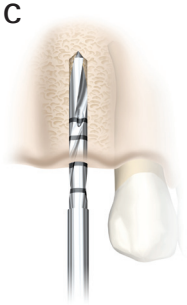


When using a flapless approach add on soft tissue height to drill depth.

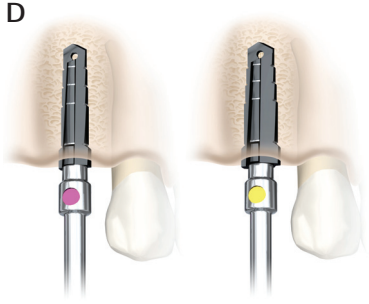
In situations where adjacent structures (natural teeth) would interfere with the angle head and prevent the drill from reaching the desired depth, a drill extension shaft may be used.

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

C



D



3. Open the implant package and pick up the implant from inner casing with implant driver (**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 implant driver is fully seated (**E**). The implants are ideally installed with low speed (maximum 25 rpm) using a drilling device or Manual Torque Wrench Surgical.

E

F

Place and tighten the implant using max **45 Ncm** installation torque (**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 see the markings on implant driver (**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.

4. Dense bone protocol – as indicated:

a. Dense Bone Drill Tapered (**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 Bone Drill.

c. For product reference line Screw Tap vs implant length see (**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 (**H:2**).

G

H:1

H:2

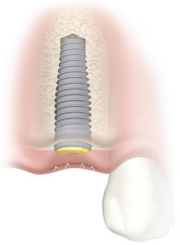
e. Switch the handpiece to reverse mode and back the Screw Tap out.

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

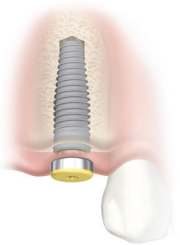
5. For Immediate Function, the implant should be able to withstand a final torque of **35–45 Ncm**.

6. Depending on surgical protocol of choice, place a cover screw or abutment and suture (**I:1, I:2**).

I:1



I:2



See table (**J**) for implant specifications.

J

Implant specification
NobelReplace® Conical Connection

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

For additional information on surgical procedures please consult the NobelReplace® Conical Connection and NobelReplace® Conical Connection Partially Machined Collar "Procedures & products" treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

NobelReplace® CC and CC PMC implant: commercially pure titanium grade 4.

CC Cover Screw: titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

Tapered Drills; Dense Bone Drill and Screw Taps: stainless steel, DLC (Diamond Like Carbon) coating.

Drill with Tip Tapered: stainless steel.

Cleaning and sterilization:

NobelReplace® CC and CC PMC implants and Drill with Tip are delivered sterile and for single use only prior to the labelled expiration date.

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

Caution: Implants and Drill with Tip Tapered are single use products not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause cross contamination.

Tapered Drills, Dense Bone Drills and Screw Taps are delivered non-sterile and must be cleaned and sterilized prior to use.

For USA: Seal single device in a pouch and steam sterilize at 270°F (132°C) for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132°C–135°C (270°F–275°F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134°C–135°C (273°F–275°F) for 3 minutes.

Warning: Use of non-sterile components may lead to infection of tissues or infectious diseases.

Full set of recommended parameters are provided in "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

MR safety information:

Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

For additional information on Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines for Nobel Biocare Products including MRI Information" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Storage and handling:

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

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Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

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

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Rx Only

Sterile using irradiation


Consult instructions for use


Use-by date


Do not re-use

Batch code


Do not use if package is damaged

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