NobelProcera® Zirconia Abutment/ Implant crown N1™ Base

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Description

The NobelProcera® Zirconia NB N1™ Base is a pre-manufactured, patient specific CAD/CAM dental prosthesis which is connected to the Nobel Biocare N1™ Base Xeal™ TCC Tri and is intended for use as an aid in prosthetic rehabilitation to restore chewing function and esthetic appearance.

The NobelProcera® Zirconia NB N1™ Base enables two restorative solutions. It can be designed as: NobelProcera® Zirconia Abutment NB N1™ Base, which requires a finalization in a dental laboratory or NobelProcera® Zirconia Implant Crown NB N1™ Base, which may be further finalized in a dental laboratory. Both solutions have an angulated screw channel.

Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base is a premanufactured prosthetic screw used to fasten NobelProcera® Zirconia Abutment NB N1™ Base or NobelProcera® Zirconia Implant Crown NB N1™ Base to the Nobel Biocare N1™ Base.

In Table 1 and Table 2 is listed the compatibility of NobelProcera® Zirconia N1™ Base with the different components.

Restoration Type	Prosthetic Screw	Screwdriver	Nobel Biocare N1™ Base Xeal™ TCC Tri
NobelProcera® Zirconia Abutment / Implant Crown NB N1™ Base NP	Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base NP	Omnigrip™ Mini	Nobel Biocare N1™ Base Xeal™ TCC Tri NP
NobelProcera® Zirconia Abutment / Implant Crown NB N1™ Base RP	Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base RP		Nobel Biocare N1™ Base Xeal™ TCC Tri RP

Table 1 – Compatibility NobelProcera® Zirconia NB N1™ Base – Prosthetic screw – Nobel Biocare N1™ Base Xeal TCC Tri

Restoration Type	Laboratory Screw	Base Replica Nobel Biocare N1™ Base	IOS Base Replica Nobel Biocare N1™ Base
NobelProcera® Zirconia Abutment / Implant Crown NB N1™ Base NP	Lab Screw NobelProcera® Zirconia Nobel Biocare N1™ Base NP	Base Replica Nobel Biocare N1™ Base Tri NP	IOS Base Replica Nobel Biocare N1™ Base Tri NP
NobelProcera® Zirconia Abutment / Implant Crown NB N1™ Base RP	Lab Screw NobelProcera® Zirconia Nobel Biocare N1™ Base RP	Base Replica Nobel Biocare N1™ Base Tri RP	IOS Base Replica Nobel Biocare N1™ Base Tri RP

Table 2 – Restoration Type Laboratory Screw - Base Replica Nobel Biocare N1™ Base IOS Base Replica Nobel Biocare N1™ Base

Intended Use / Intended Purpose

NobelProcera® Zirconia N1™ Base

Intended to be finalized into a single-unit dental prosthesis, which is connected to an endosseous dental implant to restore chewing function.

Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base

Intended for use to fasten dental implant system components to a dental implant or to another component.

Indications

The NobelProcera® Zirconia NB N1™ Base is a premanufactured prosthetic component directly connected to an endosseous dental implant abutment and is indicated for use as an aid in prosthetic rehabilitation.

The Prosthetic Screw NobelProcera® Zirconia NB N1™ Base is indicated for use to secure the implant crown/abutment to a dental abutment or base in the maxilla or mandible for supporting tooth replacements to restore chewing function.

Contraindications

It is contraindicated to use the NobelProcera® Zirconia NB N1™ Base and Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients with bruxism and clenching.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to zirconia (Y-TZP) or titanium alloy 90% Ti, 6% Al, 4% V, or DLC (Diamond Like Carbon) coating.

The NobelProcera® Zirconia NB N1™ Base NP is contraindicated for use in posterior positions of the maxilla and mandible.

The NobelProcera® Zirconia NB N1™ Base is contraindicated for angulations, lengths and thickness that do not fall within the indicated dimensions limit as stated in Table 3 and Table 4.

For contraindications specific to the implant or restorative component, refer to the Nobel Biocare Instructions for Use IFU1087 and IFU1088 or 3rd party manufacturer's Instructions for Use for the component.

It is contraindicated to use instruments and prosthetic components that are not intended to be used in combination with NobelProcera® Zirconia NB N1™ Base.

Materials

- NobelProcera® Zirconia NB N1™ Base: Nacera® Pearl (Yttria-stabilized zirconia polycrystal (Y-TZP), according to ISO 13356.
- Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base: Titanium vanadium alloy (90% Ti, 6% Al, 4% V) and DLC (Diamond Like Carbon) coating.

Cautions

General

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

NobelProcera® Zirconia NB N1™ Base and Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ must only be used with compatible Nobel Biocare instruments and prosthetic components. Use of instruments and prosthetic components that are not intended to be used in combination with NobelProcera® Zirconia NB N1™ Base and Prosthetic Screw NobelProcera® Zirconia 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 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.

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

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 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

Prosthetic screw NobelProcera® Zirconia NB N1™ Base, NobelProcera® Zirconia Abutment NB N1™ Base, NobelProcera® Zirconia Implant Crown NB N1™ Base are to be used by dental health care professionals.

Prosthetic screw NobelProcera® Zirconia NB N1™ Base, NobelProcera® Zirconia Abutment NB N1™ Base, NobelProcera® Zirconia Implant Crown NB N1™ Base are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with NobelProcera® Zirconia NB N1™ Base and Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base

NobelProcera® Zirconia NB N1™ Base and Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base are components of treatment with a dental implant system and/or dental crowns.

As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with NobelProcera® Zirconia NB N1™ Base and Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base

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

Implant prosthetics are components of a system that replaces teeth and as a result, the 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. When restoring or adapting a patient's dentition, lip biting, bruxism, and phonetic alterations may occur, and the neighboring/opposing prostheses may need adjustment or relining.

Some patients may experience discoloration in the mucosal area such as graying, or wear of neighboring/opposing dentition/ prostheses.

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 [Implantable Device Type(s)]. 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 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™ 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™ onto the working "master" model and visually confirm the fit to the base replicas. Avoid any contact of the position locator(s) to the interproximal teeth. Refer to Nobel Biocare IFU1091 and IFU1088 for information regarding position locators and Nobel Biocare N1™ Base Xeal™ TCC Tri.

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

6. Export/send the scan file to a Nobel Biocare/ KaVo-approved dental CAD/CAM software.

Clinical Procedure - CAD/CAM Scan of Patient Mouth

1. Before mounting the Position Locator(s) or IOS Healing Abutment Nobel Biocare N1™ 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 Locator(s) or IOS Healing Abutment Nobel Biocare N1™ onto the base in the patient mouth and confirm the fit. Avoid any contact of the position locator(s) to the interproximal teeth. Refer to Nobel Biocare IFU1091 for information regarding position locators and IFU1088 for information on IOS Healing Abutment and Nobel Biocare N1™ Base Xeal™ TCC Tri.

3. Perform the scan procedure with a Nobel Biocare/ KaVo-approved intra oral scanner.

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

Laboratory Procedure - Design the Nobel Procera® Zirconia Abutment NB N1™ Base or Implant Crown NB N1™ Base

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.

The following design constraints must be followed (Table 3 and Table 4).

Margin height (soft tissue height) (mm)	Maximum angulation above margin height (soft tissue height) measured from top of the implant
≤4,4 mm	30°
5	27°
6	24°
7	22°
8	19°

Table 3 – Design Constraints – Angulation of Nobel Procera® Zirconia N1™ Base

Restoration type	Min screw channel thickness (mm)	Max. Screw channel angle	Min. Post height (mm)	Max product diameter (mm)	Max product Height (mm)
Nobel Procera® Zirconia Abutment NB N1™ Base NP	0.4	25°	4.2	14.8	16.8
Nobel Procera® Zirconia Abutment NB N1™ Base RP	0.4	25°	4.2	14.8	16.8
Nobel Procera® Zirconia Implant Crown NB N1™ Base NP	0.4	25°	4.2	14.8	16.8
Nobel Procera® Zirconia Implant Crown NB N1™ Base RP	0.4	25°	4.2	14.8	16.8

Table 4 – Design Constraints – Min. / Max. Dimensions Nobel Procera® Zirconia N1™ Base

3. Send your design file to a Nobel Biocare production facility for manufacturing.

Laboratory procedure - Finalize the Nobel Procera® Zirconia Implant Crown NB N1™ Base

1. Once the implant crown has been received from Nobel Biocare, control the occlusion on the master model with the mounted base replica. Refer to Table 2 to check compatibility.

2. If necessary, make minor adjustments using diamond impregnated finishing tools with fine grit size under low pressure and using copious water irrigation, adhering to the minimum dimensions defined in the design software. The following options can be followed for the finalization.

Option 1: Stain and Glaze

– Finalize the Nobel Procera® restoration according to conventional procedures by applying the desired glaze and/or stain material intended for zirconia within the CTE (coefficient thermal expansion) value of 10.5-11x10^{-6}K^{-1}. The guidelines of the stain and glaze material manufacturer are followed when finalizing the restoration.

– Ensure the zirconia surface of the implant crown is adequately polished, using an appropriate silicone polishing set intended for polishing zirconia surfaces.

Option 2: Veneering

– Apply dental restorative material compatible with Zirconia and within a CTE (coefficient thermal expansion) value of 10.5-11x10^{-6}K^{-1} directly onto the Nobel Procera® restoration to achieve the desired shade and tooth morphology.

– It is recommended that the guidelines of the veneering material manufacturer are followed when finalizing the restoration.

– Finalize the NobelProcera® restoration according to conventional procedures by applying the desired glaze and/or stain material intended for zirconia within the CTE (coefficient thermal expansion) value of 10.5-11x10^{-6}K^{-1}. The guidelines of the stain and glaze material manufacturer are followed when finalizing the restoration.

– Ensure the zirconia surface of the implant crown is adequately polished, using an appropriate silicone polishing set intended for polishing zirconia surfaces.

Option 3: Polishing

– Ensure the zirconia surface of the implant crown is adequately polished, using an appropriate silicone polishing set intended for polishing zirconia surfaces.

Note Do not sandblast any areas in contact with tissue nor the connection with the Nobel Biocare N1™ Base surrounding area.

Caution Do not sandblast the seating surfaces.

Note Fluoride treatment and bleaching can have impact on the restoration esthetic.

Laboratory procedure - finalize the NobelProcera® Zirconia Abutment NB N1™ Base

1. Once the restoration is received, finalize it following the material manufacturer's instructions.

2. Check the design and fit of the abutment. If necessary, make minor adjustments using diamond-impregnated finishing tools with a fine grit size, under low pressure and using copious water irrigation, adhering to the minimum dimensions defined in the design software. The following options can be followed for the finalization.

Option 1: Finalizing of the NobelProcera® Zirconia Abutment NB N1™ Base with Ceramic Veneering

– Apply dental restorative material (compatible with Zirconia and within a CTE value of 10.5-11x10^{-6}K^{-1}) directly onto the NobelProcera® Abutment to achieve the desired shade and tooth morphology.

– It is recommended that the guidelines of the veneering material manufacturer are followed when finalizing the restoration.

– Finalize the NobelProcera® restoration according to conventional procedures by applying the desired glaze and/or stain material intended for zirconia within the CTE (coefficient thermal expansion) value of 10.5-11x10^{-6}K^{-1}. The guidelines of the stain and glaze material manufacturer are followed when finalizing the restoration.

Note Fluoride treatment and bleaching can have impact on the restoration esthetic.

Note Do not sandblast any areas in contact with tissue nor the connection with the Nobel Biocare N1™ Base surrounding area.

Caution Do not sandblast the seating surfaces.

Option 2: Finalizing of the Nobel Procera® Zirconia Abutment NB N1™ Base with a Cemented Restoration

– Protect the screw channel and emergence profile of the abutment before sandblasting by connecting it to a replica using the laboratory screw.

– Sandblast the contact surface of the abutment with aluminum oxide 50µm at a maximum of 2 bar.

Note Do not sandblast any areas in contact with tissue nor the connection with the Nobel Biocare N1™ Base surrounding area.

Caution Do not sandblast the seating surfaces.

– Clean the bonding surface using steam jet or an ultrasonic bath.

– Block the screw access channel using suitable material and conventional procedure.

– Bond the restoration to the NobelProcera® Zirconia Abutment NB N1™ Base according to the cement manufacturer's instructions. Use only dental cement/bonding material suitable for the glaze, stain, and/or veneering material used.

Caution Do not use temporary cement when cementing ceramic crowns due to increased risk of micro fractures.

Caution Whenever using cement to retain a restoration, it is recommended to remove any excess in order to avoid sub-mucosal cement remains.

Clinical Procedure - Placement of Final Restoration

Caution Nobel Procera® Zirconia NB N1™ Base and Prosthetic Screw Nobel Procera® Zirconia Nobel Biocare N1™ Base are delivered non-sterile, cleaning and sterilization is required before placing in patient's mouth. Refer to the Cleaning and Sterilization section for detailed information.

1. Remove the healing abutment or temporary restoration from the patient.

2. Connect the restoration to the Nobel Biocare N1™ Base Xeal™ TCC Tri and hand-tighten the prosthetic screw.
It is recommended to verify the final abutment/crown seating using radiographic imaging.
If necessary, make minor adjustments using diamond impregnated finishing tools with fine grit size and under low pressure and using copious water irrigation, adhering to the minimum dimensions defined in the design software. If adjustments are made to the restoration, adequate polishing of occlusal surface must be carried out with an appropriate silicone polishing set intended for polishing ceramic occlusal surface.

Caution Use only the compatible prosthetic screw as stated in Table 1 and do not use the laboratory screw.

Caution If modifying the restoration, use copious irrigation and appropriate protection equipment. Avoid inhalation of dust.

3. Tighten the prosthetic screw according to Table 5 using the Omnigrip™ Mini screwdriver and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1098 for information regarding the Manual Torque Wrench Prosthetic.

Caution Do not exceed the tightening torque of the prosthetic screw as reported in Table 5. Overtightening of abutment may lead to a screw fracture and/or damage of the NobelProcera® Zirconia Nobel Biocare N1™ Base.

4. Block the screw access channel using suitable material and conventional procedure.

Restoration Type	Tightening Torque	Screwdriver
Nobel Procera® Zirconia Abutment NB N1™ Base	20 Ncm	Omnigrip™ Mini
Nobel Procera® Zirconia Implant Crown NB N1™ Base	20 Ncm	Omnigrip™ Mini

Table 5 – Tightening Torque Values

Sterility and Reusability Information

NobelProcera® Zirconia NB N1™ Base is delivered non-sterile intended for single use. Prior to intraoral use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions. During processing in the dental laboratory, the product can be cleaned as necessary without disinfection or sterilization.

Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base is delivered non-sterile and is intended for single use. 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 NobelProcera® Zirconia NB N1™ Base and Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base are single use product 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.

Cleaning and Sterilization Instructions

Cleaning and sterilization instructions: NobelProcera® supra-constructions that include non-metallic materials, require cleaning and disinfection and/or sterilization prior to patient contact.

The final NobelProcera® Zirconia NB N1™ Base should be cleaned, disinfected and /or sterilized, as applicable per the glaze, stain, and/or veneering material manufacturer's instructions for use, prior to use.

Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base is delivered non sterile by Nobel Biocare and is intended for single use. Prior to use, the device must be cleaned and sterilized by the user.

The device 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 Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base is 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.
3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 20 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 20 seconds until all visible soil is removed.
5. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 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 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 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities with 20 ml lukewarm enzymatic cleaning solution (e.g. 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 10 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 10 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. 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 device with purified or sterile water for a minimum of 10 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 discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Selectomat PL/669-2CL (pre-vacuum cycle); Selectomat PL/669-2CL (gravity cycle).

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 6 presents examples of suitable sterilization pouches.

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

Table 6 – Recommended Sterilization Pouches.

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 7):

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 7 – 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 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

MRI Safety Information		
Non-clinical testing has demonstrated the NobelProcera® Zirconia N1™ Base and Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base are 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 3T MRI system.	

Performance Requirements and Limitations

To achieve the desired performance, NobelProcera® Zirconia Abutment NB N1™ Base NP, NobelProcera® Zirconia Abutment NB N1™ Base RP, NobelProcera® Zirconia Implant Crown NB N1™ Base NP, NobelProcera® Zirconia Implant Crown NB N1™ Base RP, Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base NP, and Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base RP, 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 NobelProcera® Zirconia Abutment NB N1™ Base NP, NobelProcera® Zirconia Abutment NB N1™ Base RP, NobelProcera® Zirconia Implant Crown NB N1™ Base NP, NobelProcera® Zirconia Implant Crown NB N1™ Base RP, Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base NP, and Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base RP, 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
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

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

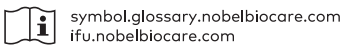
Basic UDI-DI Information

Product	Basic UDI-DI Number
NobelProcera® Zirconia Implant Crown NB N1™ Base NobelProcera® Zirconia Abutment NB N1™ Base	73327470000002106P
Prosthetic Screw NobelProcera® Zirconia Nobel Biocare N1™ Base	733274700000018179

Legal Statements

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
							
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	