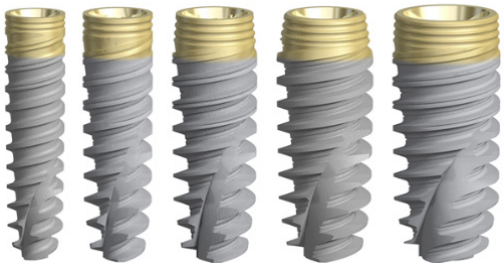
# NobelActive® TiUltra™ implant



## 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

### Implant

NobelActive® TiUltra™ dental implants are made from biocompatible commercially pure grade 4 titanium with TiUltra™ surface.

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® TiUltra™ implants are dental implants intended to be used in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore chewing function.

## Indications

NobelActive® TiUltra™ implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.

NobelActive® TiUltra™ 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

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® TiUltra™ 3.0 implants are indicated for single unit restorations only.

# Contraindications

It is contraindicated to use NobelActive® TiUltra™ implants 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 or hypersensitive to commercially pure titanium (grade 4), sodium dihydrogen phosphate ($NaH_2PO_4$) or magnesium chloride ($MgCl_2$).

NobelActive® TiUltra™ 3.0 implants are not indicated to be used to replace a central incisor, a canine, a premolar or a molar in the maxilla nor to replace a canine, a premolar or a molar in the mandible.

NobelActive® TiUltra™ 3.0 implants are not indicated to be used for multiple tooth replacements.

# Materials

### NobelActive® TiUltra™ implant

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). Implant is layered with water soluble salt mixture of Sodium dihydrogen phosphate and Magnesium chloride.

# 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. Especially, non-observance of the indicated limitations of use and working steps may result in failure.

Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

NobelActive® 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® implants can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

It is strongly recommended that clinicians, new as well as experienced users of implants, prosthetics and associated software, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

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.

### Before surgery

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

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g. cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

With respect to pediatric patients, routine treatment is not recommended until the end of the jaw bone growth phase has been properly documented.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant 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

Small diameter implants and angled abutments are not recommended for the posterior region.

Care and maintenance of 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 installation, 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 secure the long term treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

## Special instructions when placing NobelActive® TiUltra™ implants

### Full seating of implant

The unique thread design of NobelActive® TiUltra™ implants allows to redirect the implant during insertion. This feature requires special attention to execute during placement, as the implant will not necessarily stop at the bottom of the prepared site, but may go deeper into the bone.

### Insertion speed of implant

The thread pitch allows the implant to be inserted up to four times faster compared to other implants. This means that significantly less turns are required to fully seat the implant.

### Implant tightening

If a Surgical Driver is used to insert the implant, special care needs to be taken to avoid overtightening.

## Special instructions when placing NobelActive® TiUltra™ 3.0 implants

### Indications

NobelActive® TiUltra™ 3.0 implants are only intended to be used for replacement of a lateral incisor in the maxilla; lateral and/or central incisor in the mandible. NobelActive® TiUltra™ 3.0 implants are indicated only for single unit restorations

### 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 tightening torque for the 3.0 implant is 45 Ncm and the maximum prosthetic abutment tightening torque is 15 Ncm.

**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.

## Intended Users and Patient Groups

NobelActive® TiUltra™ implants are to be used by dental health care professionals.

NobelActive® TiUltra™ implants 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® TiUltra™ implants 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® TiUltra™ implants

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.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® 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

### Surgical procedure

1. During drilling procedures bone quality should be considered (please see table 1 recommended drill sequences based on bone quality to ensure optimal primary stability when applying immediate function).

**Table 1 – Recommended drill sequences based on bone quality. Drill data are stated in mm and the drill diameters listed within brackets denote widening of cortex only.**

| Implant diameter | Soft Bone Type IV | Medium Bone Type II–III | Dense Bone Type I |
|---|---|---|---|
| Ø 3.0 | 1.5 | 2.0 | 2.0<br>2.4/2.8 |
| Ø 3.5 | 2.0<br>(2.4/2.8) | 2.0<br>2.4/2.8<br>(2.8/3.2) | 2.0<br>2.4/2.8<br>2.8/3.2 |
| Ø 4.3 | 2.0<br>2.4/2.8<br>(2.8/3.2) | 2.0<br>2.4/2.8<br>3.2/3.6 | 2.0<br>2.4/2.8<br>3.2/3.6<br>(3.8/4.2) |
| Ø 5.0 | 2.0<br>2.4/2.8<br>3.2/3.6 | 2.0<br>2.4/2.8<br>3.2/3.6<br>3.8/4.2 | 2.0<br>2.4/2.8<br>3.2/3.6<br>3.8/4.2<br>(4.2/4.6) |
| Ø 5.5 | 2.0<br>2.4/2.8<br>3.2/3.6<br>(3.8/4.2) | 2.0<br>2.4/2.8<br>3.2/3.6<br>3.8/4.2<br>4.2/4.6<br>(4.2/5.0) | 2.0<br>2.4/2.8<br>3.2/3.6<br>3.8/4.2<br>4.2/5.0<br>Screw Tap |

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.

**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 Figure A for dill reference lines).

A

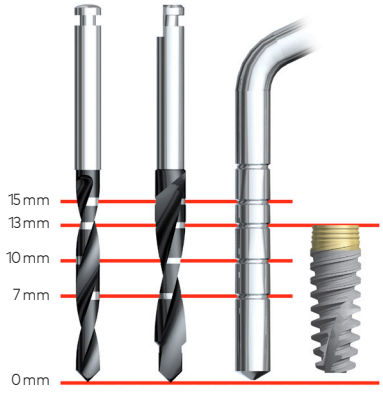



**Figure A – Shows Twist Drills and Twist Step Drills 7–15 mm and implant 13 mm.**

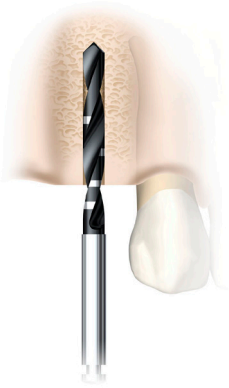
**Note** The marks on Twist Drills and Twist Step Drills indicate actual millimeter length and correspond to the implant collar. Final vertical positioning depends on several parameters, including esthetics, tissue thickness and available vertical space.

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

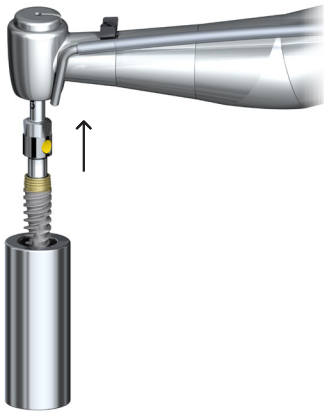
3. Measure the final depth of implant site for applicable implant length using depth probe with same measurements as Twist Drills and Twist Step Drills.

4. Open the implant package and pick up the implant from inner casing by applying light pressure on the implant driver and carefully turn the implant sleeve counterclockwise until implant driver is fully seated (Figure C). NobelActive® TiUltra™ implants are ideally installed with low speed, max 25 rpm, using drilling device or by hand using surgical driver.

B

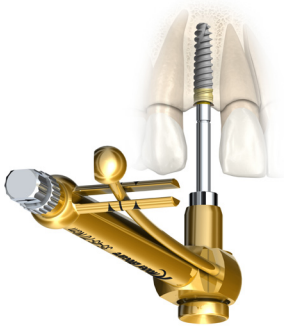


C



5. Place and tighten the implant. For NobelActive® TiUltra™ 3.0 use maximum 45 Ncm installation torque (Figure D:1) and for NobelActive® TiUltra™ 3.5, 4.3, 5.0 and 5.5 use maximum 70 Ncm installation torque (Figure D:2).

**D:1**
**NobelActive® 3.0**



**max 45 Ncm**

**D:2**
**NobelActive® 3.5, 4.3, 5.0, 5.5**

**max 70 Ncm**

**Figure D – Placement and tightening of the implant**

**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.

## Dense bone instructions

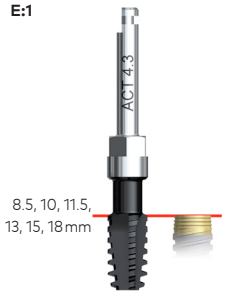
If the implant gets stuck during implant installation or 45 Ncm (NobelActive® TiUltra™ 3.0) or 70 Ncm (NobelActive® TiUltra™ 3.5, 4.3, 5.0, and 5.5) is achieved before fully seated:

a. rotate the implant counter clockwise approximately ½ turn enabling use of self-tapping capacity of the implant or

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

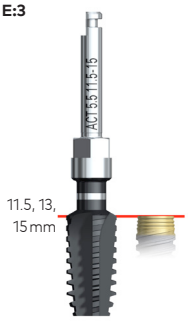
c. select a NobelActive® TiUltra™ Screw tap matching the diameter of the implant. Drill depth for screw tap (E:1 for 3.0, 3.5 and 4.3. E:2 and E:3 for 5.5).

E:1




E:2


E:3




– 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, 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 installation torque for NobelActive® TiUltra™ 3.0 implant or max 70 Ncm for NobelActive® TiUltra™ 3.5, 4.3, 5.0. and 5.5 implants.

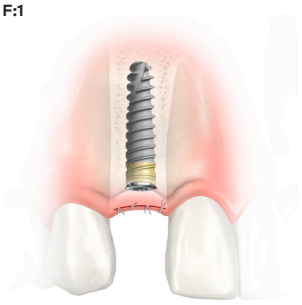
**Caution** Never exceed insertion torque of 45 Ncm for a NobelActive® TiUltra™ 3.0 implant and 70 Ncm for NobelActive® TiUltra™ 3.5, 4.3, 5.0 and 5.5 implants.

To ensure ideal prosthetic abutment orientation for internal conical connection implants position one of the internal hexagon flat surfaces in the implant towards buccal/facial. To facilitate proper orientation, see markings on implant drivers (D:1 and D:2).

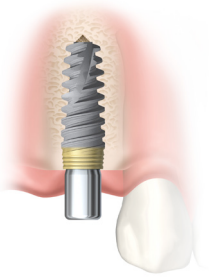
6. For Immediate Function, the implant should be able to withstand a final torque of 35–45 Ncm for NobelActive® TiUltra™ 3.0 implant and 35–70 Ncm for NobelActive® TiUltra™ 3.5, 4.3, 5.0, and 5.5 implants.

7. Depending on surgical protocol of choice, place a cover screw or abutment and suture (F).

F:1



F:2



See Table 2 for implant specifications.

**Table 2 – Implant**

| Platform | Platform diameter | Implant diameter | Abutment interface | Lengths |
|---|---|---|---|---|
| 3.0 | Ø 3.0 mm | Ø 3.0 mm | Ø 2.5 mm | 10 mm, 11.5 mm, 13 mm, 15 mm |
| 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 |
| RP | Ø 3.9 mm | Ø 4.3 mm<br>Ø 5.0 mm | Ø 3.4 mm<br>Ø 3.4 mm | 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm<br>8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm |
| WP | Ø 5.1 mm | Ø 5.5 mm | Ø 4.4 mm | 7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm |

**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.

## Sterility and Reusability Information

NobelActive® TiUltra™ implants 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 as the device sterility and/or integrity may be compromised.

**Caution** NobelActive® TiUltra™ implants are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

## 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<br>PO Box 5190, 402 26<br>Västra Hamngatan 1<br>Göteborg<br>411 17<br>Sweden<br>www.nobelbiocare.com |
| **UK Responsible Person**<br>UK RP | Nobel Biocare UK Ltd<br>4 Longwalk Road<br>Stockley Park<br>Uxbridge<br>UB11 1FE<br>United Kingdom |
| **Distributed in Turkey by** | EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş<br>Nispetiye Mah. Aytar Cad. Metro İş Merkezi<br>No: 10/7<br>Beşiktaş İSTANBUL<br>Phone: +90 2123614901,<br>Fax: +90 2123614904 |
| **Distributed in Australia by** | Nobel Biocare Australia Pty Ltd<br>Level 4, 7 Eden Park Drive<br>Macquarie Park, NSW 2113<br>Australia<br>Phone: +61 1800 804 597 |
| **Distributed in New Zealand by** | Nobel Biocare New Zealand Ltd<br>33 Spartan Road<br>Takanini, Auckland, 2105 New Zealand<br>Phone: +64 0800 441 657 |
| **CE Mark for Class IIb Devices** | CE 2797 |
| **UKCA Mark for Class 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® TiUltra™ | 733274700000001216P |

## 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.