Titanium Abutment Blank Nobel Biocare N1™ TCC

Important – Disclaimer of Liability

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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

The Titanium Abutment Blank Nobel Biocare N1™ is an individualized dental implant abutment directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitation. It is designed and made individually to fit the requirements for each patient.

It has a pre-fabricated original connection for the Nobel Biocare N1™ TCC TiUltra™ implants. It is available for NP and RP implant platforms.

The Titanium Abutment Blank Nobel Biocare N1™ is delivered copacked with the clinical screw. For detailed information on the clinical screw refer to Instruction for Use IFU1057.

The Titianium Abutment Blank Nobel Biocare N1™ is milled using DESS® dental holders.

Titanium Abutment Blank	Clinical Screw	Laboratory components	Screwdriver	Tightening Torque
Titanium Abutment Blank Nobel Biocare N1™ TCC NP Ø 10 mm	Clinical Screw Nobel Biocare N1™ TCC NP	Lab Screw Nobel Biocare N1™ TCC NP	Omnigrip™ Mini	20 Ncm
		Implant Replica Nobel Biocare N1™ TCC NP		
		IOS Implant Replica Nobel Biocare N1™ TCC NP		
Titanium Abutment Blank Nobel Biocare N1™ TCC RP Ø 10 mm	Clinical Screw Nobel Biocare N1™ TCC RP	Lab Screw Nobel Biocare N1™ TCC RP	Omnigrip™ Mini	20 Ncm
		Implant Replica Nobel Biocare N1™ TCC RP		
		IOS Implant Replica Nobel Biocare N1™ TCC RP		

Table 1 – Titanium Abutment Blank Nobel Biocare N1™, compatible components and tightening torque

Intended Use / Intended Purpose

Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.

Indications

Titanium Abutment Blank Nobel Biocare N1™ TCC is a pre-manufactured prosthetic component directly connected to an endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation for single units and multiple units of up to three units.

Contraindications

It is contraindicated to use Titanium Abutment Blank Nobel Biocare N1™ TCC in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium), DLC (Diamond Like Carbon) coating.
- Patients with parafunctional tendencies such as bruxism and clenching.

It is contraindicated to use clinical screws that are not intended to be used in combination with the Titanium Abutment Blank Nobel Biocare N1™ TCC.

The Titanium Abutment Blank Nobel Biocare N1™ TCC is contraindicated for angulations, lengths, margin heights and wall thickness that do not fall within the indicated dimensions limit as stated in the Tables 2 and 3.

For contraindications specific to the Implant and restorative components, refer to the Nobel Biocare Instructions for Use IFU1087 and IFU1057, refer to IFU1085 for more information on the Omnigrip™ Mini Screwdriver.

Cautions

General

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

Titanium Abutment Blank Nobel Biocare N1™ TCC must only be used with compatible Nobel Biocare instruments and screws. Use of instruments and screws that are not intended to be used in combination with Titanium Abutment Blank Nobel Biocare N1™ TCC 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 strongly recommended that clinicians, new as well as experienced users of implants, prosthetics and associated software, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

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.

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.

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

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism, 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 laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other component.

At Surgery

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. dental dam, gauze or a throat shield).

After the implant installation, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

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

The Titanium Abutment Blank Nobel Biocare N1™ TCC is intended to be used by dental health care professionals.

The Titanium Abutment Blank Nobel Biocare N1™ TCC is to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Titanium Abutment Blank Nobel Biocare N1™ TCC

Titanium Abutment Blank Nobel Biocare N1™ TCC is a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with Titanium Abutment Blank Nobel Biocare N1™ TCC

The placement of this device is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, swelling. During abutment placement or removal, the pharyngeal reflect (gag reflex) may be triggered in patients with a sensitive gag reflex.

Implant abutments are part 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 retained cement, calculus, mucositis, ulcers, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the Titanium Abutment Blank Nobel Biocare N1™. 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

Handling Procedure

Clinical/Laboratory Procedure – CAD/CAM Scan of Conventional Impression

Take conventional impression (clinical procedure)

1. Take an impression according to standard clinical procedures for restorative operations and send it to your dental laboratory.

Fabricate master model (laboratory procedure)

2. Fabricate a working "master" model with base replicas and removable gingival material following conventional laboratory procedures. Ensure that all components are clean and undamaged.

Obtain CAD/CAM scan of master model (laboratory procedure)

3. Before mounting the Position Locator Nobel Biocare N1™ TCC onto the working "master" model, ensure that it is clean and undamaged. Discard the position locator if it is deformed or if there are any scratches on the scan surface, as this can affect the accuracy of the scan.

4. Assemble the required amount of Position Locator Nobel Biocare N1™ TCC onto the working "master" model and visually confirm the fit to the replicas. Avoid any contact of the position locators to the interproximal teeth. Refer to Nobel Biocare IFU1091 and IFU1087 for information regarding position locators and Nobel Biocare N1™ implants.

5. Perform the scan with a dental scanner by following the scan process provided by the manufacturer.

6. Export/send the scan file to the dental CAD/CAM software.

Clinical Procedure – CAD/CAM Scan of Patient Mouth

1. Before mounting the position locators into the patient mouth ensure that all components are clean and in an undamaged condition, check and discard if any scratches on the scan surface or any other deformation.

2. Assemble the required amount of position locators onto the implant in the patient mouth and confirm the fit. Avoid any contact of the position locators to the interproximal teeth. Refer to Nobel Biocare IFU1091 and IFU1087 for information regarding position locators and Nobel Biocare N1™ implants.

3. Perform the scan procedure with a dental intra oral scanner following the scan process provided by the manufacturer.

4. Export/send the scan file(s) to the dental CAD/CAM software.

Design the prosthetic restoration

1. Import the scan file(s) into the CAD/CAM software.

2. Open the relevant CAD module and design your restoration in accordance with indications for use, following the instructions in the software tutorial and according to the patient's clinical needs.

3. The following design constraints must be followed:

Restoration type	Min screw channel thickness (mm)	Max abutment height from implant level (mm)	Minimum post height (mm)
Titanium Abutment Blank Nobel Biocare N1™ TCC NP	0.38	16	4.05
Titanium Abutment Blank Nobel Biocare N1™ TCC RP	0.49	16	4.05

Table 2 – Design constraints

The maximum margin height at 30 degree angulation is 4.6 mm.

Maximum margin height (mm)	Max abutment angulation
4.6	30°

Table 3 – Design constraints – Angulation

Milling the designed abutment

1. Place the pre-milled abutment blank into the compatible DESS® blank holder.
2. Mill the designed abutment with an appropriate milling machine and tools taking into account the design constraints in Table 2 and 3.
3. The milling machine and holder manufacturer's specific instruction for use should be considered.
4. Inspect the abutment implant connection and surface of the milled abutment for any damage that may have occurred during the milling process.
5. Clean the milled abutment with steam jet to remove any residuals.
6. Check fit of restoration on model and if adjustment of the milled abutment is needed, connect it to the implant replica using the laboratory screw.

Caution Do not modify or sandblast the seating area.

7. If applicable, fabricate a crown or bridge with CAD/CAM technique or with conventional technique.
8. Send the milled abutment(s) and if applicable the crown/bridge to the clinician.

Clinical procedure

1. Clean and sterilize the device as per cleaning and sterilization instructions.
2. Remove the cover screw or temporary restoration from the implant if applicable. Refer to Nobel Biocare Instructions for Use IFU1016, IFU1093 or IFU1094 for more information on the cover screw or temporary restorations.
3. Place the sterilized abutment in the patient's mouth onto the Nobel Biocare N1™ TCC implant.

It is recommended to verify the final abutment seating using radiographing imaging.

Note If any modification is necessary, use sterilized instruments in a controlled surgical environment using aseptic technique. Don't modify the restoration intraorally.

4. Screw the abutment to the implant using the Clinical Screw Nobel Biocare N1™ and the Omnigrip™ Mini Screwdriver.

Note Tightening torque Clinical Screw Nobel Biocare N1™: 20 Ncm.

Caution When tightening the abutment to the implant make sure to use the Clinical Screw Nobel Biocare N1™ TCC and not the laboratory screw.

Caution Do not exceed 20 Ncm when tightening the abutment to the implant. Overtightening of abutment may lead to a screw fracture and/or damage of the abutment.

5. Seat the restoration on the abutment and check the occlusion and the interproximal contacts.
6. After sealing of access hole, cement the final crown or framework using conventional procedures (e.g. using Teflon and composite) according to the manufacturer's instructions. Make sure there is no excess cement.

In case the abutment or the screw need to be removed consider the use of the Abutment Retrieval Tool Nobel Biocare N1™ described in Instruction for Use IFU1096 and the abutment screw removal instrumentation described in Instructions for Use IFU1043.

Materials

- Titanium Abutment Blank Nobel Biocare N1™ TCC: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- Clinical screw: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.

Sterility and Reusability Information

Caution Titanium Abutment Blank Nobel Biocare N1™ TCC and Clinical Screw Nobel Biocare N1™ are delivered non-sterile and are intended for single use only. 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.

Caution Titanium Abutment Blank Nobel Biocare N1™ TCC and Clinical Screw Nobel Biocare N1™ are for single use and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

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

Cleaning and Sterilization Instructions

Titanium Abutment Blank Nobel Biocare N1™ TCC and Clinical screw Nobel Biocare N1™ are delivered non-sterile by Nobel Biocare and is intended for single use. Prior to 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 Titanium Abutment Blank Nobel Biocare N1™ TCC and Clinical screw have been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following instructions.

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. Repeat this step until the lumens are free of any visually datable soil.
3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 1 minute 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 1 minute.
5. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 1 minute 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 of 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum of 10 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5% alkaline detergent (e.g. Neodisher Mediclean forte).
   - Draining.
   - Minimum of 3 minutes neutralization with 0.1% acidic neutralizing agent (e.g. neodisher Z).
   - Draining.
   - Minimum of 2 minutes rinsing with cold deionized water.
   - Draining.
4. Run drying cycle at a minimum of 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 the 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 1 minute until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm enzymatic cleaning solution (e.g. Neodisher Medizym) using an irrigation needle connected to a 20 ml syringe.
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 1 minute 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 1 minute to remove all cleaning solution.
6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute 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 discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Selectomat PL/666-1CL (pre-vacuum cycle); Selectomat PL/666-1CL (gravity cycle).

Note It is recommended to perform sterilization with a maximum load of 1 container with 8.6 kg of metal and 2 packages of linen.

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 4 presents examples of suitable sterilization pouches.

Method	Recommended Sterilization Pouch
Gravity Cycle	Steriking pouch (Wipak)
Pre-vacuum Cycle	Steriking pouch (Wipak)

Table 4 – Recommended Sterilization Pouches

2. Label the sterilization pouch with the information necessary to identify the device (e.g. 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 5):

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		

Table 5 – Recommended Sterilization Cycles

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 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 processed 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

MR Safety Information for Single Tooth Restoration and Multiple unit Restoration (up to three units)

MRI Safety Information		
Non-clinical testing has demonstrated the Titanium Abutment Blank Nobel Biocare N1™ TCC is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient.		
Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T)
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 58.9 T/m (5,890 G/cm).	
RF Excitation	Circularly Polarized (CP).	
RF Transmit Coil Type	Whole body transmit coil.	
Maximum Whole-Body SAR [W/kg]	Inferior to the neck: 2.0 W/kg Superior to the neck: 0.5 W/kg	Inferior to the xyphoid: 2.0 W/kg Between the xyphoid and neck: 1.0 W/kg Superior to the neck: 0.5 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0°C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 3 T MRI system.	

Performance Requirements and Limitations

To achieve the desired performance, Titanium Abutment Blank Nobel Biocare N1™ TCC 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 Titanium Abutment Blank Nobel Biocare N1™ TCC, 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 1 411 17 Göteborg 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 Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class IIb Devices	CE 2797
UKCA Mark for Class IIb Devices	UK CA 0086

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

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

Product	Basic UDI-DI Number
Titanium Abutment Blank Nobel Biocare N1™ TCC NP Ø 10 mm	733274700000021775
Titanium Abutment Blank Nobel Biocare N1™ TCC RP Ø 10 mm	

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 / European Union	UK Responsible Person	Authorised Representative in Switzerland	Sterilized using Ethylene Oxide	Sterilized using irradiation	Sterilized using steam or dry heat		
							
Batch code	Catalogue number	Unique Device Identifier	Serial number	Medical device	Magnetic resonance safe		
							
Caution	Magnetic resonance conditional	Non-sterile	Contains hazardous substances	Contains or presence of DEHP phthalate	Contains or presence of natural rubber latex	Contains or presence of phthalate	Contains biological material of animal origin
					Rx only	 symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com	
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	Link to Online Symbols Glossary and IFU Portal	
							
Date of manufacture	Manufacturer	Use-by date	Upper limit of temperature	Temperature limit	Do not resterilize	Do not re-use	Non-pyrogenic
							
Date	Tooth number	Patient number	Patient identification	Health care centre or doctor	Patient information website	EU Importer	Swiss Importer
Double sterile barrier system	Single sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside	Do not use if package is damaged and consult instructions for use	Keep away from sunlight	Keep dry	