Nobel Biocare N1™ TiUltra™ TCC System

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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 N1™ TiUltra TCC system, which is comprised of the Nobel Biocare N1™ TiUltra™ TCC Implants, Cover Screws Nobel Biocare N1™ TCC, and the instrumentation which is required during the surgical and handling procedure to prepare the implant site and to place the implant.

Nobel Biocare N1™ TiUltra™ TCC Implants

Nobel Biocare N1™ TiUltra™ TCC is a dental implant featuring the trioval conical connection (TCC), which is characterized by a trioval-shaped coronal zone and a round, moderately tapered body. The implant can be placed using a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, given that sufficient primary stability and appropriate occlusal loading for the selected technique have been achieved. The implant is made of biocompatible commercially pure grade 4 titanium with a protective layer comprising sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).

Nobel Biocare N1™ TiUltra TCC implants are compatible with Cover Screws Nobel Biocare N1™ TCC, which also feature the trioval conical connection (TCC). This cover screw consists of two parts (the plug and screw); both parts are made from titanium alloy Ti-6Al-4V. The screw has a Diamond Like Carbon (DLC) coating. Refer to Nobel Biocare Instructions for Use (IFU) IFU1016 for information regarding cover screws; this IFU is available for download at ifu.nobelbiocare.com.

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.

Instruments for Implant Site Preparation

- OsseoDirector™ Nobel Biocare N1™ (“OsseoDirector™”) is the first instrument of the N1™ system protocol used to prepare an osteotomy. The OsseoDirector™ determines the position of the implant.
- The Guided Pilot Drill Nobel Biocare N1™ (“Guided Pilot Drill”) is a straight drill to be used in combination with NobelGuide® components. It can be used as the first drill as an alternative to the OsseoDirector™ (for detailed instructions refer to Nobel Biocare IFU2001 and IFU2009).
- The OsseoShaper™ 1 Nobel Biocare N1™ (“OsseoShaper™ 1”) is a site preparation instrument to be used after the OsseoDirector™. It is delivered co-packed with the implant. The OsseoShaper™ 1 is used at low speed (50 rpm) and without irrigation.
- The OsseoShaper™ 2 Nobel Biocare N1™ (“OsseoShaper™ 2”) is a site preparation instrument used when the OsseoShaper™ 1 cannot reach full depth. The OsseoShaper™ 2 is color coded based on the implant diameter (magenta for implant diameter 3.5 mm, yellow

for implant diameter 4.0 mm and blue for implant diameter 4.8 mm). The OsseoShaper™ 2 is used at low speed (50 rpm) without irrigation.

– The Twist Step Drill may be used in situations where the OsseoShaper 2 cannot be fully seated.

– The OsseoShaper™ Extension Nobel Biocare N1™ ("OsseoShaper™ Extension") is compatible with OsseoShaper™, OsseoDirector™, Twist Step Drills and the Guided Pilot Drill. It can be used in situations where adjacent natural teeth interfere with the contra-angle head and prevent the drill from reaching the desired depth.

Instruments for Implant Placement

– The Implant Driver Nobel Biocare N1™ TCC ("Implant Driver") is intended to be used only in conjunction with Nobel Biocare N1 TiUltra™ TCC implants. It is color coded based on the implant platform and has three concave surfaces on the body that align with the flat side of the tri-oval implant connection. The depth marks identify the implant depth in relation to bone and soft tissue during its placement. The Implant Driver is compatible with the Manual Torque Wrench Surgical Nobel Biocare N1™. Refer to Nobel Biocare IFU1098 for information regarding the Manual Torque Wrench Surgical Nobel Biocare N1™.

– The Direction Indicator Nobel Biocare N1™ ("Direction Indicator") is used to verify the orientation of the osteotomy after using the OsseoDirector™ and the Guided Pilot Drill.

– The Depth Probe Nobel Biocare N1™ ("Depth Probe") is used to verify the depth of the osteotomy after using the OsseoDirector™, Guided Pilot drill and/or OsseoShaper™. The Depth Probe has depth markings at both ends of 8, 10, 12, 14, 16 mm representing the actual drill length.

Intended Use/Intended Purpose

Nobel Biocare N1™ TiUltra™ TCC Implants

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

Cover Screw Nobel Biocare N1™ TCC

Intended to be temporarily connected to an endosseous dental implant to protect the implant connection interface during bone healing.

OsseoDirector™ Nobel Biocare N1™, Guided Pilot Drill Nobel Biocare N1™, OsseoShaper™ 1 NobelBiocare N1™, OsseoShaper™ 2 Nobel Biocare N1™, Twist Step Drill, and OsseoShaper™ Extension Nobel Biocare N1™

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

Implant Driver Nobel Biocare N1™ TCC

Intended for use to insert or remove dental implants during dental implant surgery.

Direction Indicator Nobel Biocare N1™

Intended to be used to verify the orientation of an osteotomy during dental implant surgery.

Depth Probe Nobel Biocare N1™

Intended to be used to verify the depth of an osteotomy during dental implant surgery.

Indications

Nobel Biocare N1™ TiUltra™ TCC Implants

Nobel Biocare N1™ TiUltra™ TCC implants are indicated for use in the maxilla or mandible for anchoring or supporting prosthetic teeth, in order to restore patient esthetics and chewing function. Nobel Biocare N1™ TiUltra™ TCC implants are indicated for single or multiple unit restorations in splinted or non-splinted applications using a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, given that sufficient primary stability and appropriate occlusal loading for the selected technique have been achieved.

Cover Screw Nobel Biocare N1™ TCC

The Cover Screw Nobel Biocare N1™ TCC is indicated for use with Nobel Biocare N1™ TiUltra™ TCC implants in the maxilla or mandible.

OsseoDirector™ Nobel Biocare N1™, Guided Pilot Drill Nobel Biocare N1™, OsseoShaper™ 1 Nobel Biocare N1™, OsseoShaper™ 2 Nobel Biocare N1™, Twist Step Drill

The OsseoDirector™ Nobel Biocare N1™, Guided Pilot Drill Nobel Biocare N1™, OsseoShaper™ 1 Nobel Biocare N1™, OsseoShaper™ 2 Nobel Biocare N1™, Twist Step Drill are indicated to be used in the maxilla or mandible to prepare an osteotomy prior to placement of a Nobel Biocare N1™ TiUltra™ TCC implant.

OsseoShaper™ Extension Nobel Biocare N1™

The OsseoShaper™ Extension Nobel Biocare N1™ is indicated to be used to extend the length of a drill or OsseoShaper™ in situations where adjacent natural teeth interfere with the dental contra angle and prevent the drill from reaching the desired depth.

Implant Driver Nobel Biocare N1™ TCC

The Implant Driver Nobel Biocare N1™ TCC is indicated to be used during dental implant surgery for the insertion and removal of Nobel Biocare N1™ TiUltra™ TCC implants from an osteotomy in the maxilla or mandible.

Direction Indicator Nobel Biocare N1™

The Direction Indicator Nobel Biocare N1™ is indicated for use with osteotomies created with the OsseoDirector™ and Guided Pilot Drill in the maxilla or mandible.

Depth Probe Nobel Biocare N1™

The Depth Probe Nobel Biocare N1™ is indicated for use with osteotomies created with OsseoDirector™, Guided Pilot Drill and OsseoShaper™ in the maxilla or mandible.

Contraindications

It is contraindicated to use Nobel Biocare N1™ TiUltra™ TCC implants, Cover Screw Nobel Biocare N1™, OsseoDirector™ Nobel Biocare N1™, Guided Pilot Drill Nobel Biocare N1™, OsseoShaper™ 1 Nobel Biocare N1™, OsseoShaper™ 2 Nobel Biocare N1™, Twist Step Drill, Implant Drivers Nobel Biocare N1™ TCC, OsseoShaper™ Extension Nobel Biocare N1™, Direction Indicator Nobel Biocare N1™ and Depth Probe Nobel Biocare N1 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 parafunctional loads.

– Patients who are allergic or hypersensitive to the following material components used: Commercially pure titanium (grade 4), titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), stainless steel, sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$) and DLC (Diamond Like Carbon) coating.

Products and their corresponding materials are listed under the chapter "Materials".

Refer to Nobel Biocare IFU1016 for specific contraindications for the Cover Screws Nobel Biocare N1™ TCC.

Materials

Nobel Biocare N1™ 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). Implant is layered with water soluble salt mixture of Sodium dihydrogen phosphate and Magnesium chloride.

Osseoshaper: Titanium alloy ELI (Extra Low Interstitial) composed of Titanium balanced with 6 wt.% Aluminium and 4 wt.% Vanadium.

OsseoShaper 1 Nobel Biocare N1™ and OsseoShaper 2 Nobel Biocare N1™

Osseoshaper: Titanium alloy ELI (Extra Low Interstitial) composed of Titanium balanced with 6 wt.% Aluminium and 4 wt.% Vanadium.

OsseoDirector Nobel Biocare N1™ and Twist Step Drill

Drill: Stainless Steel type 420F Mod.

Guided Pilot Drill Nobel Biocare N1™

Drill: Stainless Steel type 420F Mod. Drill is partly coated with Diamond like Carbon coating.

Implant Driver Nobel Biocare N1™

Driver: Stainless Steel type UNS S46910.

Sleeve: Titanium alloy ELI (Extra Low Interstitial) composed of Titanium balanced with 6 wt.% Aluminium and 4 wt.% Vanadium.

Direction Indicator Nobel Biocare N1™ and Depth Probe Nobel Biocare N1™

Indicator/Probe: Stainless Steel type 304 (UNS S30400).

OsseoShaper Extension Nobel Biocare N1™

Extension: Stainless Steel type UNS S46910.

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.

Nobel Biocare N1™ implants, implant site preparation tooling and instruments must only be used with compatible Nobel Biocare instruments and components and prosthetic components. Use of instruments and components and prosthetic components that are not intended to be used in combination with Nobel Biocare N1™ System 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

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

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).

Where applicable regular platform (RP) 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.

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

Nobel Biocare N1 TiUltra™ TCC implants and instrumentation are to be used by dental health care professionals.

Nobel Biocare N1 TiUltra™ TCC 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

Nobel Biocare N1™ TiUltra™ TCC implants and the Nobel Biocare N1™ TiUltra™ TCC system instruments are components 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 Nobel Biocare N1™ TiUltra™ TCC Implants and the Nobel Biocare N1™ TiUltra TCC System Instruments

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

During the submerged healing period, bone may grow over the cover screw. In some cases, cover screws may get exposed prematurely.

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 Nobel Biocare N1™ TiUltra™ TCC 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 and Handling Procedure

General Guidance Regarding Placement of the Nobel Biocare N1™ TiUltra™ TCC Implant

Nobel Biocare N1™ TiUltra™ TCC implants are available in five lengths for the diameter 4.0 mm RP platform, four lengths for the diameter 3.5 mm NP platform and three lengths for the diameter 4.8 mm RP platform.

The implant should be positioned such that the flat side of the tri-oval shape faces buccally to maximize buccal wall volume at the time of implant placement as showed in Figure A.

The implants require a minimum of 1.5 mm distance to the neighboring teeth. Inter-implant distance must be at least 3 mm.

Note For the 15 mm implant length it is necessary to use the new Depth Probe with the 16 mm marking, OsseoDirector™ 8-18 mm, Guided Pilot Drill (10+) 8-18 mm and the Twist Step Drill 8-18 mm.

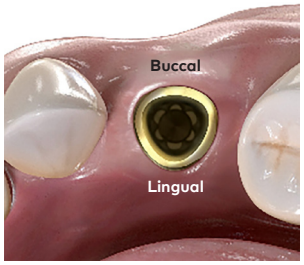

Figure A – Implant Position

Depth Marking on the OsseoDirector™, Twist Step Drills, and OsseoShaper™

The OsseoDirector™ and Twist Step Drills have a depth measurement system which, as shown in Figure B, correlates to the implant length. Two versions of the OsseoDirector™ and Twist Step drill are available, one with length 8-14 mm that can be used for implants length up to 13 mm and one with length 8-18 mm that can be used for implants up to 15 mm. Below a representation of the depth marking lines with the example of the 4.0 x 11 mm implant.

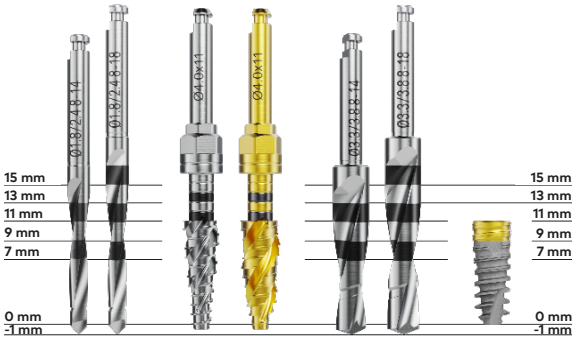

Figure B – Depth Marking reference on OsseoDirector™, OsseoShaper™ and Twist Step Drills

Each implant has a corresponding OsseoShaper™ 1 and OsseoShaper™ 2, which matches the implant length. The black markings on the OsseoShaper™ (see Figure C) indicate the insertion depth and are particularly useful during a flapless procedure to help verify when the OsseoShaper™ is fully seated. Each line is 1 mm thick. The color coding for the OsseoShaper™ 2 is magenta for 3.5 mm implants, yellow for 4.0 mm implants and blue for the 4.8 mm implants.

Note The OsseoShaper™ extend 0.5 mm more than the implant.

Figure C – Depth Markings on OsseoShaper™ 1 and OsseoShaper™ 2

The Guided Pilot Drill is available in two lengths (10+) 8-14 mm for implants up to 13 mm and (10+) 8-18 mm for implants up to 15 mm. Below the image showing the depth marking that correlate to the implant length.

Note The drills are 1 mm longer than the implants.

Figure D – Guided Pilot Drill Marking

Caution The OsseoDirector™ Nobel Biocare N1™, Guided Pilot Drill Nobel Biocare N1™, and Twist Step Drill extend up to 1 mm longer than the implant length when seated. Allow for this additional length when drilling near vital anatomical structures.

Surgical Protocol

The osteotomy is created using either the OsseoDirector™ or Guided Pilot Drill, and OsseoShaper™. OsseoShaper™ are threaded devices that are inserted and removed at low speed without irrigation. The following illustration describes the Nobel Biocare N1™ site preparation protocol. For the detailed instructions on the surgical protocol, drill unit set up and the use of the specific tools follow the surgical steps described in the next sections.

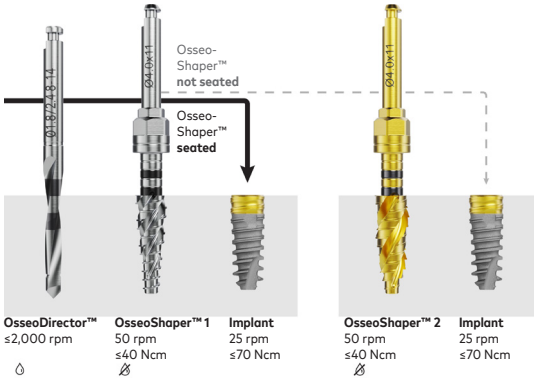

Figure E – Surgical protocol

The Guided Pilot Drill can optionally replace the OsseoDirector™ in this protocol.

The surgical protocol is applicable to the majority of bone qualities and anatomical situations, including extraction sockets, where sufficient bone volume is available to fully seat the selected implant.

A. Prepare the Drill Unit

It is mandatory to use a contra-angle with a hexagon clamping connection (DIN EN ISO 17509) – see Figure F.

Figure F – Contra-angle with hexagonal clamping connection

Caution The drill unit maximum torque during implant site preparation must be set to 40 Ncm. Exceeding 40 Ncm may damage the contra-angle and related tooling.

B. Prepare the Osteotomy

Warning The OsseoDirector™, Guided Pilot Drill, OsseoShaper™ and Twist Step Drills are sharp instruments. Handle with care to prevent injury.

1. Set up the drill unit at 2,000 rpm and with irrigation on.

2. Prepare the pilot osteotomy with the OsseoDirector™ Nobel Biocare N1 (Figure G) or the Guided Pilot Drill. The OsseoDirector™ or Guided Pilot Drill must proceed at high speed, max 2,000 rpm, under constant and profuse irrigation by sterile saline at room temperature.

Figure G – OsseoDirector™

Note It is important to drill until the full planned depth in order to successfully seat the implant.

Caution The OsseoDirector™, Guided Pilot Drill and Twist Step Drill extend up to 1 mm longer than the implant length when seated. Allow for this additional length when drilling near vital anatomical structures (see Figure B and D for drill reference lines).

3. In situations where adjacent natural teeth interfere with the contra-angle head preventing the drill from reaching the desired depth, use the OsseoShaper™ Extension Nobel Biocare N1.

4. When using a flapless approach add-on soft tissue height to drill depth.

5. The Depth Probe Nobel Biocare N1 can be used to check the depth of the osteotomy after using the OsseoDirector™ or Guided Pilot Drill.

Note A new Depth Probe (Figure H) is available and need to be used for the 15 mm implant site preparation. An additional laser marking corresponding to the 16 mm depth has been added to both sides.

Figure H – Depth Probe

Caution Use of the wrong depth probe can result in incorrect measurement of the osteotomy depth. The Depth Probe Nobel Biocare N1™ has to be used.

6. In order to check the orientation of the osteotomy, use the Direction Indicator. The Direction Indicator has two sides (see Figure I); side one (tapered) fits the osteotomy created with the OsseoDirector™ and the other side (straight) fits the osteotomy created with the Guided Pilot Drill.

Note It is recommended to use a suture thread through the hole to prevent aspiration.

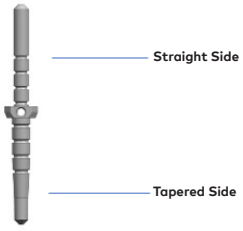

Figure I – Direction Indicator

Warning The OsseoDirector™, Guided Pilot Drill, OsseoShaper™ and Twist Step Drills are sharp instruments. Handle with care to prevent injury.

C. Use the OsseoShaper™ 1 Nobel Biocare N1™

The OsseoShaper™ 1 is delivered co-packed with the respective implant (see Figure J).

Figure J – Co-packing of OsseoShaper™ 1 with Implant

1. Set the torque limit of the drilling unit to 40 Ncm, the speed at 50 Rpm and no irrigation.

2. Engage the OsseoShaper™ 1 with the contra-angle directly from the packaging (Figure K). Once it is engaged, push the white fingers (Figure L) and gently pull out the OsseoShaper™ 1.

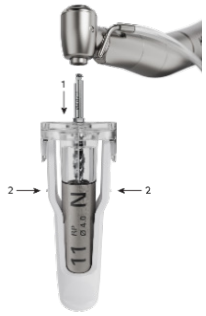

Figure K – OsseoShaper™ 1 Nobel Biocare N1™ engagement

Figure L – OsseoShaper™ 1 Nobel Biocare N1™ extraction

3. Insert the OsseoShaper™ 1 to full depth, if possible, and remove by setting the reverse turning mode on the drill unit.
   - Drill in a forward direction at 50 rpm without irrigation.
   - Allow the OsseoShaper™ 1 to feed in without pressure to full depth or until it prematurely stops.
   - Drill in a reverse direction at 50 rpm without irrigation.

Figure M – OsseoShaper™ 1

4. Proceed to Step D in case the OsseoShaper™ 1 cannot be fully seated. Otherwise proceed to Step F.

Warning Do not apply excessive forces while using the OsseoShaper™ 1 to avoid injuring underlying vital structures.

Caution Do not pull the OsseoShaper™ 1 out from the osteotomy without setting the reverse turning mode to avoid damaging the osteotomy.

Caution Ensure the OsseoShaper™ is fully inserted in the contra-angle. The OsseoShaper™ may become stuck if incorrectly assembled. Using the OsseoShaper™ at speeds greater than 50 rpm may damage your contra-angle, tooling or the bone.

Caution Never exceed insertion torque of 40 Ncm for the OsseoShaper™. Overtightening of the OsseoShaper™ may lead to fracture or necrosis of the bone, to damage the tooling such as contra-angle or drill extension.

Caution The drill unit maximum torque must be set to 40 Ncm. Exceeding 40 Ncm may damage the contra-angle and related tooling.

5. In situations where adjacent natural teeth interfere with the contra-angle head preventing the drill from reaching the desired depth, use the OsseoShaper™ Extension Nobel Biocare N1™.

Caution Exceeding maximum recommended torque might cause the OsseoShaper™ 1 to get stuck in the OsseoShaper™ Extension Nobel Biocare N1.

D. Use the OsseoShaper™ 2

In case it is not possible to fully seat the OsseoShaper™ 1 proceed with the OsseoShaper™ 2.

1. Set the torque limit of the drilling unit at 40 Ncm, the speed at 50 Rpm and no irrigation.

2. Select the OsseoShaper™ 2 length that corresponds to the implant length. The OsseoShaper™ 2 are color coded based on the implant diameter, magenta for implant diameter 3.5 mm, yellow for implant diameter 4.0 mm (Figure N) and blue for implant diameter 4.8 mm.

Figure N – Coding for OsseoShaper™ 2

3. Connect the OsseoShaper™ 2 and insert it to full depth (Figure O), if possible, and remove it from the osteotomy by setting the reverse turning mode on the drill unit.
   - Drill in a forward direction at 50 rpm without irrigation.
   - Allow the OsseoShaper™ 2 to feed in without pressure to the full depth or until it prematurely stops.
   - Drill in a reverse direction at 50 rpm without irrigation.

Figure O – OsseoShaper™ 2

Warning Do not apply excessive forces while using the OsseoShaper™ 2 to avoid injuring underlying vital structures.

4. In situations where adjacent natural teeth interfere with the contra-angle head preventing the drill from reaching the desired depth, the OsseoShaper™ Extension may be used.

5. If the OsseoShaper™ 2 cannot be fully seated proceed to Step E, otherwise proceed to Step F.

Caution Ensure the OsseoShaper™ 2 is fully inserted in the contra-angle. The OsseoShaper 2 may become stuck if incorrectly assembled. Using the OsseoShaper™ 2 at speeds greater than 50 rpm may damage your contra-angle, tooling or the bone.

Caution Never exceed insertion torque of 40 Ncm for the OsseoShaper™. Overtightening of the OsseoShaper™ may lead to fracture or necrosis of the bone, to damage of tooling such as contra- angle or OsseoShaper™ Extension.

Caution The drill unit maximum torque must be set to 40 Ncm. Exceeding 40 Ncm may damage the contra-angle and related tooling.

Caution Exceeding maximum recommended torque might cause the OsseoShaper™ 2 to get stuck in the OsseoShaper™ Extension.

E. Use the Twist Step Drill

The Twist Step Drill needs to be used in cases where the OsseoShaper™ 2 cannot be fully seated at the recommended insertion torque.

1. Set up the drill unit at 2,000 rpm and with irrigation on.
2. Prepare the osteotomy to the planned depth with the Twist Step Drill and then remove it (Figure P).
3. The Twist Step Drill must proceed at high speed (max. 2,000 rpm) under constant and profuse irrigation by sterile saline at room temperature.

Figure P – Twist Step Drill

4. In situations where adjacent natural teeth interfere with the contra-angle head preventing the drill from reaching the desired depth, the OsseoShaper™ Extension may be used.

In the table is reported a summary of the drills that can be used for each implant.

Table 1 – Implant Site Preparation Tooling

Implant	Compatible Components and Dimensions (mm)				
	Osseo Director	**Guided Pilot Drill**	**Osseo Shaper 1**	**Osseo-Shaper™ 2 (Used when Osseo-Shaper™ 1 cannot be fully seated)**	**Twist Step Drill (Used when OsseoShaper™ 2 cannot be fully seated)**
Nobel Biocare N1™ TiUltra™ TCC NP 3.5 x 9 mm	Ø 1.8-2.4 x 8-14 Ø 1.8-2.4 x 8-18	Ø 2.0 x (10+) 8-14 Ø 2.0 x (10+) 8-18	Ø 3.5 x 9	Ø 3.5 x 9	Ø 2.5/3.4 x 10-14 Ø 2.5/3.4 x 10-18
Nobel Biocare N1™ TiUltra™ TCC NP 3.5 x 11 mm			Ø 3.5 x 11	Ø 3.5 x 11	
Nobel Biocare N1™ TiUltra™ TCC NP 3.5 x 13 mm			Ø 3.5 x 13	Ø 3.5 x 13	
Nobel Biocare N1™ TiUltra™ TCC NP 3.5 x 15 mm	Ø 1.8-2.4 x 8-18	Ø 2.0 x (10+) 8-18	Ø 3.5 x 15	Ø 3.5 x 15	Ø 2.5/3.4 x 10-18
Nobel Biocare N1™ TiUltra™ TCC RP 4.0 x 7 mm	Ø 1.8-2.4 x 8-14 Ø 1.8-2.4 x 8-18	Ø 2.0 x (10+) 8-14 Ø 2.0 x (10+) 8-18	Ø 4 x 7	Ø 4 x 7	Ø 3.3/3.8 x 8-14 Ø 3.3/3.8 x 8-18
Nobel Biocare N1™ TiUltra™ TCC RP 4.0 x 9 mm			Ø 4 x 9	Ø 4 x 9	
Nobel Biocare N1™ TiUltra™ TCC RP 4.0 x 11 mm			Ø 4 x 11	Ø 4 x 11	
Nobel Biocare N1™ TiUltra™ TCC RP 4.0 x 13 mm			Ø 4 x 13	Ø 4 x 13	
Nobel Biocare N1™ TiUltra™ TCC RP 4.0 x 15 mm	Ø 1.8-2.4 x 8-18	Ø 2.0 x (10+) 8-18	Ø 4 x 15	Ø 4 x 15	Ø 3.3/3.8 x 8-18
Nobel Biocare N1™ TiUltra™ TCC RP 4.8 x 7 mm	Ø 1.8-2.4 x 8-14 Ø 1.8-2.4 x 8-18	Ø 2.0 x (10+) 8-14 Ø 2.0 x (10+) 8-18	Ø 4.8 x 7	Ø 4.8 x 7	Ø4.2/4.4 x 8-18 mm
Nobel Biocare N1™ TiUltra™ TCC RP 4.8 x 9 mm			Ø 4.8 x 9	Ø 4.8 x 9	
Nobel Biocare N1™ TiUltra™ TCC RP 4.8 x 11 mm			Ø 4.8 x 11	Ø 4.8 x 11	

F. Pick up the implant

1. Turn the white case upside down and remove it as shown in Figure Q, engage the implant from inner titanium case by applying light rotation with Implant Driver until Implant Driver is fully seated into the implant (Figure Q).

Figure Q – pick up of the implant

The Nobel Biocare N1™ Implant Driver is color coded based on the implant platform, magenta for NP and yellow for RP platform, and has three concave surfaces on the body that align with the flat side of the tri-oval implant interface. The depth marks identify the implant depth in relation to bone and soft tissue during its placement. See Figure R.

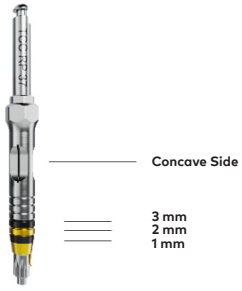

Figure R – Implant Driver marking

G. Insert the implant

1. Ensure the drill unit is set to a maximum torque of 70 Ncm.
2. Insert the implant to a maximum of 70 Ncm using the contra-angle followed by the manual surgical torque wrench for the final seating. Refer to Nobel Biocare Instruction for Use IFU1098 for detailed information on the use of the Manual Torque Wrench.
3. For placing the implant, drill in a forward direction at 25 rpm without irrigation.
4. When placing the implant, visually check that the top of the implant is positioned at crestal level such that one of the flat sides faces buccally in order to maximize the space for the buccal bone volume. Make sure to check correct positioning and correct the orientation if needed. See Figure A.

Caution Never exceed insertion torque of 70 Ncm for the implant. Overtightening an implant may lead to damaging it, fracture or necrosis of the bone site. If a surgical driver is used to insert the implant, special care needs to be taken to avoid overtightening. For immediate loading the implant should withstand a final insertion torque of at least 35 Ncm. If this insertion torque value is not achieved, other loading protocols may be considered in accordance with the indications for use of the device.

If the implant gets stuck during implant installation or maximum insertion torque is achieved before fully seated, rotate the implant counter clockwise using reverse turning mode or Manual Torque Wrench Surgical and remove the implant from site. Replace the implant back into inner casing before proceeding further. Follow the surgical protocol and proceed with the surgical steps before proceeding again with implant insertion.

5. To facilitate the removal of hard tissue around the implant head, Bone Mills are available (Table 2). Refer to Nobel Biocare Instructions For Use IFU1089 for detailed information).

Table 2 – Compatible Bone Mills and Bone Mill Guides

Implant	Bone Mill	Bone Mill Guide
Nobel Biocare N1™ TiUltra™ TCC NP	Bone Mill Nobel Biocare N1™ TCC Ø 4.0	Bone Mill Guide Nobel Biocare N1™ TCC NP Ø 4.0
	Bone Mill Nobel Biocare N1™ TCC Ø 5.2	Bone Mill Guide Nobel Biocare N1™ TCC NP Ø 5.2
Nobel Biocare N1™ TiUltra TCC RP	Bone Mill Nobel Biocare N1™ TCC Ø 5.2	Bone Mill Guide Nobel Biocare N1™ TCC RP Ø 5.2

H. Place Cover Screw or Abutment

1. Depending on the surgical protocol of choice, place a cover screw or abutment and suture. Refer to Nobel Biocare Instructions For Use IFU1016 for detailed information on the cover screws.

Caution Tighten the cover screw only finger-tight to avoid excessive loads that might damage the cover screw parts.

For more information on prosthetic procedures refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

Implant, Abutment, and Abutment Screw Retrieval Instruments

Should the removal of an implant, abutment or abutment screw be required refer to Nobel Biocare Instructions for Use IFU1097 Implant Retrieval Instruments, IFU1043 Abutment Screw Retrieval Instruments, IFU1096 Abutment Retrieval Instrument.

Table 3 – Compatible Retrieval instruments with Nobel Biocare N1™ TiUltra implants

Implant	Retrieval instruments
Nobel Biocare N1™ TiUltra TCC NP	Implant Retrieval Instrument CC 3.0 & TCC NP Trephine drill 3.8/4.6 mm Screw Tap Repair Tool Nobel Biocare N1™ TCC NP Rescue Drill Guide Nobel Biocare N1™ TCC NP
Nobel Biocare N1™ TiUltra TCC RP	Implant Retrieval Instrument CC RP & Tri-Ch WP & TCC RP Trephine drill 4.4/5.2 mm Screw Tap Repair Tool Nobel Biocare N1™ TCC RP Rescue Drill Guide Nobel Biocare N1™ TCC RP

Sterility and Reusability Information

Nobel Biocare N1™ TiUltra™ TCC implants, Cover Screw Nobel Biocare N1™, OsseoShaper™ 1 and 2, OsseoDirector™ Nobel Biocare N1™, Guided Pilot Drill Nobel Biocare N1™, Twist Step Drill have been sterilized using irradiation and are intended for single use. 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 Nobel Biocare N1™ TiUltra™ TCC implants, Cover Screw Nobel Biocare N1™, OsseoShaper™ 1 and 2, OsseoDirector™ Nobel Biocare N1™, Guided Pilot Drill Nobel Biocare N1™, Twist Step Drill 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.

The Implant Driver Nobel Biocare N1™ TCC, OsseoShaper™ Extension Nobel Biocare N1™, Direction Indicator Nobel Biocare N1™ and Depth Probe Nobel Biocare N1™ are delivered non-sterile and are intended for reuse. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Before each use, inspect the devices for signs of degradation that may limit the useful life of the device, such as the following:

Implant Driver

- Inspect for visible corrosion.
- Inspect for mechanical wear/damage to driver sleeve and tip.
- Ensure that laser marking of device is clearly legible.

OsseoShaper™ Extension

- Inspect for visible corrosion.
- Inspect for mechanical wear/damage between drill/ OsseoShaper™ and OsseoShaper™ Extension/handpiece assembly.
- Ensure that laser marking of device is clearly legible.

Direction Indicator, Depth Probe

- Inspect for visible corrosion.
- Ensure that depth marking of device is clearly legible.

Dispose of the devices if any of these signs of degradation are evident.

Note Implant Driver Nobel Biocare N1™ TCC, OsseoShaper™ Extension Nobel Biocare N1™, Direction Indicator Nobel Biocare N1™ and Depth Probe Nobel Biocare N1™ can be processed as individual devices as described in the Cleaning and Sterilization Instructions below, or together with other devices in a PureSet tray following the cleaning and sterilization instructions in Nobel Biocare Instructions for Use (IFU) IFU1067. This IFU is available in ifu.nobelbiocare.com.

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
CE Mark for Class Ir/IIa/IIb Devices	CE 2797
UKCA Mark for Class I Devices	UKCA
UKCA Mark for Class IIa/IIb Devices	UKCA 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
Nobel Biocare N1™ TiUltra™ TCC	73327470000002126T
OsseoDirector Nobel Biocare N1™	7332747000001206M
Guided Pilot Drill Nobel Biocare N1™	7332747000001206M
Twist Step Drill	7332747000001206M
OsseoShapers Nobel Biocare N1™	7332747000001206M
Implant Driver Nobel Biocare N1™	7332747000001597G
OsseoShaper Extension Nobel Biocare N1™	7332747000001226R
Depth Probe Nobel Biocare N1™	7332747000001606Z
Direction Indicator Nobel Biocare N1™	733274700000016377

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.