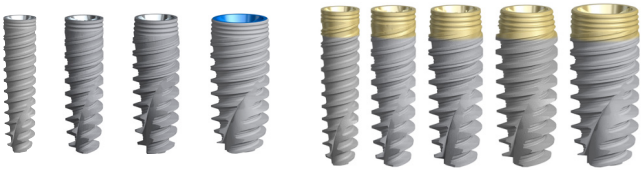
NobelActive® TiUnite® and NobelActive® TiUltra™ Implants



Important – 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

This Instructions for Use (IFU) describes the Nobel Biocare NobelActive® TiUnite® and NobelActive® TiUltra™ Implants and supporting components, including the instrumentation which is required during the surgical and handling procedure to prepare the implant site and to place the implant.

NobelActive® TiUnite®/TiUltra™ Implants

NobelActive® TiUnite®/TiUltra™ Implants are endosseous threaded implants available in diameters of 3.0, 3.5, 4.3, 5.0 and 5.5 mm. The implant has the following features:

- The NobelActive® TiUnite®/TiUltra™ Implants macroshape is characterized by an expanding tapered body, expanding double thread, and drilling blades at apex.
- NobelActive® TiUnite®/TiUltra™ Implants feature an internal conical connection (CC) and are available in platform sizes 3.0, Narrow Platform (NP), Regular Platform (RP) and Wide Platform (WP). The implants are compatible with Nobel Biocare restorative components featuring the internal conical connection.
- NobelActive® TiUnite® Implants feature a TiUnite® anodized surface.
- NobelActive® TiUltra™ Implants feature a TiUltra™ anodized surface. The TiUltra™ have the additional protective layer on comprising of sodium dihydrogen phospha (NaH_2PO_4) and magnesium chloride ($MgCl_2$).

Table 1

	Platform	Platform diameter	Implant diameter	Abutment interface	Lengths	Cover Screw
●	3.0	Ø 3.0 mm	Ø 3.0 mm	Ø 2.5 mm	10 mm, 11.5 mm, 13 mm, 15 mm	Not co-packed
●	NP	Ø 3.5 mm	Ø 3.5 mm	Ø 3.0 mm	8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm	Not co-packed
●	RP	Ø 3.9 mm	Ø 4.3 mm	Ø 3.4 mm	8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm	Not co-packed
●	RP	Ø 3.9 mm	Ø 5.0 mm	Ø 3.4 mm	8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm	Not co-packed
●	WP	Ø 5.1 mm	Ø 5.5 mm	Ø 4.4 mm	7.0 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm	Co-packed only for Nobel Active WP TiUnite®

Note The NobelActive® TiUnite® WP 5.5 mm implant is co-packaged with a cover screw. NobelActive® TiUltra™ Implants and other NobelActive TiUnite® Implants are not co-packed with a cover screw.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1016 for information regarding cover screws. This IFU is available for download at ifu.nobelbiocare.com.

Instrumentation

The following instrumentation is required during the surgical and handling procedures to place NobelActive® TiUnite® and NobelActive® TiUltra™ Implants:

- The Guide Drill, Precision Drill, Twist Drills, and Twist Step Drills are required to prepare the osteotomy for placement of NobelActive® TiUnite® and NobelActive® TiUltra™ Implants. Twist Drills and Twist Step Drills are available in different diameters and lengths in order to widen the osteotomy step-by-step to the appropriate diameter and depth.
- Screw Taps NobelActive® 3.0/NP/RP/WP can be used to cut threads in an osteotomy in dense bone.
- The Depth Probe 7-18 mm Z-shaped is used to verify the depth of the osteotomy. Refer to Nobel Biocare IFU1090 for information regarding the Depth Probe 7-18 mm Z-shaped.
- Implant Drivers Conical Connection 3.0/NP/RP/WP must be used to place NobelActive® TiUnite® and NobelActive® TiUltra™ Implants. Refer to Nobel Biocare IFU1090 for information regarding the implant drivers.

Caution The implant drivers, healing abutments, and prosthetic components, as well as the cover screw for the NobelActive® TiUnite® WP 5.5 mm implant, are color-coded according to Table 1 in order to indicate the compatible implant diameter and platform size (3.0, NP, RP, WP). The NobelActive® TiUnite®/ TiUltra™ Implant packaging also is color-coded; however, it is important to note that the implants themselves do not have color-coding, with the exception of WP 5.5 mm (blue).

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.

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/Intended Purpose

NobelActive® TiUnite® Implants/NobelActive® TiUltra™

Intended for use as an endosseous dental implant in the maxilla or mandible for anchoring or supporting dental prostheses to restore chewing function.

Guide Drill, Precision Drill, Twist Drills, Twist Step Drills, and Screw Taps NobelActive®

Intended for use to prepare or support the preparation of an osteotomy for placement of an endosseous dental implant.

Indications

NobelActive® TiUnite®/TiUltra™ Implants, NobelActive® TiUnite®/TiUltra™ 3.0 Implants

NobelActive® TiUnite® implants are indicated to support restorations ranging from single tooth to fixed-removable full arch dental procedures 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.

NobelActive® TiUltra™ implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. 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.

NobelActive® TiUnite®/TiUltra™3.0 Implants are indicated for single unit restorations only, to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

Screw Taps NobelActive®

Screw Taps NobelActive are indicated for use in the maxilla or mandible to prepare an osteotomy in dense bone for placement of NobelActive® TiUnite®/TiUltra™ Implants.

Twist Drills/Twist Step Drills

Twist Drills and Twist Step Drills are indicated for use in the maxilla or mandible to prepare an osteotomy for the placement of a dental implant.

The Guide Drill/Precision Drill

The Guide Drill/Precision Drill are indicated for use in the maxilla or mandible to prepare the entrance point for an osteotomy prior to implant placement.

Contraindications

It is contraindicated to use NobelActive® TiUnite® Implants/ NobelActive® TiUltra™, cover screws, and tooling 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 to commercially pure titanium (grade 4), titanium alloy Ti-6AL-4V, stainless steel, or DLC (Diamond Like Carbon) coating, Sodium dihydrogen phosphate and magnesium chloride.

NobelActive® TiUnite® 3.0/NobelActive® TiUltra™ 3.0, Implants are contraindicated to replace a central incisor, canine, premolar or molar in the maxilla, as well as to replace a canine, premolar or molar in the mandible.

NobelActive® TiUnite® 3.0/NobelActive® TiUltra™ 3.0, Implants are contraindicated for multiple tooth replacements. Refer to Nobel Biocare IFU1016 for contraindications specific to the cover screws.

Materials

NobelActive® TiUnite® 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).

NobelActive® TiUltra™ 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). Layered by sodium dihydrogen phosphate and magnesium chloride.

Cover screw

Titanium alloy: Titanium-6Aluminium-4Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen. (max.-maximum value).

Twist Drills, Twist Step Drills, and Precision Drill

Stainless Steel type 420F Mod partly coated with Dimond like Carbon coating.

Screw Taps

Stainless Steel UNS S17400 (type 630) partly coated with Dimond like Carbon coating.

Guide Drill

Stainless Steel type 420F Mod.

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.

Cautions

General

One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's 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.

NobelActive® TiUnite®/TiUltra™ implants must only be used with compatible Nobel Biocare instruments and components. Use of instruments or components that are not intended to be used in combination with NobelActive® TiUnite®/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. Nobel 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 must 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

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

Care and maintenance of sterile 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. gauze, dental dam, 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.

Intended Users and Patient Groups

NobelActive® TiUnite®/NobelActive® TiUltra™ Implants and instrumentation are to be used by dental health care professionals.

NobelActive® TiUnite®/NobelActive® TiUltra™ Implants and instrumentation are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Devices in the IFU

NobelActive® TiUnite®/NobelActive® TiUltra™ Implants and instrumentation are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with NobelActive® TiUnite®/NobelActive® TiUltra™ Implants and Instrumentation

The placement of a dental implant constitutes an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, and swelling. Drilling into the jaw or subsequent placement of the implant may also lead (in rare cases) to bone fracture, damage/perforation of neighboring structures/restorations, sinusitis, or sensory/motor disturbances, depending on the location. During placement of an implant the pharyngeal (gag) reflex may be triggered in patients with a sensitive reflex.

Dental implants are the substructure of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to those associated with teeth, such as mucositis, calculus, peri-implantitis, fistulas, ulcers, soft tissue hyperplasia, soft and/or hard tissue recession/loss. Some patients may experience discoloration in the mucosal area such as graying.

Drills and screw taps are devices used to prepare the implant sites. The use of this device constitutes an invasive treatment which may be associated with typical side effects such as bone necrosis, inflammation, infection, bleeding, hematoma, pain, swelling. Depending on its location of use it may, in rare cases, lead to fenestration or fracture of bone, damage/perforation of neighboring structures/restorations, sinusitis, or sensory/motor disturbances. During use of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the NobelActive® TiUnite®/NobelActive® TiUltra™ Implants. The SSCP can be obtained at the following website: ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED)

Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Surgical Procedure

Warning Drills are sharp instruments. Handle with care.

During drilling procedures bone quality should be considered. Refer to Table 2 which presents the recommended drill sequences based on bone quality to ensure optimal primary stability when applying immediate function.

The recommended drill sequences are based on bone quality. Drill data are stated in mm and the drill diameters listed within brackets denote widening of cortex only.

Table 2 – Recommended Drill Sequences Based on Bone Quality

Platform	Implant	Soft bone Type IV	Medium bone Type II-III	Dense bone Type I
3.0	3.0 mm	1.5	2.0	2.0 2.4/2.8
NP	3.5 mm	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	4.3 mm	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	5.0 mm	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)

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

Depth measurement system: the parallel drills have a true depth measurement system. All drills, drill stops, and components are marked to prepare the site to the correct depth and obtain a secure and predictable position.

Drills are available for implant lengths (laser marks) of 7-10, 7-15 and 10-18 mm. The correct diameter and length of the drills is indicated on the label.

Note The actual implant length is 0.5 mm shorter than the indicated name.

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 (refer to Figure A for drill reference lines).

Caution There are no laser marks for 8.5 mm and 11.5 mm implant lengths. The 8.5 mm is between the 7 mm and 10 mm laser mark. The 11.5 mm is between the 10 mm and 13 mm laser mark (refer to Figure A for drill reference lines).

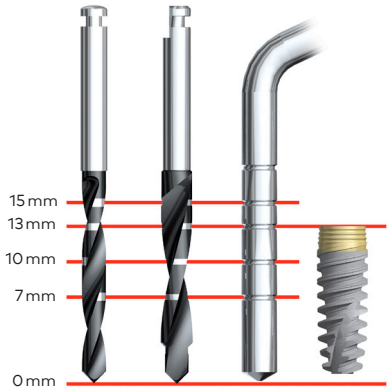


Figure A – Twist Drills and Twist Step Drills 7–15 mm and Implant 13

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

1. Prepare implant site (Figure B). When using a flapless approach add-on soft tissue height to drill depth.

2. Measure the final depth of implant site for applicable implant length using depth probe with same measurements as Twist Drills and Twist Step Drills.

3. Open the implant package and pick up the implant from inner casing by applying light pressure on the implant driver (3.0, NP, RP, WP) and carefully turn the implant sleeve counterclockwise until implant driver is fully seated (Figure C).

NobelActive® TiUnite®/TiUltra™ Implants are ideally installed with low speed, maximum 25 rpm, using a handpiece or by hand using the surgical driver and corresponding implant driver (3.0, NP, RP, WP).

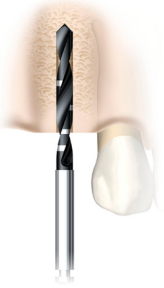


Figure B – Preparation of Implant Site

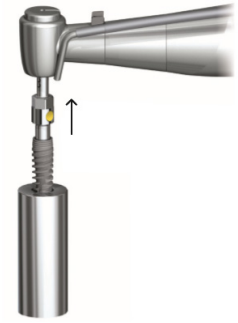
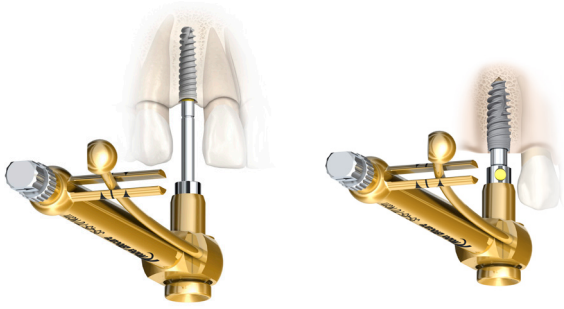


Figure C – Seating the Implant Driver

4. Place and tighten the implant. For NobelActive® TiUnite®/TiUltra™ Implants 3.0 use maximum 45 Ncm installation torque and for NobelActive® TiUnite®/TiUltra™ Implants 3.5, 4.3, 5.0 and 5.5 use maximum 70 Ncm installation torque (Figure D). To facilitate proper orientation, see markings on implant drivers (D1 and D2 in Figure D).

D1
NobelActive® 3.0

D2
NobelActive® 3.5, 4.3, 5.0, 5.5



max 45 Ncm

max 70 Ncm

Figure D – Placement and Tightening of Implant

Note The double lead thread allows NobelActive® TiUnite®/TiUltra™ Implants to be inserted faster compared to other implants. This means that less turns are required to fully seat the implant.

Caution Never exceed insertion torque of 45 Ncm for a NobelActive® TiUnite®/TiUltra™ 3.0 Implant and 70 Ncm for NobelActive® TiUnite®/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.

Caution The unique thread design of NobelActive® TiUnite®/TiUltra™ Implants allows to redirect the implant during insertion. This feature requires special attention toexecute during placement, as the implant will not necessarily stop at the bottom of the prepared site but may go deeper into the bone (refer to Figure E).

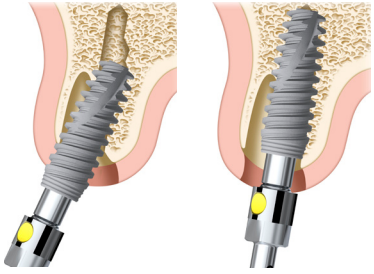


Figure E – Redirection of the Implant During Insertion

Special instructions when placing NobelActive® TiUnite®/TiUltra™ 3.0 implants:

Insertion torque for NobelActive® TiUnite®/TiUltra™ 3.0: Due to the narrow implant diameter and narrow implant abutment connection the maximum insertion torque for NobelActive® TiUnite®/TiUltra™ 3.0 differs from the entire NobelActive® TiUnite®/TiUltra™ assortment.

Caution Never exceed insertion tightening 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.

Procedure for Implant Placement in Dense Bone

If the implant gets stuck during implant installation, or the maximum torque is achieved before fully seated (45 Ncm for NobelActive® TiUnite™/TiUltra™ 3.0 or 70 Ncm for NobelActive® TiUnite®/TiUltra™ 3.5, 4.3, 5.0, and 5.5), one of the following procedures should be followed:

a. Rotate the implant counterclockwise for a few turns enabling the use of the self- tapping capacity of the implant; or

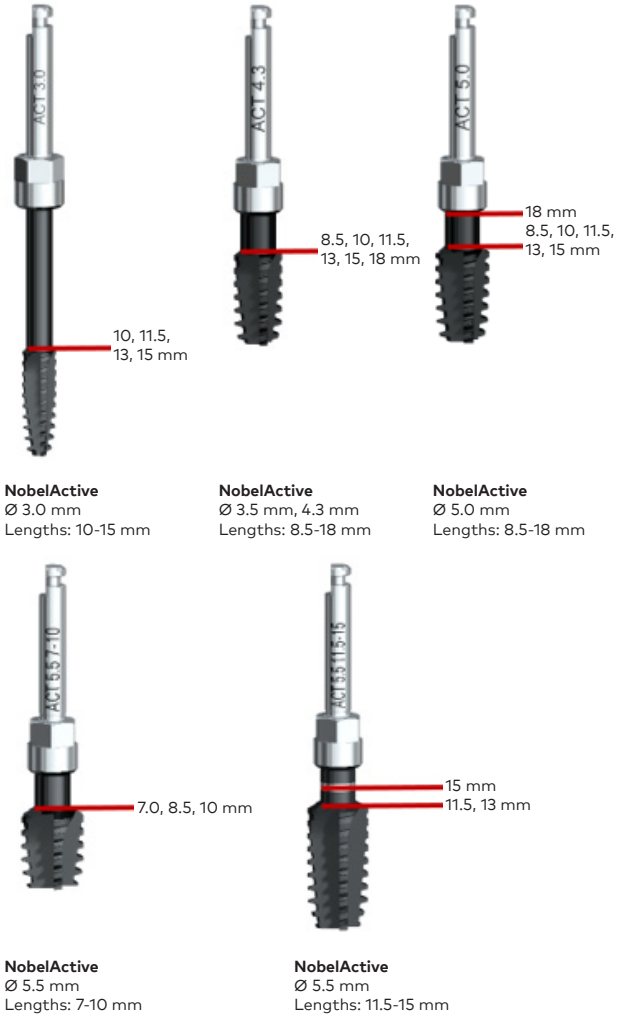
b. Back out implant and widen the site with a wider drill according to drill protocol; or

c. Select a NobelActive® TiUnite®/TiUltra™ Screw Tap which matches the diameter of the implant and desired drilling depth (refer to Figure F).

– Place screw tap into prepared implant site using low speed (25 rpm).

– Apply firm pressure and begin rotating the screw tap slowly. When the threads engage, continue to thread the screw tap to the defined depth without applying additional pressure.

– Switch the drill unit with handpiece to reverse mode and back the screw tap out.



NobelActive
Ø 3.0 mm
Lengths: 10-15 mm

NobelActive
Ø 3.5 mm, 4.3 mm
Lengths: 8.5-18 mm

NobelActive
Ø 5.0 mm
Lengths: 8.5-18 mm

NobelActive
Ø 5.5 mm
Lengths: 7-10 mm

NobelActive
Ø 5.5 mm
Lengths: 11.5-15 mm

Figure F – Screw Taps for Installation of NobelActive® Implants in Dense Bone

5. Continue with implant installation until desired position is achieved using max 45 Ncm installation torque for NobelActive® TiUnite®/TiUltra™ 3.0 implant or max 70 Ncm for NobelActive® TiUnite®/TiUltra™ 3.5, 4.3, 5.0. and 5.5 Implants.

6. When placing the implant, align one of the black hex indicators on the implant driver parallel to the buccal wall (refer to G1 in Figure G). This ensures that one of the flat sides of the hexagon is parallel to the buccal side, ensuring preferred prosthetic abutment orientation (refer to G2 in Figure G).

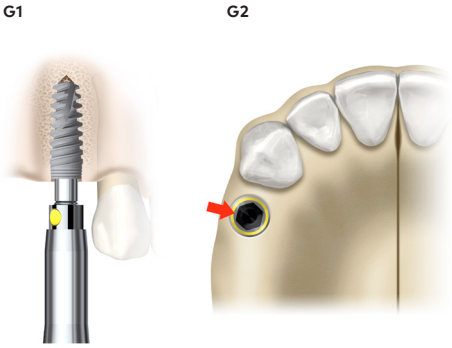


Figure G – Final Implant Placement (G1) and Alignment (G2)

7. For Immediate Function, the implant should be able to withstand a final torque of 35–45 Ncm for NobelActive® TiUnite®/TiUltra™ 3.0 implant and 35–70 Ncm for NobelActive® TiUnite®/TiUltra™ 3.5, 4.3, 5.0, and 5.5 implants

8. Depending on the surgical protocol of choice, place a cover screw (refer to H1 in Figure H), healing abutment (refer to H2 in Figure H) or a provisional restoration in case of immediate loading approach.

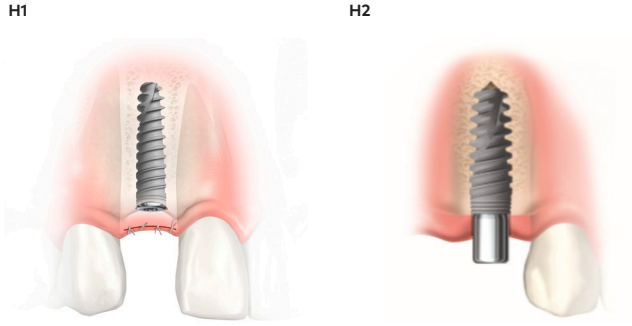


Figure H – Placement of a cover screw (H1) or healing abutment (H2)

Sterility and Reusability Information

NobelActive® TiUnite®/NobelActive® TiUltra™ Implants, Guide Drill, Precision Drill, Twist Drills, Twist Step Drills and Cover Screws have 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.

Caution NobelActive® TiUnite®/NobelActive® TiUltra™, Implants, Guide Drill, Precision Drill, Twist Drills, Twist Step Drills and Cover Screws 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.

Screw Taps NobelActive® have been sterilized using irradiation and are intended for reuse. Do not use after the labeled expiration date.

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

Prior to reuse clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

Screw Taps NobelActive® are re-usable devices which shall be inspected before each re-use to ensure that the integrity and performance continues to be maintained. Please check if any wear deformation or corrosion is visible on the screw tap. In particular, if any corrosion or deformation is visible, the screw tap shall be discarded.

Nobel Biocare recommends that Screw Taps NobelActive® are replaced after 20 uses, or when cutting efficiency declines. Worn-out or damaged screw taps must be discarded and replaced with new, sharp screw taps. Overuse may cause bone overheating and lead to implant failure.

Warning Use of a non-sterile device may lead to infection of tissues or infectious diseases.

Cleaning and Sterilization Instructions

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

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.

Performance Requirements and Limitations

To achieve the desired performance, the devices must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with the devices, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.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 influence device characteristics leading to failure.

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
UK Responsible Person UK RP	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class IIa/IIb Devices	CE 2797
UKCA Mark for Class IIa/IIb Devices	UK CA 0086

Note Refer to the product label to determine the applicable conformity marking for each device.

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

Basic UDI-DI Information

Product	Basic UDI-DI Number
NobelActive® TiUnite® Implants	73327470000001216P
NobelActive® TiUltra™ Implants	
Screw Taps NobelActive® 3.0/NP/RP/WP	3327470000001226R
Single-patient use Drills	73327470000001206M

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.