

Surgical procedures

A detailed image of a Nobel Parallel TiUltra dental implant. It features a gold-colored hexagonal top section with horizontal ridges, and a grey, textured body with vertical ridges. The implant is centered vertically and horizontally on the page.

Nobel Parallel™

CONICAL CONNECTION

TiUltra™

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Introduction

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

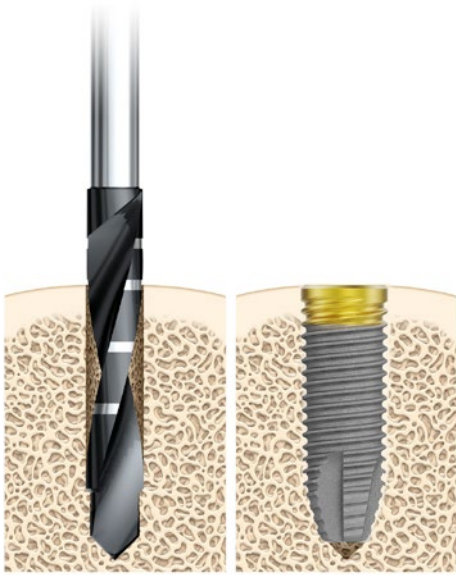
This surgical procedures manual does not replace the Instructions For Use (IFU).

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.

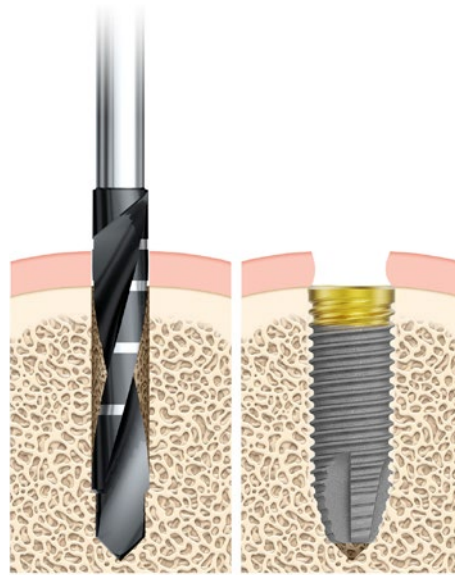
Surgical access



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

May be used when:

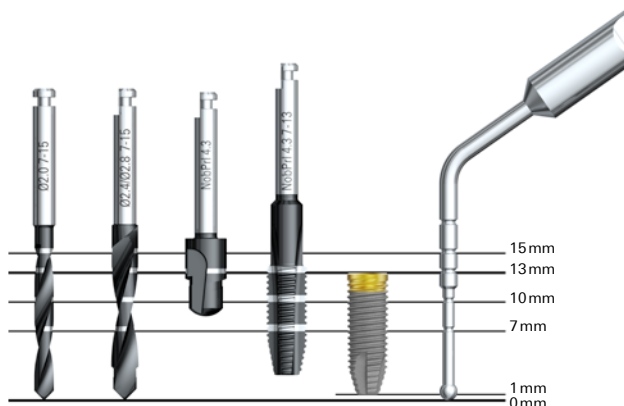
- there is sufficient quantity and quality of alveolar bone and soft tissue.
- it is not necessary to raise a flap to safely direct the drilling procedure in relation to the anatomy.

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.

Drill sequence



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

Caution: 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.

Drills are made of stainless steel with a diamond like carbon (DLC) coating, which gives them their black color. They are used with external irrigation and are available in three lengths: 7–10, 7–15 and 10–18 mm.

- In dense bone situations, drill with continuous back and forth motion.
- Move the drill up without stopping the handpiece motor. This allows the irrigation to flush away debris.
- Proceed until the desired depth reference line is reached.
- Screw taps are available for dense bone situations to avoid excessive torque during implant insertion (max. 45 Ncm).
- In situations where adjacent natural teeth interfere with the contra-angle head and prevent the drill from reaching the desired depth, a drill extension shaft may be used.
- Stop drilling if there is no irrigation.
- When using a drill extension shaft, it is important to supplement cooling at the tip of the drill with manual irrigation.
- Drills and Screw Taps are delivered sterile and are for single use only.

Caution: Drills are for single use and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Depth measurement system

All drills and components are marked to prepare the site to the correct depth and obtain a secure and predictable position.

Note: The marks on the Twist Drills and Twist Step Drills indicate actual millimeter lengths and correspond to the implant collar. Final vertical positioning depends on several clinical parameters, including esthetics, tissue thickness and available vertical space.

Please note that actual implant length is 0.5 mm shorter than the indicated name.

When using a flapless approach: Measure soft tissue thickness with a probe. Add-on soft tissue thickness to drilling depth for correct site preparation.

Drill protocols according to bone quality*

During drilling procedures bone quality should be considered. Recommended drill sequences are based on bone quality to ensure optimized primary stability when applying Immediate Function. Drills are used to the full drilling depth. Drill data are stated in mm.

Optional Drills

The drill protocol has been developed to achieve an implant insertion torque between 35 and 45 Ncm for all bone densities. This is to ensure sufficient primary stability to enable Immediate Function where appropriate.

If bone density is inconsistent (varying between medium and soft or medium and dense bone), optional drills can be added to the drill protocol to ensure the torque level does not exceed 45 Ncm. These optional Twist Step Drills and Screw Taps are denoted below in parentheses.

Platform	Implant ø	Soft bone Type IV	Medium bone Type II–III	Dense bone Type I
NP	3.75	2.0 [2.4/2.8]	2.0 2.4/2.8 Cortical Drill 3.75 [Screw Tap 3.75]	2.0 2.4/2.8 2.8/3.2 Cortical Drill 3.75 Screw Tap 3.75
RP	4.3	2.0 2.4/2.8 [3.2/3.6]	2.0 2.4/2.8 3.2/3.6 Cortical Drill 4.3 [Screw Tap 4.3]	2.0 2.4/2.8 3.2/3.6 Cortical Drill 4.3 Screw Tap 4.3
RP	5.0	2.0 2.4/2.8 3.2/3.6 [3.8/4.2]	2.0 2.4/2.8 3.2/3.6 3.8/4.2 Cortical Drill 5.0 [Screw Tap 5.0]	2.0 2.4/2.8 3.2/3.6 3.8/4.2 Cortical Drill 5.0 Screw Tap 5.0
WP	5.5	2.0 2.4/2.8 3.2/3.6 4.2/4.6 [4.2/5.0]	2.0 2.4/2.8 3.2/3.6 4.2/5.0 Cortical Drill 5.5 [Screw Tap 5.5]	2.0 2.4/2.8 3.2/3.6 4.2/5.0 Cortical Drill 5.5 Screw Tap 5.5

Note: All data are in mm and the drills within square brackets denoted as optional.

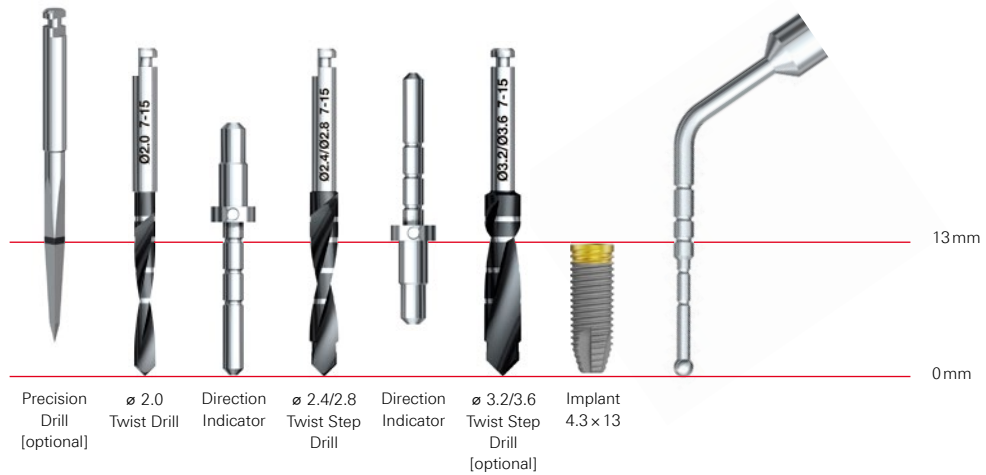
Drilling must proceed at high speed (max. 2'000 rpm for Twist Drills and Twist Step Drills) under constant and profuse irrigation by sterile saline at room temperature.

* According to classification by Lekholm U, Zarb GA. Patient selection and preparation. In: Brånemark PI, Zarb GA, Albrektsson T, editors: Tissue-integrated prostheses: Osseointegration in clinical dentistry. Quintessence, Chicago, 1985, pp 199-209.

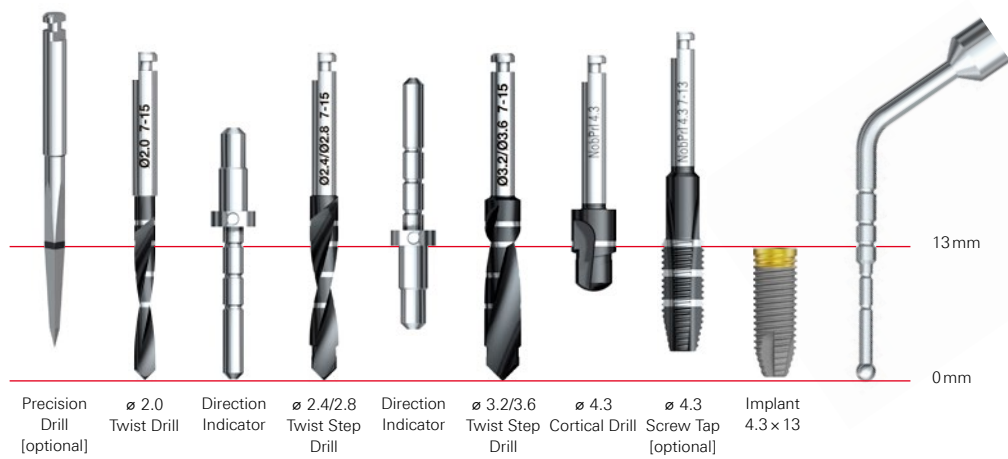
Drill protocols/Product reference lines

Demonstration of the drill protocol for a $\varnothing 4.3 \times 13$ mm implant in soft, medium and dense bone.

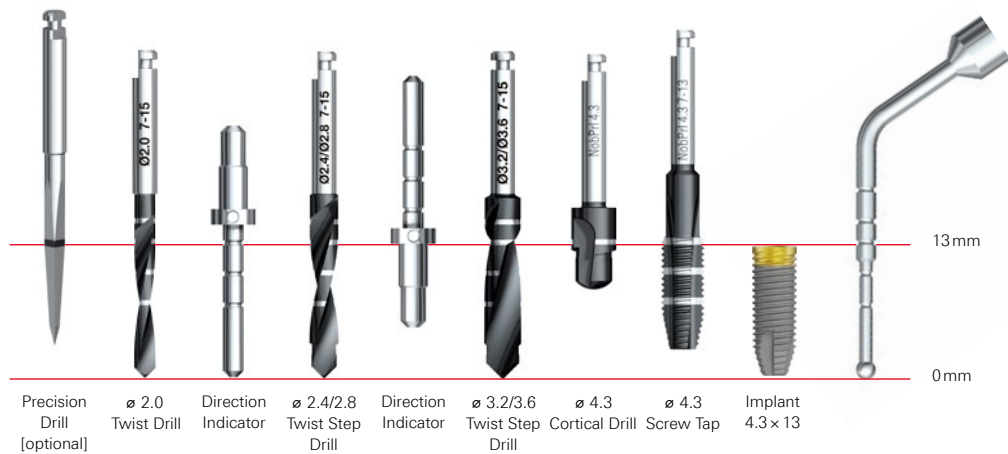
Soft bone



Medium bone



Dense bone

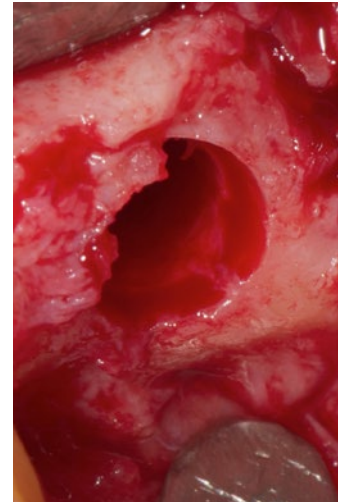


Dense bone situations

Use of a Cortical Drill

In situations with dense bone or a thick cortex, it is mandatory to use the cortical drill to avoid compression.

Please note that it is not recommended to use a Cortical Drill for sinus lift procedures. This is in order to maximize the potential for primary stability.

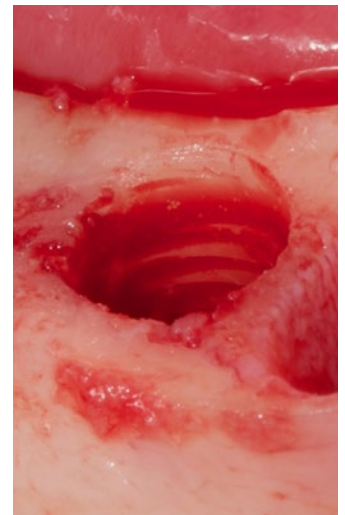


Courtesy of Dr. Claude Authelain, Strasbourg

Use of a Screw Tap

In situations with dense bone or a thick cortex, it is mandatory to use the Screw Tap in order to fully seat the implant.

Please note that when the depth marking of the screw tap is aligned with the implant length the apical portion is not pre-tapped to allow direct engagement in the apical portion.




Courtesy of Dr. Claude Authelain, Strasbourg

Flapless procedure

Choose between the following two options and continue with the drill sequence on page 10, starting with step 4.

Option A


- Drill to the appropriate depth using the Twist Drill with Tip \varnothing 2 mm. A drill stop can be used.

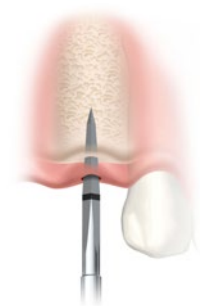
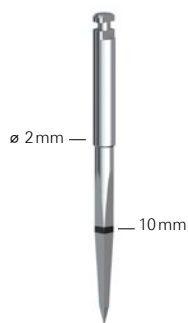
Maximum speed  2000rpm

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 Twist Drill with Tip \varnothing 2 mm.
- Drill with the precision drill through soft tissue and into the alveolar crest.

Maximum speed  2000rpm



Flap procedure

The following illustrations show the drill sequence for NobelParallel Conical Connection TiUltra RP 4.3 in medium and dense bone. For other implant diameters and bone densities, see page 6.


1 Raise a flap

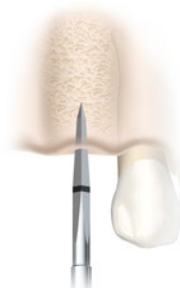
When using a flap procedure, make an incision and raise a flap.



2 Drill with Precision Drill


To facilitate creation of a crestal starting point, the Precision Drill can be used before Twist Drill with Tip \varnothing 2.0mm.

Maximum speed  2000 rpm



3 Drill with Twist Drill with Tip \varnothing 2 mm

Drill to the appropriate depth using the Twist Drill with Tip \varnothing 2 mm. A drill stop can be used.

Maximum speed  2000 rpm



4 Check osteotomy direction


Check correct direction using Direction Indicator \varnothing 2.0/2.4–2.8mm.

- If applicable, take a radiograph to verify correct direction.
- When placing multiple implants, proceed to the next implant site before continuing to next drill sequence.



5 Drill with Twist Step Drills

- Continue site preparation using Twist Step Drill \varnothing 2.4/2.8mm.
- Check orientation using Direction Indicator \varnothing 2.0/2.4–2.8mm.
- Continue site preparation using Twist Step Drill \varnothing 3.2/3.6 mm.

Maximum speed  2000 rpm



6 Drill with Cortical Drill

Finalize site preparation using Cortical Drill RP 4.3mm.

- It is mandatory to use a Cortical Drill in medium/dense bone and with thick cortical layers in order to fully seat the implant and release pressure around the implant neck.
- It is not recommended to use a Cortical Drill for sinus lift procedures in order to maximize the potential for primary stability.

Maximum speed  2000rpm

For more information about the use of a Cortical Drill, please refer to page 8.




7 Determine implant length

Use the Depth Probe to verify the desired depth has been achieved (including soft tissue thickness, if applicable).



8 Use of Screw Tap in dense bone

- It is mandatory to use a Screw Tap in dense bone and with thick cortical layers in order to fully seat the implant.
- Place Screw Tap RP 4.3mm into prepared implant site using low speed to appropriate reference line of implant.
- When the threads engage, allow Screw Tap to feed without pressure to defined depth.
- Switch the handpiece to reverse mode and back the Screw Tap out.
- Continue with implant installation until desired position achieved using max. 45 Ncm installation torque.

Low speed 25rpm 

For more information about the use of a Screw Tap, please refer to page 8.



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

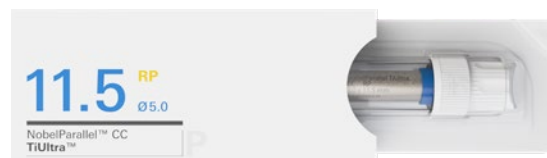


Fig. 4 - Cardboard box

2 Choose insertion instrument

Depending on the clinical situation and accessibility, there are two different options to insert the implant:

- A With a drilling unit and contra-angle
- B With Manual Torque Wrench Surgical

It is possible to start the implant insertion manually, using the Manual Torque Wrench. See page 18 for more information on how to operate the Manual torque wrench.



A Drilling unit with contra-angle

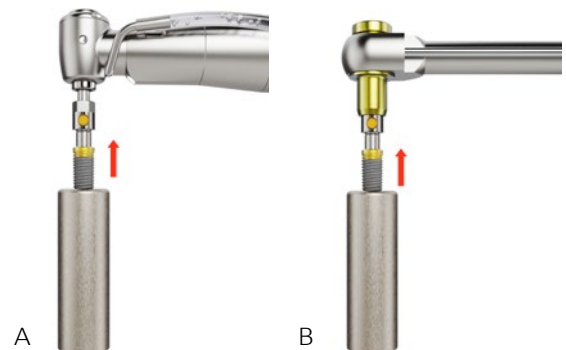


B Manual Torque Wrench Surgical

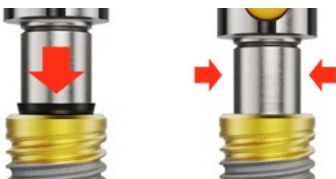
3 Pick up implant

- Connect the appropriate Implant Driver to the insertion instrument.
- Pick up the implant from the 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.



Make sure that the Implant Driver is fully seated.



4 Insert implant

- Begin inserting the implant into the osteotomy.
- When using a drilling unit, start inserting the implant using low speed.

Low speed 25rpm  Max. torque 45 Ncm

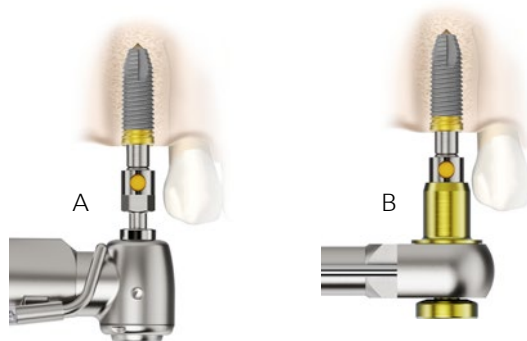
Caution: Never exceed insertion torque of 45 Ncm for the implants. Overtightening an implant may lead to damage of the implant, fracture or necrosis of the bone site. If a Surgical Driver is used to insert the implant, special care needs to be taken to avoid overtightening.

If the implant gets stuck during implant installation or 45 Ncm of insertion torque is achieved before it is fully seated, rotate the implant counterclockwise using drilling device (reverse mode) or Manual Torque Wrench and re- move the implant from site. Replace the implant back into the inner casing before proceeding further.

Medium and dense bone protocol:

- In cases of a thick cortical layer or dense bone a Cortical Drill and/or a Screw Tap is mandatory to be able to get the implant fully seated and to release pressure around the implant neck.
 - Select the Cortical Drill and/or use Screw Tap matching the diameter of the implant:
 - If Cortical Drill is used: proceed with drilling at high speed max. 2'000 rpm and drill to appropriate depth (see image on page 5).
 - If Screw Tap is used: place the Screw Tap into prepared implant site using low speed 25 rpm and drill to appropriate depth (see image on page 5). Switch the drill device with handpiece to reverse mode and remove the Screw Tap.
- Continue with implant installation as outlined in steps 3 and 4 above, until desired position is achieved using max. 45 Ncm of insertion torque.

Please refer to Dense bone situations chapter for additional information on Cortical Drills and Screw Taps.



5 Tighten manually

- Connect the Manual Torque Wrench Surgical to the Manual Torque Wrench Adapter and place the implant to final depth.
- For Immediate Function, the implant should withstand a final insertion torque of at least 35 Ncm. Do not exceed 45 Ncm.
- Remove Implant Driver.
- If the Implant Driver is difficult to remove, slightly rotate it counterclockwise before disengaging.

If insufficient stability is attained for Immediate Function, do not load the implant. Wait for sufficient conventional healing (one- or two-stage approach).

In case of strong resistance

Excessive torque while inserting the implant must be avoided. It can cause deformation of the implant or connection and may result in excessive compression of the bone. If strong resistance (max 45 Ncm) is encountered at any point during insertion, remove the implant and place it back into the inner casing. Widen the implant site according to the drill protocol or use Screw Tap matching the diameter of the implant.

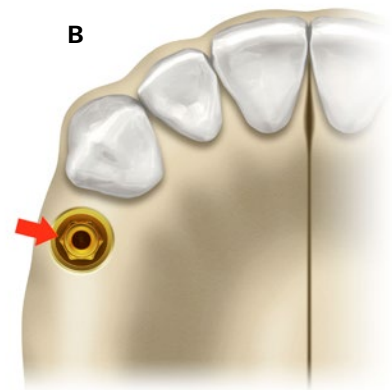
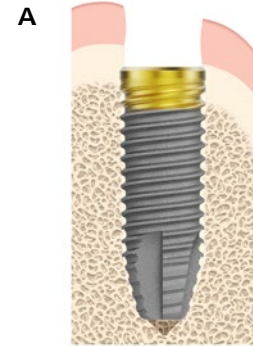
See page 18 for more information on how to operate the Manual torque wrench.



Markings for 15, 35 and 45 Ncm.

6 Final implant placement

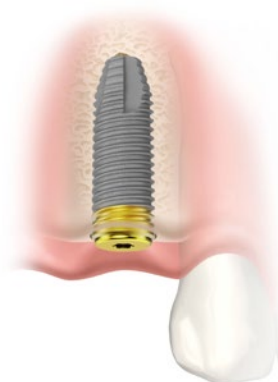
- For maximized esthetic results, place the implant on the level of the buccal bone or 0.5 – 1 mm below (A).
- When placing the implant, align one of the black hex indicators on the implant driver parallel to the buccal wall. This ensures that one of the flat sides of the hexagon is parallel to the buccal side (B), ensuring preferred prosthetic abutment orientation.
- The implant driver has a 3 mm height indicator to facilitate vertical implant positioning and six black lines correlating to the flat sides of the implant hexagon (C).



Hex and height indicators on implant driver

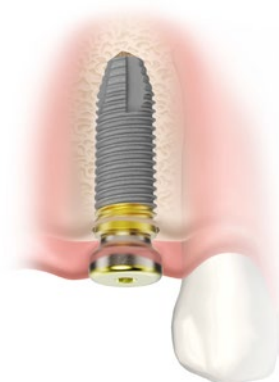
Finalization of implant surgery

There are three options for finalizing the implant surgery.



Two-stage delayed function

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



One-stage delayed function

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



One-stage Immediate Function

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

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.

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

Caution: Please note the NobelParallel 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

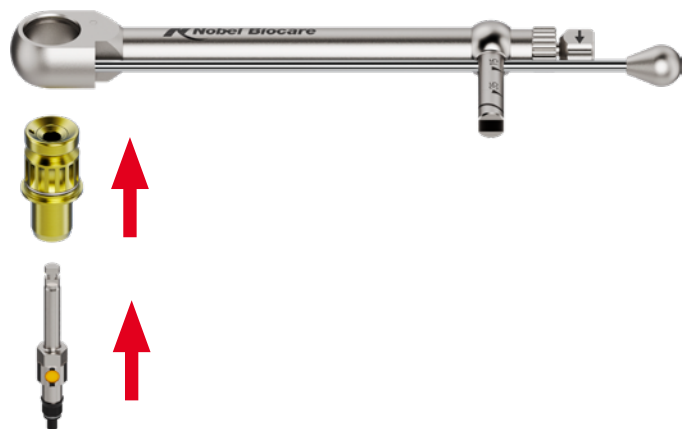
For the surgeon, the torque required to place implants provides insight into the primary stability of the implant. For restorative procedures, tightening the abutment and prosthetic screws to the recommended torque specifications will more effectively control screw-joint integrity during patient function.

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

Manual Torque Wrench – Surgical

Intended for tightening or adjusting implant position.

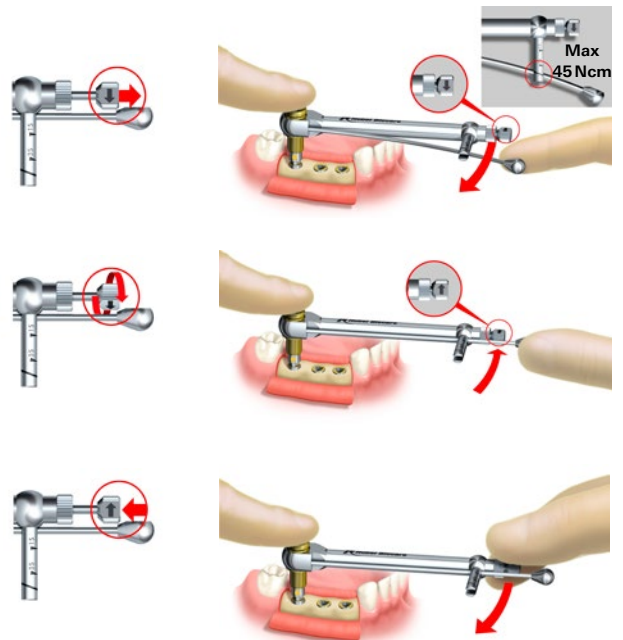
– Insert Implant Driver NobelReplace or Conical Connection.



Use of the 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

NobelParallel 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: NobelParallel 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.



Twist and Twist Step Drills, Precision Drill and Screw Taps

Twist Drills, Twist Step Drills, Cortical Drills and Screw Taps are delivered sterile and for single use only.



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