

Surgical procedures



Nobel Replace®

CONICAL CONNECTION

TiUltra™

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Contents

Introduction 3

Surgical procedure 4

Surgical access 4

Drilling sequence 5

Dense bone protocol 11

Implant insertion 12

Finalization of implant surgery 15

Appendices 16

Manual torque wrench 16

Cleaning and sterilization 17

Introduction

The scope of this surgical procedures manual is to provide a comprehensive overview of the surgical steps and options during the placement of NobelReplace® Conical Connection TiUltra™ implants.

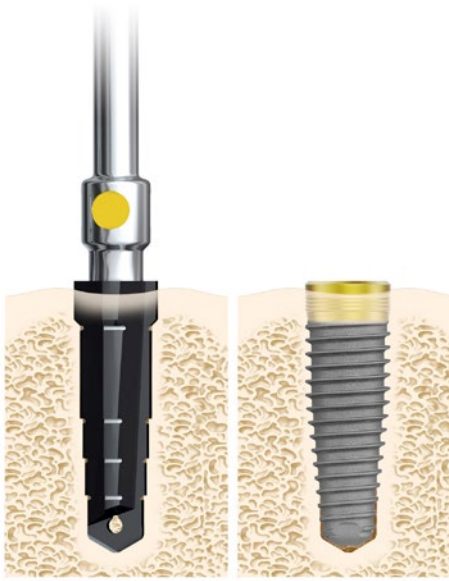
This surgical procedures manual does not replace the Instructions For Use (IFU).

Please review the Instructions For Use, including Indications For Use, Contraindications, Warnings and Cautions before using the products.

Instructions for Use are available at ifu.nobelbiocare.com.

For a full list of article numbers and for ordering information, refer to the Product overview - Conical connection implants and prosthetics available at nobelbiocare.com or contact a Nobel Biocare representative.

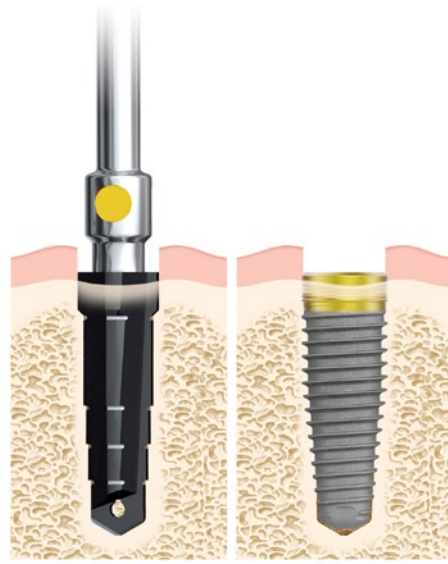
Surgical access



Standard flap procedure

Used when it is necessary:

- to observe the underlying alveolar bone and adjacent anatomical structures.
- to place bone and/or connective tissue grafts.



Flapless procedure

Used when:

- there is sufficient quantity and quality of alveolar bone and soft tissue.
- it is not necessary to raise a flap to safely direct drilling procedure in relation to the anatomy.

When using a flapless approach:

- Add soft tissue height to drill depth
- Confirm available bone and significant anatomical landmarks, such as blood vessels, nerves, and concavities. Use conventional diagnostic tools, such as radiographic imaging, probing and palpation, and 3D imaging if indicated.

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

Drilling sequence

Drill technique

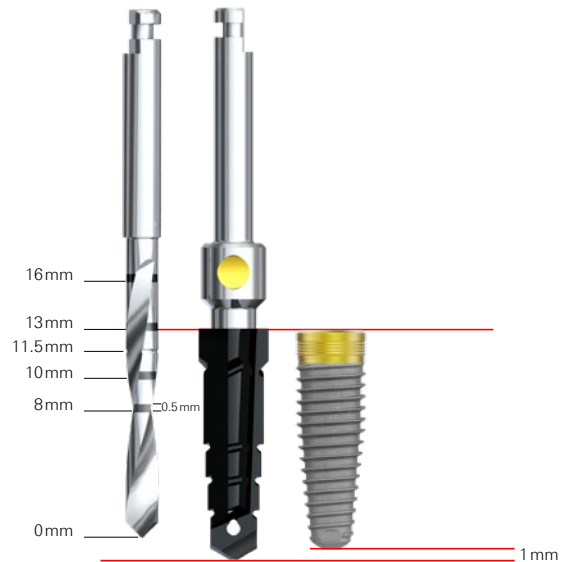
Reusable tapered drills and screw taps are made of stainless steel with a diamond like carbon (DLC) coating. Drills are irrigated internally to prevent heat build-up and burning bone. Drilling must proceed at high speed (maximum 800 rpm for Tapered Drills) under constant and profuse irrigation by sterile 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. This also allows the irrigation to flush away bone debris.
- Proceed until desired depth reference line is reached.
- If a drill becomes plugged, remove the drill from the handpiece and clear the irrigation hole using the needle provided in the surgical kit.
- Stop drilling if there is no irrigation.
- A drill extension shaft may be used to facilitate the procedure. If the drill extension shaft is used together with the drill, external irrigation at the contra-angle should be supplemented. Only use the drill extension shaft with drills.

Irrigate the site with saline solution (using a syringe) to remove bone chips before using the next drill.

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.

Product reference lines



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.

Disposable and reusable drills

Drill with Tip Tapered Ø 2 mm is disposable and should be used for one surgery only.

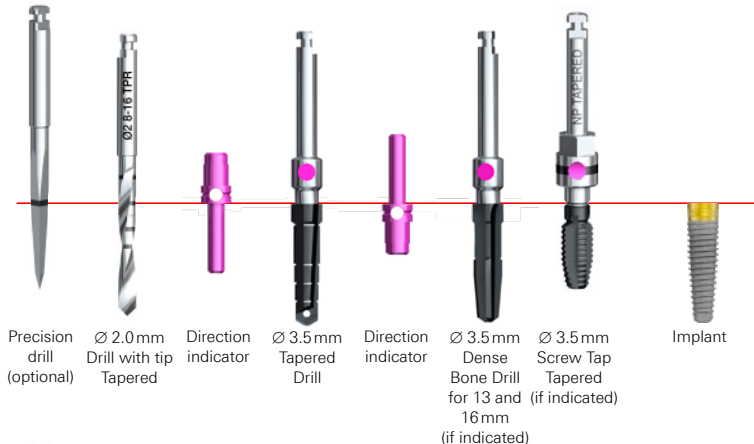
Caution: Drill with Tip Tapered Ø 2 mm is a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause local or systemic infection.

Tapered drills, dense bone drills, and screw taps are reusable and should be replaced after 20–30 uses, or when cutting efficiency declines. Worn-out and damaged drills need to be discarded and replaced with new sharp drills.

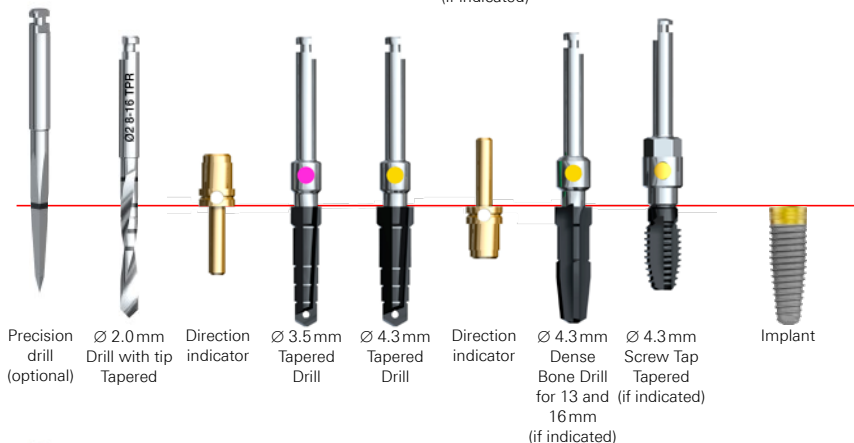


Drill protocols/Product reference lines

**Implant
Ø 3.5 mm**



**Implant
Ø 4.3 mm**



**Implant
Ø 5.0 mm**




Flapless procedure

Choose between the following two options and continue with the drill sequence on page 8, starting with step 3.

Option A

- Drill through gingival tissue and into alveolar crest with the Drill with Tip Tapered Ø 2mm.

Maximum speed  800 rpm

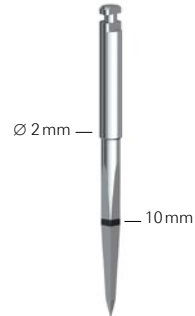
Measure the soft tissue thickness with a probe. Add this tissue thickness to the drilling depth for correct site preparation. Be aware of anatomical landmarks.



Option B

- To facilitate initial soft tissue penetration and creation of a crestal starting point (also after flap preparation), the Precision Drill can be used before Drill with Tip Tapered Ø 2mm.
- Drill with the precision drill through soft tissue and into the alveolar crest.

Maximum speed  2000 rpm



Flap procedure


1 Raise a flap

When using a flap procedure, make an incision and raise a flap.



2 Drill with Twist Drill with Tip Tapered Ø2.0mm

– Drill to the appropriate depth using the Drill with Tip Tapered Ø 2 mm and copious irrigation.

Maximum speed  800 rpm

When placing multiple implants, proceed to next implant site before continuing with next drill sequence.

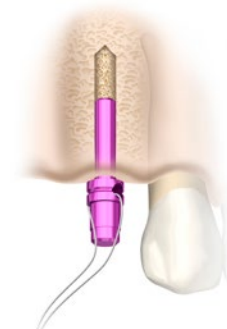
Irrigate the site with saline solution (using a syringe) to remove bone chips before using the next drill.



3 For all implant diameters: check osteotomy direction


– Check correct direction and seating using Direction Indicator Tapered.

– If necessary, adjust site preparation.



4 For all implant diameters: drill with**Drill Tapered NP 3.5**

- Drill to depth corresponding to length of the implant being placed. If unsure of exact drill depth, stop short.
- Flapless procedure: measure tissue thickness with probe. Add tissue thickness to drilling depth for correct site preparation. Be aware of anatomical landmarks.
- Check correct orientation and seating using Direction Indicator Tapered NP.
- If necessary, adjust site preparation.


Maximum speed  800 rpm

This is the final tapered drill for a 3.5 mm implant.



5 For implants Ø 4.3 and 5.0 mm: drill with**Drill Tapered RP 4.3**

- Continue site preparation using Drill Tapered RP 4.3.
- Check correct orientation and seating using Direction Indicator Tapered RP.


Maximum speed  800 rpm

This is the final tapered drill for a 4.3 mm implant.



**6 For implants \varnothing 5.0 mm: drill with
Drill Tapered WP 5.0**

- Continue site preparation using the Drill Tapered WP 5.0.
- Check correct orientation and seating using Direction Indicator Tapered WP.

Maximum speed  800 rpm

This is the final tapered drill for a 5.0 mm implant.



Dense bone protocol

If the bone is dense or locally dense, the Dense Bone Drill Tapered and Screw Tap Tapered may be required.

The dense bone drill is only needed for 13mm and 16mm implants. For implants shorter than 13mm, the screw tap functions as a dense bone drill.


Design comparison



1 Use dense bone drill

- Select the drill that matches the diameter and length (13mm or 16mm) of the final tapered drill.
- Drill one pass into the prepared site with high speed (800 rpm) using the dense bone drill.

Always use a screw tap after using a dense bone drill.

Maximum speed  800 rpm



2 Use screw tap

- Select the screw tap matching the diameter of the final tapered drill.
- Insert the screw tap into the prepared implant site using low speed (25rpm).
- Apply firm pressure and begin rotating the screw tap slowly. When the threads engage, allow screw tap to feed without pressure.
- For 8mm implants, proceed to the first height marking. For 10, 11.5, 13, and 16mm implants, proceed to the second height marking (see picture).
- Switch the handpiece to reverse mode and back the screw tap out.

Low speed 25 rpm

Use the Screw Tap Tapered NP for all 3.5 mm NobelReplace Conical Connection TiUltra implants.



Implant insertion

1 Unpack implant

Each implant comes in a double sterile packaging: the implant held in an inner titanium vial (fig. 1) that is packed in a plastic vial with screw top lid, which acts as the first sterile barrier (fig. 2). The plastic vial with screw top lid is packed in a blister sealed with a lid, which is the second sterile barrier (fig. 3). The blister is packed together with an implant card and patient record labels in a cardboard box (fig. 4).

The cardboard box and the blister have a printed label with product data including diameter and length.

The vial is laser marked with implant data including name, diameter and length (fig. 1). The inner titanium vial cap is color coded to identify the implant diameter.

Open the box and ensure implant card and patient record labels are removed.

Peel off the sealed blister lid in order to open it and allow the plastic vial onto the sterile field.

Unscrew the lid and take out the sterile titanium vial, then lift off the color-coded cap to gain access to the implant.

Record the implant size and LOT number on the patient's profile records with the provided peel-off labels available in the box. After surgery provide the implant card, completed with the implant information, to the patient to keep for future reference.



Fig. 1 - Inner vial



Fig. 2 - Plastic vial



Fig. 3 - Blister

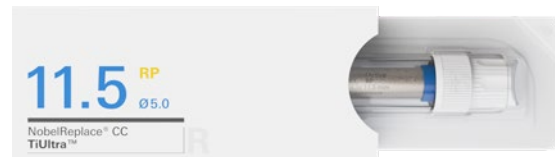


Fig. 4 - Cardboard box

2 Pick up implant

- Connect the appropriate Implant Driver NobelReplace to the hand-piece.
- Pick up implant from inner titanium vial by applying light pressure on the implant driver and carefully turning the vial counterclockwise until the implant driver is fully seated.

The implant drivers have markings to facilitate the insertion of the driver into the implant.



3 Insert implant

- Insert the implant into the osteotomy using low speed (25 rpm) and torque between 20–45 Ncm.
- Insert the implant until fully seated. Do not exceed 45 Ncm.
- Ensure that the implant driver is in alignment with the implant during insertion.
- Remove the driver with a gentle upward motion.

Low speed 25 rpm  Max. torque 45 Ncm

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.

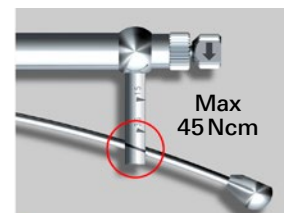
If the implant gets stuck during implant installation or 45 Ncm of insertion torque is achieved before fully seated, rotate the implant counter clockwise using drilling device (reverse mode) or manual torque wrench and remove implant from site. Replace the implant back into inner casing before proceeding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

Please refer to Dense bone protocol chapter on page 11 for the next steps in drilling sequence.



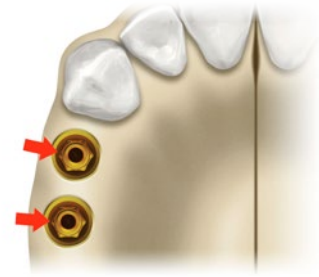
4 Adjust and tighten manually

- Connect the appropriate implant driver to the NobelReplace Manual Torque Wrench Surgical and place the implant to its final depth.
- For Immediate Function, the implant should be able to withstand a final tightening torque of 35–45 Ncm.
- Do not exceed 45 Ncm.
- If insufficient stability is attained for Immediate Function, do not load the implant. Wait for sufficient conventional healing (one- or two-stage approach).



5 Orient implant

When placing the implant, align one of the black hex indicators on the implant driver parallel to the buccal wall. This ensures that one of the flat sides of the hexagon is parallel to the buccal side (see figure), ensuring preferred prosthetic abutment orientation.



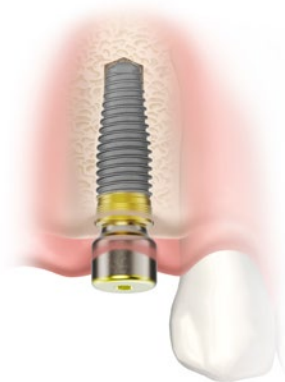
Finalization of implant surgery

There are three options for finalizing the implant surgery.



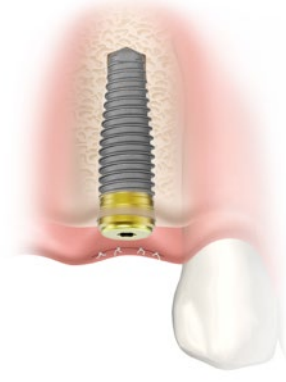
One-stage Immediate Function

Provisionalize implant for immediate esthetics and function, using Nobel Biocare temporary or final abutments.



One-stage delayed function

Use Screwdriver Unigrip to connect a healing abutment to the implant. If applicable, suture back the soft tissue.



Two-stage delayed function

Use Screwdriver Unigrip to connect a cover screw to the implant. Suture tissue flap using desired technique.

If the final restoration is an implant-level NobelProcera Implant Bridge or a non-engaging GoldAdapt Abutment, use a Healing Abutment Bridge to prevent tissue overgrowth on the horizontal implant platform.

NobelReplace Conical Connection TiUltra implants are compatible with temporary and final abutments featuring the Nobel Biocare Conical Connection.

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 a detailed overview of the latest available conical connection restorative options, refer to the Product overview - Conical connection implants and prosthetics, available at nobelbiocare.com and review their respective Instructions For Use available at ifu.nobelbiocare.com

Manual torque wrench

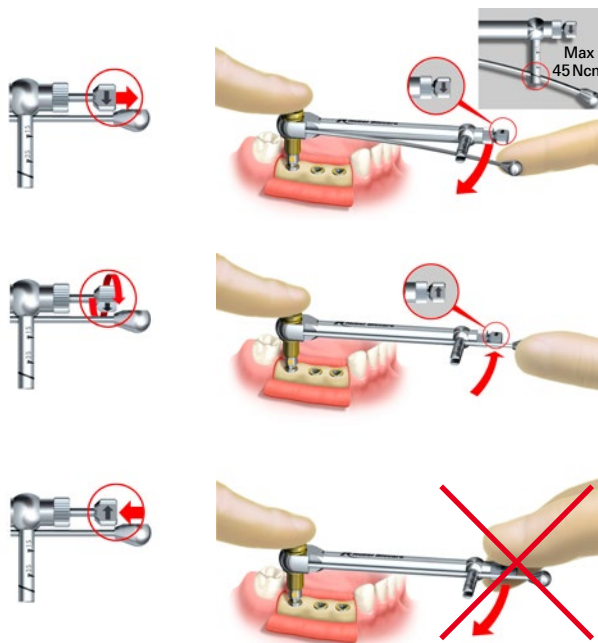
For the surgeon, the torque required to place implants provides insight into the primary stability of the implant. For restorative procedures, tightening the abutment and prosthetic screws to recommended torque specifications will more effectively control screw-joint integrity during patient function.

The manual torque wrench is a convenient tool for achieving the desired torque.

Use of Manual Torque Wrench Surgical

- Assemble the torque wrench by inserting the implant driver.
- To tighten an implant, adjust the direction indicator so that the arrow is pointing toward the level arm and rotate clockwise.
- To loosen an implant, adjust the direction indicator so that the arrow is pointing away from the level arm and rotate counterclockwise.

Warning: If force is applied to the main body of the Manual Torque Wrench Surgical and not to the lever arm, the applied torque cannot be measured. High forces may cause over compression of the bone leading to bone resorption, especially in case of a thin buccal/lingual marginal bone crest.



Cleaning and sterilization

Implants

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: NobelReplace CC 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.



Drill with Tip Tapered Ø 2 mm

The drill is disposable, delivered sterile, and should be discarded after use.

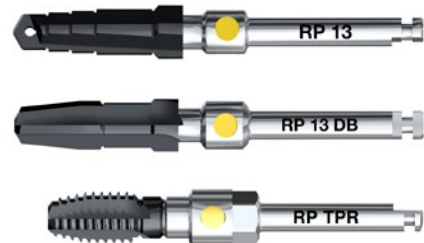


Tapered drills and screw taps

Drills, dense bone drills, and screw taps for NobelReplace Tapered and Replace Select Tapered implants are reusable and should be replaced after 20–30 uses, or when cutting efficiency declines. Worn-out and damaged drills need to be discarded and replaced with new sharp drills.

The tapered implant drills are to be cooled internally via irrigation and require specific cleaning procedures prior to sterilization.

See current cleaning and sterilization guidelines for details: nobelbiocare.com/sterilization



nobelbiocare.com/en-us/nobelreplace



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