

Surgical procedures

A detailed 3D rendering of a NobelActive TiUltra™ dental implant. The implant is shown vertically, with a yellow-colored threaded top section and a grey-colored textured body with a fluted design. The background is a solid light orange color.

NobelActive® TiUltra™

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ONE.

Contents

Introduction 4

Surgical procedure 5

Surgical access 5

Drill sequence 6

Implant insertion 11

Finalization of implant surgery 16

Advanced surgical procedure 17

NobelActive TiUltra 3.0 17

Implant orientation adjustments 18

Stabilization in wide sockets 19

Active placement in extraction sockets 20

Appendices 22

Manual torque wrench 22

Cleaning and sterilization 23

Introduction

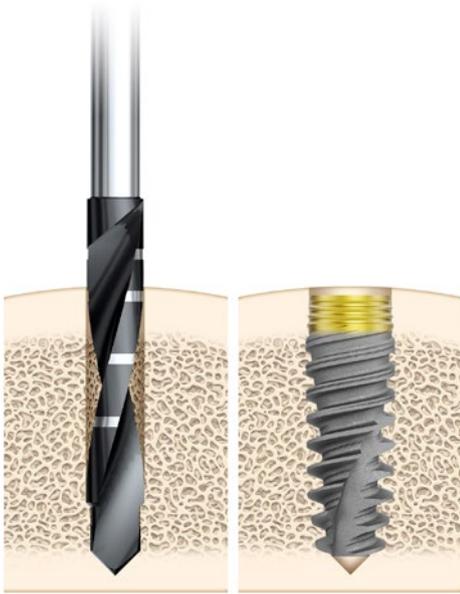
The scope of this surgical procedures manual is to provide a comprehensive overview of the surgical steps and options during the placement of NobelActive® TiUltra™ implants. This surgical procedures manual does not replace the Instructions For Use (IFU).

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.

Note: In order to improve readability, Nobel Biocare does not use ™ or ® in the running text. By doing so, however, Nobel Biocare does not waive any right to the trademark or registered mark and nothing herein shall be construed to the contrary.

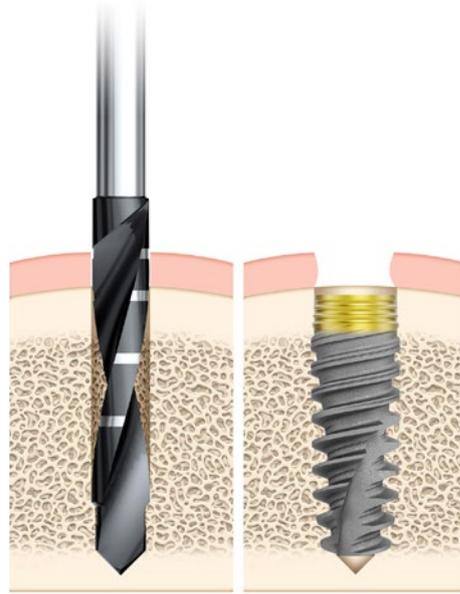
Surgical access



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:

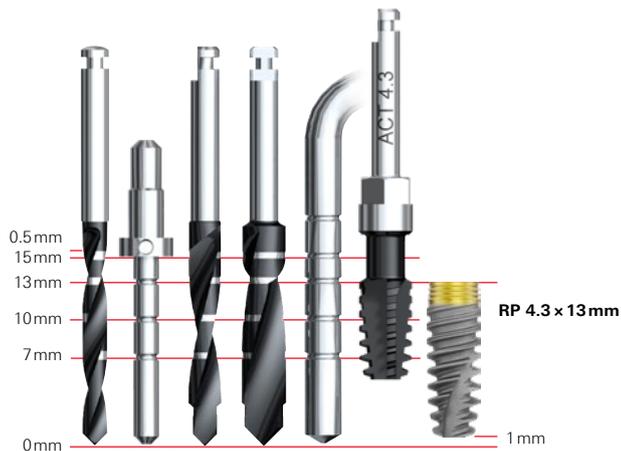
- there is sufficient quantity and quality of alveolar bone and soft tissue.
- it is not necessary to raise a flap to safely direct drilling procedure in relation to the anatomy.

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 (please see the figure above for drill reference lines).

All measurements from the tip of the drill to the bottom edge of the marking.

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 mm, 7–15 mm and 10–18 mm.

- Use an in-and-out motion and drill the bone for 1–2 seconds.
- 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. 70 Ncm for NP, RP, and WP and 45 Ncm for 3.0 implants).
- 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 are delivered sterile and are for single use only.
- Screw Taps are delivered sterile and for multiple use. Re-sterilize according to cleaning and sterilization guidelines.

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:

The parallel drills have a true 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.

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*
Recommended to ensure optimized primary implant stability when planning for Immediate Function.

Platform	Ø Implant	Soft Bone Type IV	Medium Bone Type II-III	Dense Bone Type I
3.0	Ø 3.0	1.5	2.0	2.0 2.4/2.8
NP	Ø 3.5	2.0 (2.4/2.8)	2.0 2.4/2.8 (2.8/3.2)	2.0 2.4/2.8 2.8/3.2
RP	Ø 4.3	2.0 2.4/2.8 (2.8/3.2)	2.0 2.4/2.8 3.2/3.6	2.0 2.4/2.8 3.2/3.6 (3.8/4.2)
RP	Ø 5.0	2.0 2.4/2.8 3.2/3.6	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 (4.2/4.6)
WP	Ø 5.5	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 4.2/4.6 (4.2/5.0)	2.0 2.4/2.8 3.2/3.6 3.8/4.2 4.2/5.0 Screw Tap

Note: All data is stated in mm.

Drills within brackets (-) denote widening of the cortex only, not drilling to the full drilling depth.

Drilling must proceed at high speed (max. 2000 rpm for Twist Drills and Twist Step Drills) under constant and profuse external irrigation by sterile saline at room temperature.

Dense bone considerations

Screw Taps should be used if the standard dense bone protocol is not sufficient to fully seat the implant without exceeding the recommended maximum insertion torque (max. 70Ncm for NP, RP and WP and 45Ncm for 3.0 implants).

*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.

Flapless procedure

Choose between the following two options and continue with the drill sequence on page 9, 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  2000 rpm

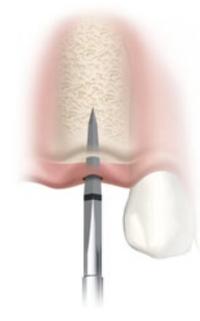
Measure the soft tissue thickness with a probe. Add this tissue thickness to the drilling depth for correct site preparation. Be aware of anatomical landmarks.



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

Maximum speed  2000 rpm



Flap procedure

The following illustrations show the drill sequence for NobelActive TiUltra RP 4.3 in medium and dense bone. For other implant diameters and bone densities, see page 7. For specific information regarding NobelActive 3.0, see page 17.

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 the 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.
- Finalize site preparation using Twist Step Drill \varnothing 3.2/3.6 mm.

Maximum speed  2000 rpm



6 Determine implant length

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



7 For dense bone only: widen cortex

Widen cortex to full cortex depth using Twist Step Drill \varnothing 3.8/4.2 mm. Do not drill to full drilling depth.

Maximum speed  2000 rpm



8 Use of Screw Tap in dense bone

- Place Screw Tap RP 4.3 into prepared implant site using low speed (25 rpm).
- Apply firm pressure and begin rotating the Screw Tap slowly. When the threads engage, allow Screw Tap to feed without pressure to defined depth (until all threads on the Screw Tap have engaged bone).
- Switch the handpiece to reverse mode and back the screw tap out.

Low speed 25rpm 

Please note that the Screw Tap WP 5.5 11.5–15 mm has a special depth marking indicating the defined depth.



Special depth marking for the Screw Tap WP 5.5 11.5–15mm

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 three different options for inserting the implant:

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

- In the anterior region it is recommended to use the manual surgical driver to facilitate good control during insertion and angulation changes.
- The surgical driver is intended to be used while grasped with fingertips only to avoid excessive insertion torque.
- It is possible to start the implant insertion manually, using the NobelActive Implant Driver and Surgical Wrench Adapter.
- For NobelActive 3.0, the NobelReplace Manual Torque Wrench Surgical or the Manual Torque Wrench Prosthetic with Surgical Wrench Adapter can also be used, as they both have a 45 Ncm marking.
- See page 22 for more information on how to operate the Manual torque wrench.



A NobelActive Manual Torque Wrench Surgical



B Surgical Driver



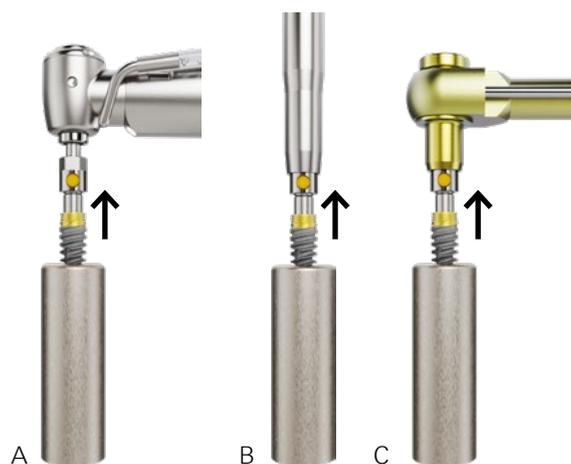
C Drilling unit with contra-angle

3 Pick up implant

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

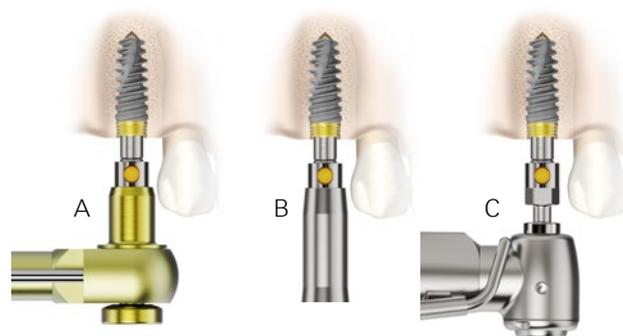
Make sure that the implant driver is fully seated.



4 Insert implant

- Begin inserting the implant into the osteotomy.
- When using a drilling unit, start inserting the implant using low speed: max 25 rpm.

Caution: Never exceed insertion torque of 45 Ncm for a NobelActive TiUltra 3.0 implant and 70 Ncm for NobelActive TiUltra 3.5, 4.3, 5.0 and 5.5 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 over tightening.



Low speed 25rpm 

Max. torque 45 Ncm for NobelActive TiUltra 3.0

Max. torque 70 Ncm for NobelActive TiUltra 3.5, 4.3, 5.0 and 5.5

5 Tighten manually

- Connect the NobelActive Manual Torque Wrench Surgical to the Manual Torque Wrench Adapter and place the implant to final depth. See page 22 for more information on how to operate the Manual torque wrench.
- For Immediate Function, the implant should be able to withstand a final torque of 35–45 Ncm for NobelActive TiUltra 3.0 implant and 35–70 Ncm for NobelActive TiUltra 3.5, 4.3, 5.0, and 5.5 implants.
- Remove driver with an easy upward motion.

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

Procedure for implant placement in dense bone:

If the implant gets stuck during implant insertion or the maximum torque is achieved before fully seated (45 Ncm for NobelActive TiUltra 3.0 or 70 Ncm for NobelActive TiUltra 3.5, 4.3, 5.0, and 5.5):

- Rotate the implant counterclockwise approximately $\frac{1}{2}$ turn enabling use of self-tapping capacity of the implant; or
- Back out the implant and widen the site with a wider drill according to drill protocol; or
- Select a NobelActive Screw Tap which matches the diameter of the implant and desired drilling depth (see figure).

Place the Screw Tap into the prepared implant site using low speed (25 rpm).

Apply firm pressure and begin rotating the Screw Tap slowly. When the threads engage, allow Screw Tap to feed without pressure to defined depth.

Switch the drill device with handpiece to reverse mode and back the Screw Tap out.

Continue with implant installation until desired position is achieved using max 45 Ncm insertion torque for NobelActive TiUltra 3.0 implant or max 70 Ncm for NobelActive TiUltra 3.5, 4.3, 5.0. and 5.5 implants.

Caution: Never exceed insertion torque of 45 Ncm for a NobelActive TiUltra 3.0 implant and 70 Ncm for NobelActive TiUltra 3.5, 4.3, 5.0 and 5.5 implants.



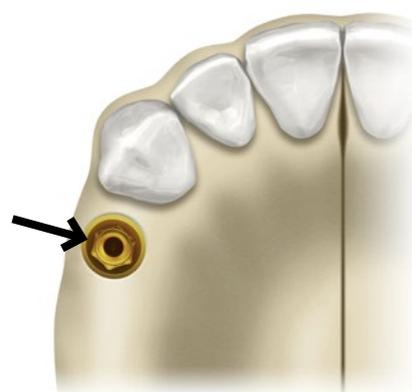
Markings for 35, 45 and 70 Ncm.



Drill depth for Screw Taps (fig1 for 3.0, 3.5, 4.3 and 5.0; fig2 and fig3 for 5.5)

6 Final implant placement

- Available abutment margin height needs to be considered during the planning of implant placement to assure appropriate seating depth of the implant relative to the available soft tissue thickness and the planned emergence of the restoration.
- For maximized esthetic results place the implant between 0–1 mm below buccal bone.
- 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, ensuring preferred prosthetic abutment orientation.
- The implant driver has a 3 mm height indicator to facilitate vertical implant positioning.
- If the implant driver is difficult to remove, slightly rotate it counterclockwise before lifting it up.



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 a cover screw to the implant. Suture the tissue flap using the desired technique.



One-stage delayed function

Use Screwdriver Unigrip to connect a 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.

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

Caution: Please note the NobelActive 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

NobelActive TiUltra 3.0

Indications

- Lateral incisors in the maxilla
- Lateral and central incisors in the mandible
- Single-unit applications in the above-mentioned positions

1 Prepare implant site

Prepare the implant site according to drill protocol (see page 7).

2 Pick up implant

Open the implant package and pick up the implant from the inner casing with the implant driver for NobelActive TiUltra 3.0.

3 Place and tighten implant

- Insert the implant with low speed, maximum 25 rpm, using drilling machine or by hand using Manual Torque Wrench Surgical.
- Tighten the implant with an insertion torque of maximum 45 Ncm (see marking on torque wrench). For Immediate Function a minimum installation torque of 35 Ncm is required.

Insertion torque for NobelActive TiUltra 3.0:

Due to the narrow implant diameter and narrow implant abutment connection the maximum insertion torque for NobelActive TiUltra 3.0 differs from the entire NobelActive TiUltra assortment. The maximum insertion torque for the 3.0 implant is 45 Ncm and the maximum prosthetic abutment tightening torque is 15 Ncm.

Caution: Never exceed insertion torque of 45 Ncm for the implant and 15 Ncm prosthetic tightening torque for the abutment screw. Overtightening of implant may lead to damage of the implant, fracture or necrosis of the bone site. Overtightening of the abutment screw may lead to screw fracture.

Please refer to Procedure for Implant Placement in Dense Bone on page 7 for additional information

For NobelActive TiUltra 3.0, the NobelReplace Manual Torque Wrench Surgical or the Manual Torque Wrench Prosthetic with Surgical Wrench Adapter can also be used, as they both have a 45 Ncm marking.

4 Temporary restoration

Depending on the surgical protocol of choice, place a cover screw or abutment and suture.

Caution: All prosthetic components for NobelActive 3.0 must be tightened to 15 Ncm only using a Screwdriver Machine Unigrip and Manual Torque Wrench Prosthetic. Overtightening may lead to screw fracture.



Implant orientation adjustments

The self-drilling capacity of NobelActive TiUltra makes it possible to change direction of the implant during implant placement. This helps to facilitate parallelism between implants and optimize implant placement in the anterior zone.

If a further change in implant alignment is desired after placing the implant:

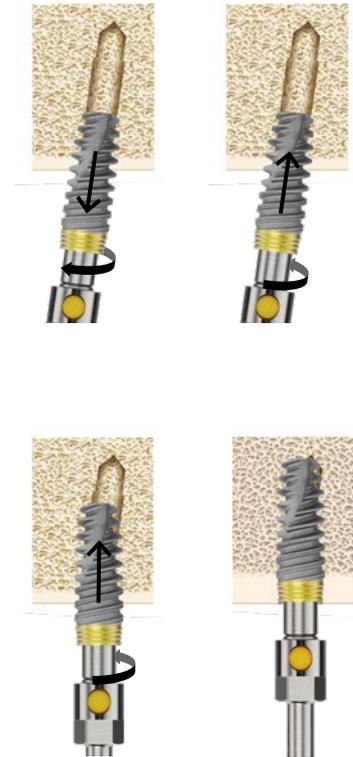
- Reverse 2–3 turns.
- Start to insert the implant into the new direction as described previously. Do not exceed 70 Ncm for NP, RP and WP and 45 Ncm for 3.0 implants.
- Continue the insertion until the implant is fully seated in the desired position.

If experiencing 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. 70 Ncm for NP, RP and WP and 45 Ncm for 3.0 implants) is encountered at any point during insertion, rotate the implant counterclockwise approximately $\frac{1}{2}$ turn to enable the self-tapping capacity of the implant, then continue to insert the implant.
- If there is still strong resistance, remove the implant and place it back into the titanium casing. Widen the implant site according to the drill protocol or use Screw Tap matching the diameter of the implant.

Please refer to Procedure for Implant Placement in Dense Bone on page 14 for additional information



Stabilization in wide sockets

Due to the special design of the NobelActive TiUltra implant, it is possible to insert it into underprepared sites allowing the bone condensing feature of the implant to take effect.

- In these situations, a one-stage or Immediate Function surgical approach is not recommended.
- NobelActive 3.0 implants are not indicated for posterior use.
- NobelActive NP implants are not recommended for posterior use.

Procedure

- Drill apically in the extraction socket, using Twist Drill with Tip \varnothing 2 mm or Precision Drill.
- Depending on the diameter of the implant and the bone density, continue site preparation following the drill protocol.
- Start inserting the implant into the under-prepared site as described previously. Do not exceed 70 Ncm. Due to the unique thread design and bone-condensing capacity, sufficient retention and stabilization may be achieved.
- Bone augmentation may immediately follow implant placement if indicated.
- Place a cover screw and suture.

If experiencing 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. 70 Ncm for NP, RP and WP implants) is encountered at any point during insertion, rotate the implant counter-clockwise approximately 1/2 a turn to enable the self-tapping capacity of the implant, then continue to insert the implant.
- If there is still strong resistance, remove the implant and place it back into the titanium casing. Widen the implant site according to the drill protocol or use Screw Tap matching the diameter of the implant.

Please refer to Procedure for Implant Placement in Dense Bone on page 14 for additional information

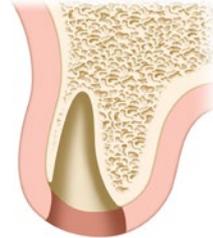


Active placement in extraction sockets

Achieving esthetic results in the anterior can be challenging. The buccal bone plate is usually very thin and often missing entirely, and maintaining bone height and soft tissue architecture requires at least 1.5 mm of bone thickness buccal to the implant.

In order to achieve the desired results, bone augmentation must often be performed prior to implant placement. In many cases NobelActive TiUltra simplifies this procedure.

The implant's ability to self-drill and actively change direction allows stabilization adjacent to the palatal wall, leaving ample space for bone augmentation on the buccal aspect.



The tooth is extracted and the socket is prepared in the regular manner.

1 Option: Create starting point

For creation of a starting point in the palatal wall of the extraction socket, use the Precision Drill.

Maximum speed  2000 rpm



2 Prepare implant site

- For maxillary anterior teeth, the objective is to utilize bone palatal to the remaining socket in the apical 1/3 to 1/2 for stabilization of the implant. The palatal wall is first penetrated from a more perpendicular approach to gain a starting point with either the Precision Drill or the Twist Drill with Tip Ø 2 mm.
- Continue to drill with the Twist Drill with Tip Ø 2 mm while gradually changing the direction to a more vertical direction.
- Depending on implant diameter and bone density, continue to drill as described above, following the drill protocol.



When using a flapless procedure, 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.

3 Insert implant

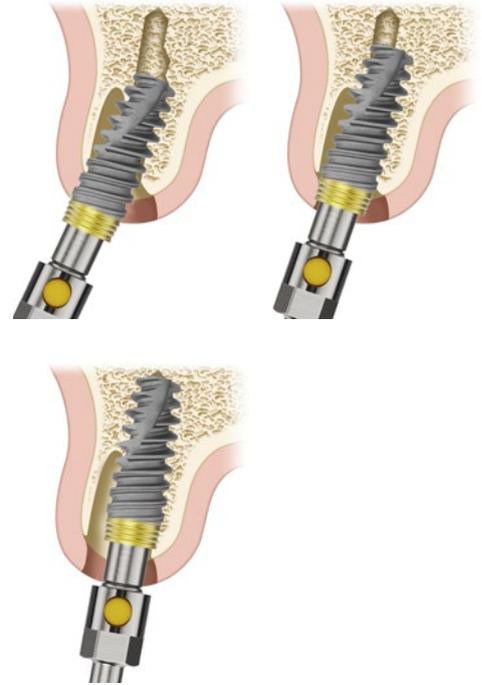
- Begin inserting the implant at the same angle as for the initial drilling. Do not exceed 70 Ncm for NP, RP and WP and 45 Ncm for 3.0 implants.
- Continue implant insertion to final position, while gradually changing the angulation.

If experiencing 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. 70 Ncm for NP, RP and WP and 45 Ncm for 3.0 implants) is encountered at any point during insertion, rotate the implant counterclockwise approximately $\frac{1}{2}$ turn to enable the self-tapping capacity of the implant, then continue to insert the implant.
- If there is still strong resistance, remove the implant and place it back into the titanium casing. Widen the implant site according to the drill protocol or use Screw Tap matching the diameter of the implant.

Please refer to Procedure for Implant Placement in Dense Bone on page 14 for additional information



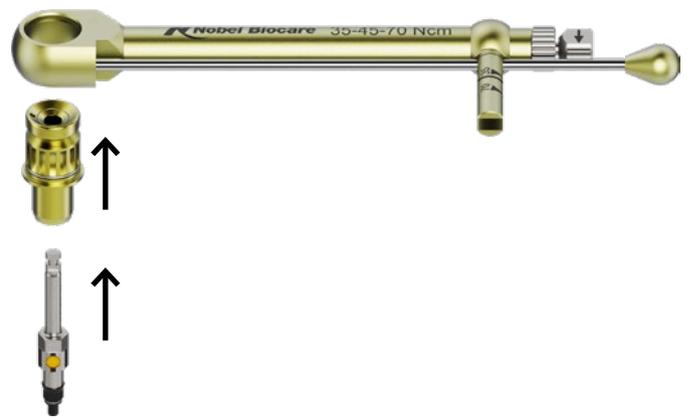
Manual torque wrench

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

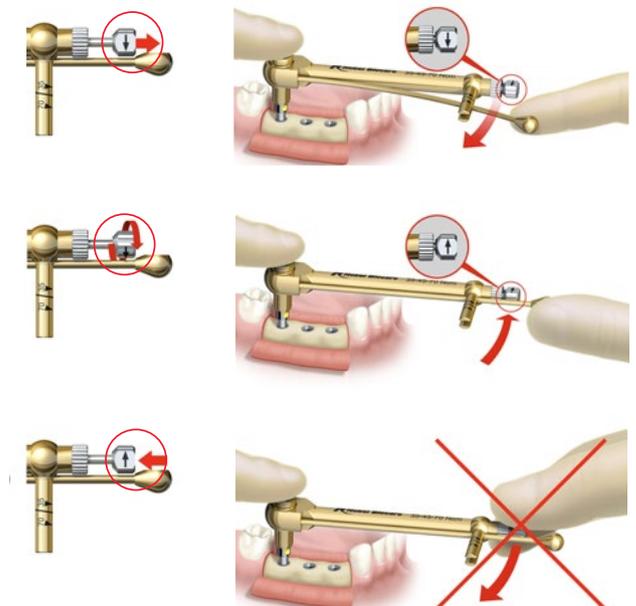
Intended for tightening or adjusting implant position.
– Insert Implant Driver Conical Connection.



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

NobelActive 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.



Twist and Twist Step Drills, Precision Drill and Screw Taps

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



nobelbiocare.com/en-us/nobelactive



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