NobelActive® TiUltra™ implant
Instructions for use

Important: Please read.

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, it is his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instructions 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.

Intended use:

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 placing 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.

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.

It is strongly recommended that NobelActive® TiUltra™ implants are used only with dedicated Nobel Biocare surgical instruments and prosthetic components, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental 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 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 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.

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.

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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).

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 2.4/2.8
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
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)
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)
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

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 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 image **A** for dill reference lines).

A

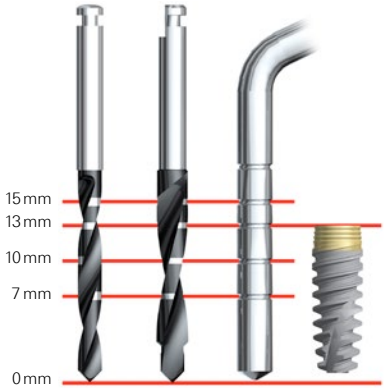
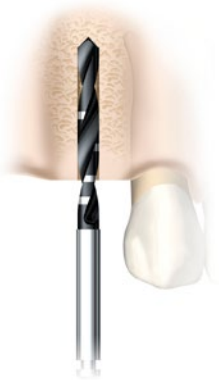


Image **A** shows Twist Drills and Twist Step Drills 7–15 mm and implant 13 mm.

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 counter clockwise until implant driver is fully seated (**C**). NobelActive® TiUltra™ implants are ideally installed with low speed, max 25 rpm, using drilling device or by hand using surgical driver.

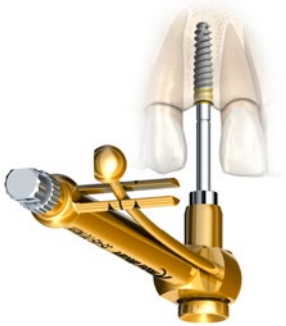
B



C

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

D:1
NobelActive® 3.0



max 45 Ncm

D:2
NobelActive® 3.5, 4.3, 5.0, 5.5

max 70 Ncm

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.

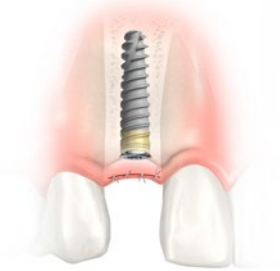
Continue with implant installation until desired position is achieved using max **45 Ncm** installation torque for NobelActive® TiUltra™ 3.0 implant or max **70 Ncm** for NobelActive® TiUltra™ 3.5, 4.3, 5.0. and 5.5 implants.

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.

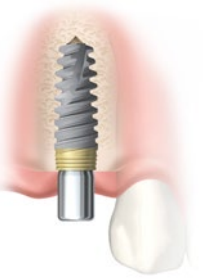
To ensure ideal prosthetic abutment orientation for internal conical connection implants position one of the internal hexagon flat surfaces in the implant towards buccal/facial. To facilitate proper orientation, see markings on implant drivers (**D:1** and **D:2**).

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.

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2 Implant specifications

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 Ø 5.0 mm	Ø 3.4 mm Ø 3.4 mm	8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm 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.

For additional information on surgical procedures please consult the NobelActive® TiUltra™ "Procedures & products" treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

NobelActive® TiUltra™ implant: commercially pure titanium grade 4, sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).

Sterility and reusability information:

NobelActive® TiUltra™ implants are delivered sterile 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™ implants are single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.

Magnetic resonance (MR) safety information:

The NobelActive® TiUltra™ implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of NobelActive® TiUltra™ implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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:

Manufacturer: Nobel Biocare AB, Box 5190, 402 26
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Phone: +46 31 81 88 00. Fax: +46 31 16 31 52. www.nobelbiocare.com

CE 2797

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Canada license exemption: Please note that not all products may have been licenced in accordance with Canadian law.

For Prescription Use Only.
Caution: Federal (United States) law restricts this device to sale by or on the order of a clinician, medical professional or physician.

Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

Authorized representative in the European Community

Batch code

Catalogue number


Caution


CE marking


Consult instructions for use


Contains hazardous substances

Contains or presence of phthalate

Date


Date of manufacture


Do not resterilize


Do not re-use


Do not use if package is damaged

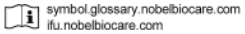

Double sterile barrier system

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional


Manufacturer

Medical device


Non-pyrogenic

Non-sterile


Patient identification


Patient information website


Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

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Sterilized using ethylene oxide

Sterilized using irradiation

Temperature limit

Tooth number

Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier

Use-by date

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