Nobel Biocare N1™ TiUltra™ TCC System

Instructions for use

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 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 Table 1 for the compatible cover screw and implant driver for each implant. 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 N1™ TiUltra TCC implants are compatible with Nobel Biocare abutments which feature the trioval conical connection (TCC). Refer to Table 2 for the complete list of compatible abutments, as well as the reference to the respective Nobel Biocare IFU which contains additional information regarding the abutment.

Table 1: Implant Compatibility Table

Implant	Implant Driver	Cover Screw
Nobel Biocare N1™ TiUltra™ TCC NP 3.5x9 mm	Implant Driver Nobel Biocare N1™ TCC NP	Cover Screw Nobel Biocare N1™ TCC NP (IFU1016)
Nobel Biocare N1™ TiUltra™ TCC NP 3.5x11 mm		
Nobel Biocare N1™ TiUltra™ TCC NP 3.5x13 mm		
Nobel Biocare N1™ TiUltra™ TCC RP 4.0x7 mm	Implant Driver Nobel Biocare N1™ TCC RP	Cover Screw Nobel Biocare N1™ TCC RP (IFU1016)
Nobel Biocare N1™ TiUltra™ TCC RP 4.0x9 mm		
Nobel Biocare N1™ TiUltra™ TCC RP 4.0x11 mm		
Nobel Biocare N1™ TiUltra™ TCC RP 4.0x13 mm		

Table 2: Compatible Abutment Systems and Impression Copings

Implant System	Abutment System and Impression Copings
Nobel Biocare N1™ TiUltra™ TCC NP	Healing Abutment Nobel Biocare N1™ TCC NP (IFU1094)
	Temporary Abutment Nobel Biocare N1™ TCC NP (IFU1093)
	Universal Abutment Nobel Biocare N1™ TCC NP (IFU1023)
	Impression Cop Open Tray Nobel Biocare N1™ TCC NP (IFU1086)
	Impression Cop Closed Tray Nobel Biocare N1™ TCC NP (IFU1086)
	Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC NP (IFU1075)
	17° Multi-unit Abut Xeal™ Nobel Biocare N1™ TCC NP (IFU1075)
Nobel Biocare N1™ TiUltra™ TCC RP	Healing Abutment Nobel Biocare N1™ TCC RP (IFU1094)
	Temporary Abutment Nobel Biocare N1™ TCC RP (IFU1093)
	Universal Abutment Nobel Biocare N1™ TCC RP (IFU1023
	Impression Cop Open Tray Nobel Biocare N1™ TCC RP (IFU1086)
	Impression Cop Closed Tray Nobel Biocare N1™ TCC RP (IFU1086)
	Multi-unit Abutment Xeal™ Nobel Biocare N1™ TCC RP (IFU1075)
	17° Multi-unit Abut Xeal™ Nobel Biocare N1™ TCC RP (IFU1075)
	30° Multi-unit Abut Xeal™ Nobel Biocare N1™ TCC RP (IFU1075)

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, and yellow for implant diameter 4.0 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 OsseoShapers, Implant Drivers, OsseoDirectors, 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, the Guided Pilot Drill or the OsseoShapers.
- 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 OsseoShapers. The Depth Probe has depth markings at both ends of 8, 10, 12, 14 mm representing the actual drill length.

* Class IIb device; **Class IIa device; ***Class Ir device. See last page of IFU for applicable CE Mark.

Intended Use:

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 to be used for the insertion and removal of endosseous 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, OsseoShaper or Implant Driver 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 OsseoDirector, Guided Pilot Drill and OsseoShapers 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 OsseoShapers 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" on page 5.

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

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.

It is strongly recommended that Nobel Biocare N1™ implants, implant site preparation tooling and instruments are used only with compatible Nobel Biocare instruments and components and prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Nobel Biocare N1™ 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 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. a throat shield).

Where applicable regular platforms (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, Cover Screws Nobel Biocare N1™ TCC, and Nobel Biocare N1™ TiUltra TCC system instruments are to be used by dental health care professionals.

Nobel Biocare N1™ TiUltra TCC Implants, Cover Screws Nobel Biocare N1™ TCC, and Nobel Biocare N1™ TiUltra TCC system instruments are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Nobel Biocare N1™ TiUltra TCC Implants, Cover Screws Nobel Biocare N1™ TCC, and the Nobel Biocare N1™ TiUltra TCC System Instruments:
Nobel Biocare N1™ TiUltra TCC implants, Cover Screw Nobel Biocare N1™ TCC, 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, Cover Screws Nobel Biocare N1™ TCC, 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. Drilling into the jaw or subsequent placement of the implant may also lead (in rare cases) to fenestration or fracture of bone, perforation of neighboring structures, sinusitis, or sensory/motor disturbances, depending on the location. 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.

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
https://www.nobelbiocare.com/complaint-form

Surgical and Handling Procedures:

General Guidance Regarding Placement of the Nobel Biocare N1™ TiUltra™ TCC Implant:
Nobel Biocare N1™ TiUltra™ TCC implants are available in four lengths for the RP platform, and three lengths for NP platform. Refer to Table 1 for the complete list of available implants.

The implant must 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 2 mm.

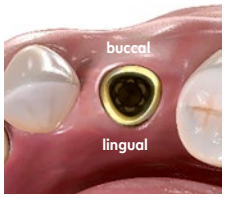

Figure A: Implant Position

Depth Marking on the OsseoDirector, Twist Step Drills, and OsseoShapers:
The OsseoDirector and Twist Step Drills have a depth measurement system which as shown in Figure B, correlates to the implant length.

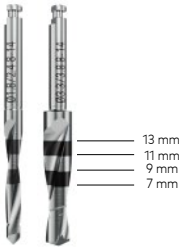

Figure B: Depth Marking on OsseoDirectors, Guided Pilot Drills, and Twist Step Drills

Each implant has a corresponding OsseoShaper 1 and OsseoShaper 2, which matches the implant length. The black markings on the OsseoShapers (see Figure C) indicate the insertion depth can be used 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, and yellow for 4.0 mm implants.

Figure C: Depth Marking on OsseoShaper 1 and OsseoShaper 2

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 (see Figure D for drill reference lines).

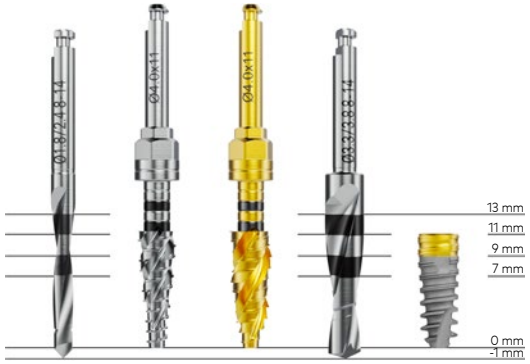

Figure D: Drill Depth Marking (Example for 4.0 x 11 mm Implant)

Surgical Protocol:

The osteotomy is created using either the OsseoDirector or Guided Pilot Drill, and OsseoShapers. OsseoShapers are threaded devices that are inserted and removed at low speed without irrigation. They allow to replace the usual drills used for the creation of the osteotomy. Below is a pictorial representation of the surgical protocol. For the detailed surgical procedure see section "Surgical Steps".

To achieve correct implant seating ensure the illustrated protocol is followed.

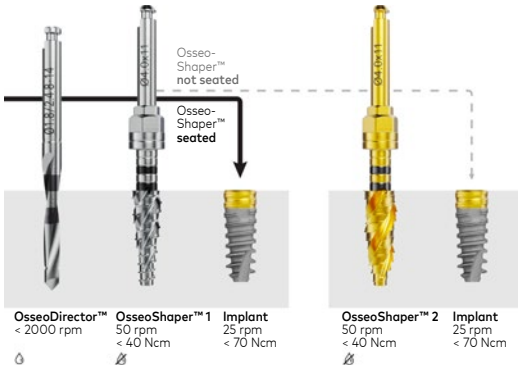

Figure E: Surgical protocol

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:

1. Prepare pilot osteotomy with the OsseoDirector (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 applicable depth mark 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 D for drill reference lines).

2. In situations where adjacent natural teeth interfere with the contra-angle head preventing the drill from reaching the desired depth, use the OsseoShaper Extension.
3. When using a flapless approach add-on soft tissue height to drill depth.
4. The Depth Probe can be used to check the depth of the osteotomy after using the OsseoDirector or Guided Pilot Drill.

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.

5. In order to check the orientation of the osteotomy, use the Direction Indicator. The Direction Indicator has two sides (see Figure H); 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.

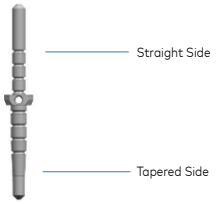

Figure H: Direction Indicator

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

C. Use the OsseoShaper 1: The OsseoShaper 1 is delivered co-packed with the respective implant (see Figure I).

Figure I: Co-packing of OsseoShaper 1 with Implant

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

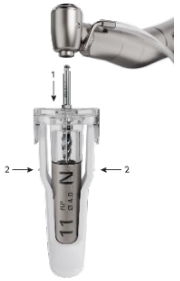

Figure J: OsseoShaper 1 Nobel Biocare N1™ Engagement

Figure K: OsseoShaper 1 Nobel Biocare N1™ Extraction

2. 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.

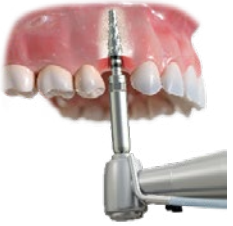

Figure L: OsseoShaper 1

3. 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 OsseoShapers. Overtorquing 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.

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

Caution: Exceeding maximum recommended torque might cause the OsseoShaper 1 to get stuck in the OsseoShaper Extension.

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

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

Figure M: Color Coding for OsseoShapers 2

2. Connect the OsseoShaper 2 and insert it to full depth (Figure N), 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 N: OsseoShaper 2

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

3. 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

4. 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. Overtorquing 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. Prepare the osteotomy to the planned depth with the Twist Step Drill and then remove it (Figure O).

2. 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 O: Twist Step Drill

3. 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.

Table 3: Implant Site Preparation Tooling

Implant	Compatible Components and Dimensions (mm)				
	Osseo Director	**Guided Pilot Drill**	**Osseo Shaper 1**	**OsseoShaper 2 (Used when OsseoShaper 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 2.0 x (10+) 8-14	Ø 3.5 x 9	Ø 3.5 x 9	Ø 2.5/3.4 x 10-14
Nobel Biocare N1™ TiUltra™ TCC NP 3.5 x 11 mm			Ø 3.5 x 11	Ø 3.5 x 11	Ø 2.5/3.4 x 10-14
Nobel Biocare N1™ TiUltra™ TCC NP 3.5 x 13 mm			Ø 3.5 x 13	Ø 3.5 x 13	Ø 2.5/3.4 x 10-14
Nobel Biocare N1™ TiUltra™ TCC RP 4.0 x 7 mm			Ø 4 x 7	Ø 4 x 7	Ø 3.3/3.8 x 8-14
Nobel Biocare N1™ TiUltra™ TCC RP 4.0 x 9 mm			Ø 4 x 9	Ø 4 x 9	Ø 3.3/3.8 x 8-14
Nobel Biocare N1™ TiUltra™ TCC RP 4.0 x 11 mm			Ø 4 x 11	Ø 4 x 11	Ø 3.3/3.8 x 8-14
Nobel Biocare N1™ TiUltra™ TCC RP 4.0 x 13 mm			Ø 4 x 13	Ø 4 x 13	Ø 3.3/3.8 x 8-14

F. Pick up the implant:

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

Figure P: Pick up of the implant

2. 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 Q.

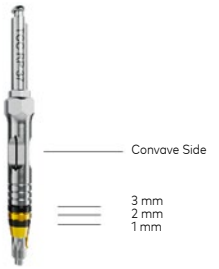

Figure Q: Implant Driver Marking

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 4, refer to Nobel Biocare Instructions For Use IFU1089 for detailed information).

Table 4: 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 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 IFU1094, IFU1093, IFU1023, IFU1088, IFU1086, IFU1075 for the TCC abutment or base.

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.

In the table below the compatible retrieval instrumentation with Nobel Biocare N1™ TiUltra TCC.

Table 5: Compatible Retrieval Instrumentation

Implant	Bone Mill Guide
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

Materials:

- Implant: Commercially pure titanium (grade 4), sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$) (ASTM F67).
- Cover Screw: Titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium) and DLC (Diamond Like Carbon) coating (ASTM F136 and ISO 5832-3).
- OsseoShapers: Titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium) (ASTM F136 and ISO 5832-3).
- OsseoDirector, and Twist Step Drill: Stainless steel (ASTM A899 and ISO 15608, ASTM A895).
- Guided Pilot Drill: Stainless steel and DLC coating (ASTM A899 and ISO 15608, ASTM A895).
- Implant driver: Titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium) and stainless steel (ASTM F899, ASTM F136 and ISO 5832-3).
- OsseoShaper Extension: Stainless steel (ASTM F899).
- Depth Probe: Stainless steel (ASTM F899).
- Direction indicator: Stainless steel (ASTM F899).

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.

The Implant Driver Nobel Biocare N1™ TCC, OsseoShaper Extension Nobel Biocare N1™, Direction Indicator Nobel Biocare N1™ and Depth Probe Nobel Biocare N1™ are reusable instruments. 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.

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

Warning: Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

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 on ifu.nobelbiocare.com.

Cleaning and Sterilization Instructions:

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 by Nobel Biocare and are intended for reuse. Prior to each use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12.
- Sterilization: AAMI ST79 and ISO 17665-1.

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note: The manufacturer's instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note: The Implant Driver Nobel Biocare N1™ TCC, OsseoShaper Extension Nobel Biocare N1™, Direction Indicator Nobel Biocare N1™ and Depth Probe Nobel Biocare N1™ have been validated to withstand these cleaning and sterilization procedures.

Initial Treatment at Point of Use Prior to Reprocessing:

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.
3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Note: Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning):

Pre-cleaning:

1. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
2. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe. For the Osseoshaper Extension repeat this step three times.
3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 30 seconds until all visible soil is removed.
4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 60 seconds until all visible soil is removed.
5. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with lukewarm tap water for a minimum of 30 seconds to remove all cleaning solution.
6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying:

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note: It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying:

1. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 30 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP and Neodisher Medizym; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
4. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 30 seconds until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 30 seconds to remove all cleaning solution.
6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP and Neodisher Medizym) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/ maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
8. Thoroughly rinse the outer surfaces of the devices with purified or sterile water for a minimum of 30 seconds to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly dispose any devices that fail the inspection.

Sterilization:

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 and Selectomat PL/669-2 CL (pre-vacuum cycle); Amsco Century Sterilizer and Selectomat PL/669-2CL* (gravity cycle).

* The Selectomat PL/669-2CL was used only during cleaning process validation for the Osseoshaper Extension.

Note: It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

1. Seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - EN ISO 11607 and/or DIN 58953-7.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 3 presents examples of suitable sterilization containers, pouches, and wraps.

Table 3: Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch Steriking pouch (Wipak)
Pre-vacuum Cycle	SteriCLIN® pouch Steriking pouch (Wipak)

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 4):

Table 4: Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar[4]
Pre-Vacuum Cycle[1]	132°C (270°F)	4 minutes		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

[1] Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

[2] Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

[3] Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.

[4] Saturated steam pressure at 132°C as per required by EN ISO 17665-2.

[5] Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note: Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance:

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/Shipping to Point of Use:

The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Magnetic Resonance (MR) Safety Information:

The Nobel Biocare N1™ TiUltra™ TCC and Cover Screw Nobel Biocare N1™ contain metallic materials which can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that the Nobel Biocare N1™ TiUltra™ TCC and Cover Screw Nobel Biocare N1™ are unlikely to impact patient safety under the following MRI conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

Note: Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Under the conditions defined above, these devices are expected to produce a maximum temperature rise of 4.1°C (39.4°F) after 15 minutes of continuous scanning.

In the non-clinical testing, the image artifact caused by the devices extends approximately 30 mm from the devices when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Note: Although the non-clinical testing demonstrates that the Nobel Biocare N1™ TiUltra™ TCC and Cover Screw Nobel Biocare N1™ are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to support a claim of MR Safe or MR Conditional for the Nobel Biocare N1™ TiUltra™ TCC and Cover Screw Nobel Biocare N1™.

Performance Requirements and Limitations:

To achieve the desired performance, Nobel Biocare N1™ TiUltra™ TCC, Cover Screw Nobel Biocare N1™, OsseoShaper 1 and 2, OsseoDirector Nobel Biocare N1™, Guided Pilot Drill Nobel Biocare N1™, Twist Step Drill, Implant Driver Nobel Biocare N1™ TCC, OsseoShaper Extension Nobel Biocare N1™, Direction Indicator Nobel Biocare N1™ and Depth Probe Nobel Biocare N1™ 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 Nobel Biocare N1™ TiUltra™ TCC, Cover Screw Nobel Biocare N1™, OsseoShaper 1 and 2, OsseoDirector Nobel Biocare N1™, Guided Pilot Drill Nobel Biocare N1™, Twist Step Drill, Implant Driver Nobel Biocare N1™ TCC, OsseoShaper Extension Nobel Biocare N1™, Direction Indicator Nobel Biocare N1™ and Depth Probe Nobel Biocare N1™ , 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:
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CE 2797
CE Mark for Class Ir, IIa, IIb Devices

Notice Regarding Canadian Device Licensure: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Product	Basic UDI-DI Number
Nobel Biocare N1™ TiUltra™ TCC	7332747000002126T
Cover Screw Nobel Biocare N1™ TCC	7332747000002116R
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

Implant Card:

Nobel Biocare N1™ TiUltra™ TCC is accompanied by an Implant Card which contains important information for patients regarding the device.

Complete the Implant Card by filling it out with the patient- and device-specific information as indicated and provide the completed Implant Card to the patient.

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

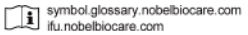
Rx Only

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

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