NobelProcera® Zirconia Implant Bridge

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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

NobelProcera® Zirconia Implant Bridge is a patient-specific, implant supported screw-retained dental implant bridges which is connected to a compatible Nobel Biocare dental implant or implant abutment and is intended to restore chewing function in partially- and fully-edentulous patients.

NobelProcera® Zirconia Implant Bridge is manufactured from zirconia (Yttria-stabilized tetragonal zirconia) and is designed in a dental laboratory, hospital, or dental practice by scanning, designing, and ordering the restoration using dental CAD/CAM software and a Nobel Biocare-approved dental scanner. The design must adhere to the pre-defined minimum geometries in the design software. The finished design is then sent to Nobel Biocare for fabrication. After receiving the NobelProcera® Implant Bridge from Nobel Biocare, the dental laboratory finalizes the prosthesis per the clinical situation and desired esthetic outcome.

NobelProcera® Zirconia Implant Bridge is available for use with Nobel Biocare's Internal Conical Connection, External Hex connection, Internal Tri-Channel connection, and MUA (Multi-unit Abutment) connections.

NobelProcera® Zirconia Implant Bridge is delivered with the compatible clinical screw. For information specific to the Clinical Screws, refer to the Nobel Biocare Instructions for Use for the component (IFU1057).

NobelProcera® Zirconia Implant Bridges featuring the Internal Conical Connection additionally require a Metal Adapter Implant Bridge Clinical CC in the compatible platform size (NP, RP, or WP), which is also delivered with the bridge.

Metal Adapters Implant Bridge Clinical CC NP/RP/WP are designed to protect the connecting surface of implant bridge and facilitate a secure attachment to the implant.

Laboratory components such as laboratory screws, laboratory adapters, and position locators are sold separately.

Intended Use / Intended Purpose

NobelProcera® Zirconia Implant Bridge

Intended to be finalized into a multi-unit dental prosthesis, which is connected to endosseous dental implants to restore chewing function.

Metal Adapter Implant Bridge Clinical CC NP/RP/WP

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

	Connection Type											
	External Hex			**Internal Tri-Channel**				**CC**			**MUA**	
NobelProcera® Implant bridge Zirconia	NP	RP	WP	NP	RP	WP	6.0	NP	RP	WP	NP/RP	WP
Clinical Adapter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Metal Adapter Implant Bridge Clinical CC			N/A	N/A
Lab Adapter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Metal Adapter Implant Bridge Lab CC			N/A	N/A
Clinical Screw	Screw Ceramic Abutment Brånemark System®							Omnigrip™ Clinical Screw CC			Prosthetic Screw Multi-unit Abutment Omnigrip™ Mini	
Lab Screw	Lab Screw Implant Level External Hex		N/A (*)	N/A (*)	N/A (*)	N/A (*)	N/A (*)	Omnigrip™ Lab Screw CC Lab Screw Implant Level Conical Connection			Lab Screw Multi-unit Abutment Omnigrip™ Mini	
Implant/MUA Replicas	Implant Replica Brånemark System® Elos Accurate Analog for Printed Model External Hex			Implant Replicas NobelReplace® Elos Accurate Analog for Printed Model Tri-Channel				Implant Replica Conical Connection IOS Model Implant Replica CC			Multi-unit Abutment Plus Replica Elos Accurate Analog for Printed Model Multi-unit	Multi-unit Abutment Plus Replica Abutment Replica Multi-unit Bmk Syst Elos Accurate Analog for Printed Model
Protection Analogs	Protection Analog Bmk Syst			Protection Analog NobelReplace®				Protection Analog/Drill Guide CC			Protection Analog Multi-unit	Protection Analog Multi-unit Protection Analog M-u Bmk Syst
MUAs	Multi-unit Abutment Bmk Syst 17° Multi-unit Abutment Bmk Syst 30° Multi-unit Abutment Bmk Syst Zygoma Abutment Brånemark System® Zygoma Zygoma 17° Brånemark System® Zygoma 17° 45° Multi-unit Abutment Ext Hex 60° Multi-unit Abutment Ext Hex			Multi-unit Abutment NobRpl 17° Multi-unit Abutment NobRpl 30° Multi-unit Abutment NobRpl				Multi-unit Abutment Plus Conical Connection 17° Multi-unit Abutment Plus Conical Connection 30° Multi-unit Abutment Plus Conical Connection Multi-unit Abutment Xeal™ Conical Connection 17° Multi-unit Abutment Xeal™ Conical Connection 30° Multi-unit Abutment Xeal™ Conical Connection			N/A	N/A
Implants	NobelSpeedy® Groovy® NobelSpeedy® Shorty	Brånemark System® Mk III Brånemark System® Mk III TiUnite® NobelSpeedy® Groovy® NobelSpeedy® Shorty Zygoma Implant NobelZygoma™	NobelSpeedy® Groovy® NobelSpeedy® Shorty	Replace Select™ TC				NobelActive® NobelActive® TiUltra™ NobelParallel™ CC NobelParallel™ CC TiUltra™ NobelReplace® CC NobelReplace® CC PMC NobelReplace® CC TiUltra™	NobelActive® NobelActive® TiUltra™ NobelParallel™ CC NobelParallel™ CC TiUltra™ NobelReplace® CC NobelReplace® CC PMC NobelReplace® CC TiUltra™	NobelActive® NobelActive® TiUltra™ NobelParallel™ CC NobelParallel™ CC TiUltra™	N/A	N/A

Table 1 – Compatibility table for NobelProcera® Implant bridge Zirconia

(*): Clinical screws need to be used in the lab

Indications

NobelProcera® Zirconia Implant Bridge

NobelProcera® Zirconia Implant Bridge is indicated for use as a multi-unit dental prosthesis which can be connected to an endosseous dental implant and/or abutment connections. Indicated for all positions of the maxilla and mandible.

NobelProcera® Zirconia Implant Bridge is indicated to be seated on the following implant and/or abutment connections: Nobel Biocare: Internal Conical Connection, Internal Tri-Channel Connection, External Hex, Multi-unit Abutments and Multi-unit Abutment Plus.

NobelProcera® Zirconia Implant Bridge is indicated for a bridge span of 2 to up 14 units, on 2 up to 10 implants.

Metal Adapter Implant Bridge Clinical CC NP/RP/WP

Metal Adapter Implant Bridge Clinical is indicated for use as an interface between an implant bridge and an endosseous dental implant featuring the Internal Conical Connection, in order to protect the connecting surface of the implant bridge and to facilitate a secure attachment to the implant.

Contraindications

It is contraindicated to use NobelProcera® Zirconia Implant Bridges, Clinical/Prosthetic Screws and Clinical Metal Adapters in:

- Patients who are allergic or hypersensitive to Zirconia (Y-TZP), Titanium Alloy (90% Ti, 6% Al, 4% V) and DLC (Diamond Like Carbon) coating.
- Patients who are medically unfit for an oral surgical procedure.

– 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 have parafunctional tendencies for example bruxism and/or clenching.

– Patients who are contraindicated for treatment with Nobel Biocare implants or restorative components.

For contraindications specific to the clinical screws, refer to Nobel Biocare IFU1057.

Materials

– NobelProcera® Zirconia Implant Bridge: Yttria-stabilized Zirconium oxide according to ISO 13356.

– Metal Adapters Implant Bridge Clinical CC NP/RP/WP: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.

– Clinical screws: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.

Cautions

General

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

Nobel Biocare surgical instruments and prosthetic components must only be used with compatible Nobel Biocare implants. Use of Nobel Biocare surgical instruments and prosthetic components that are not intended to be used in combination with Nobel Biocare surgical instruments and prosthetic components can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment for the first time, working with a colleague who is experienced with the new device/treatment 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.

Do not sandblast the seating area of the implant bridge that connects with the implant, abutment or metal adapter, nor any area which will come into contact with surrounding tissue.

Before Surgery

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 for pediatric patients until the end of the jaw bone growth phase has been properly documented.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

All components, instruments and tooling used during the clinical and/or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. gauze, dental dam, or throat shield).

Never exceed recommended tightening torque for the prosthetic screw. Overtightening of the restoration may lead to a screw fracture and/or damage of the product.

Bending moments: Forces that cause bending moments are known to be the most unfavorable, as they can potentially jeopardize the long-term stability of an implant-supported restoration. In order to decrease bending moments, the distribution of forces should be optimized by cross-arch stabilization, minimizing distal cantilevers, having a balanced occlusion as well as decreased cuspal inclination of the prosthetic teeth.

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

After Surgery

To 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

NobelProcera® Zirconia Implant Bridge is to be used by dental health care professionals.

NobelProcera® Zirconia Implant Bridge is to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with NobelProcera® Implant Bridge

NobelProcera® Zirconia Implant Bridge 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 NobelProcera® Zirconia Implant Bridge

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, and swelling. During placement of a NobelProcera® Zirconia Implant Bridge, the pharyngeal reflex (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 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. 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.

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

NobelProcera® Zirconia Implant Bridge is designed and manufactured based on a digital scan performed on a conventional impression, or on a scan performed directly in the patient's mouth (digital impression).

1. Obtain Conventional or Digital Impression

1a. Conventional Impression (Clinical/Laboratory Procedures)

Take Conventional Impression (Clinical Procedure)

- Take an impression according to standard clinical procedures for restorative operations and send to the dental laboratory.

Fabricate Master Model (Laboratory Procedure)

- Fabricate a working "master" model with implant 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)

- Before mounting the position locator(s) 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.
- Assemble the required amount of position locator(s) onto the working "master" model and visually confirm the fit to the implant replicas. Avoid any contact of the position locator(s) to the interproximal teeth.
- Perform the scan with a dental scanner by following the scan process.
- Export the scan file to a Nobel Biocare-approved dental CAD/CAM software.

1b. Digital Impression (Clinical Procedure)

Note Most intra-oral scanners are limited for bridge restorations and may only be used for short-span bridges.

- Before mounting the position locator(s) 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.
- Assemble the required amount of position locator(s) onto the implant(s) in the patient mouth and confirm the fit. Avoid any contact of the position locator(s) to the interproximal teeth.
- Perform the scan procedure with a Nobel Biocare-approved intra oral scanner.
- Export/send the scan file(s) to the dental CAD/CAM software.

2. Design the Zirconia Implant Bridge (Laboratory Procedure)

- Import the scan file(s) into the CAD/CAM software.
- 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 design constraints that must be followed are stated in Figures A–D and Table 2.

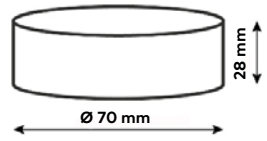

Figure A – Maximum Dimensions for Outer Shape

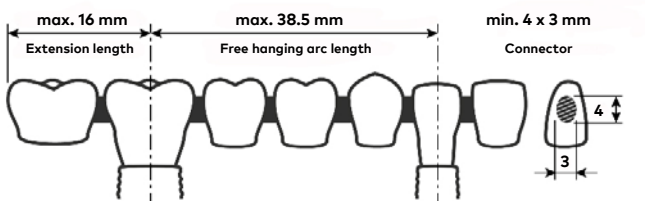

Figure B – Dimensional Requirements for Zirconia Implant Bridge

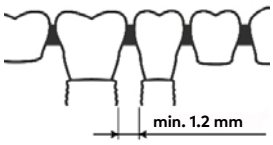

Figure C – Minimum Distance Between Implants

Connection Type	Max. Divergence Angle
Multi-unit Abutments	45°
Internal Conical Connection	30°
Internal Tri-channel	30°
External Hex	20°

Table 2 – Divergence Angle per Platform

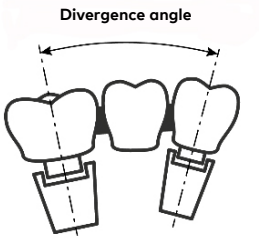

Figure D – Divergence Angle

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

3. Finalization of the Zirconia Implant Bridge (Laboratory Procedure)

After receiving the NobelProcera® Zirconia Implant Bridge from the Nobel Biocare production facility, finalize the restoration per one of the following two sets of instructions, depending on the type of design (3a. for finalization of Implant Bridge via veneering and/or staining/glazing, and 3b. for finalization Implant Bridge via placement of cemented restoration).

Note Use only laboratory screws and adapters during finalization procedure. For Internal Tri-Channel and External Hex WP connections, the clinical screw must be used instead of a laboratory screw but must be discarded after finalization.

Caution Do not use separating discs, sharp diamond-burs and/or anything causing sharp grooves and/or sharp edges on the NobelProcera® Zirconia Implant Bridge as this may negatively affect its strength or fit.

3a. Finalization of Zirconia Implant Bridge via Ceramic Veneering and/or Stain and Glaze

- Check the design and fit of the bridge. 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.
- Apply dental restorative material (compatible with Zirconia and within a CTE value of 10.5-11 x 10^{-6} K^{-1}) directly onto the NobelProcera® Implant Bridge to achieve the desired shade and tooth morphology.
- Polish the occlusal surface with an appropriate silicone polishing set, intended for polishing ceramic occlusal surfaces.

3b. Finalization of Zirconia Implant Bridge with a Cemented Restoration

- Check the design and fit of the finalized implant bridge. If necessary, make minor adjustments using diamond impregnated finishing tools with fine grit size, under low pressure and using copious water irrigation.
- Finalize the restoration according to the restorative material manufacturer's recommendations.

4. Placement of the Final Restoration (Clinical Procedure)

Caution The final restoration must be cleaned and disinfected and/or sterilized prior to placement in the patient's mouth, following the instructions of the restorative material manufacturer. Refer to the Cleaning and Sterilization Instructions for greater detail.

Caution Clinical Metal Adapters must be used when placing implant bridges featuring the Conical Connection directly on the implant level, in order to avoid damaging the bridge.

Caution Laboratory screws and adapters must not be used to place the finalized restoration in order to avoid damaging the bridge.

- Remove the healing cap(s) or temporary restoration from the abutment or implant(s).
- Insert the appropriate clinical screw(s) into the screw access hole and hand tighten to the abutment or implant. It is recommended to verify the final bridge seating using radiographic imaging.
- Tighten the clinical screws with dedicated screwdriver and Manual Torque Wrench prosthetic, according to Table 3.
- Seal the screw access channel(s) using suitable material.
- Verify occlusion and function using conventional procedures.
- If adjustments are made to the restoration, adequate polishing of occlusal surface must be done with any appropriate silicone polishing set intended for polishing ceramic occlusal surface.

Note During regular checkups it is recommended to check the occlusion and adjust if needed (procedure as described above). In case occlusal surface becomes dull (loses gloss), polish as described above.

Connection Type	Screw Torque	Screwdriver
Multi-unit Abutments	15 Ncm	Omnigrip™ Mini
Internal Conical Connection	35 Ncm	Omnigrip™
Internal Tri-channel	35 Ncm	Unigrip™
External Hex	35 Ncm	Unigrip™

Table 3 – Tightening Torque and Compatible Screwdriver

Caution Never exceed recommended maximum tightening torque for the screw. Overtightening of restoration may lead to a fracture.

Sterility and Reusability Information

NobelProcera® Zirconia Implant Bridge is delivered non-sterile for single use only and must be cleaned and then disinfected and/or sterilized prior to intraoral use following the procedures for supra-constructions in the Cleaning and Sterilization Instructions. During processing in the dental laboratory, the supra-construction can be cleaned as necessary without disinfection or sterilization.

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

Caution NobelProcera® Zirconia Implant Bridge is a 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.

Metal Adapter Implant Bridge Clinical CC NP/RP/WP and clinical screws are also 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. Refer to Nobel Biocare Instructions for Use (IFU) IFU1057 for cleaning and sterilization instructions for the clinical screw.

Caution Metal Adapter Implant Bridge Clinical CC NP/RP/WP is a 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 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.

Cleaning and Sterilization Instructions

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

Clean, disinfect, and sterilize the NobelProcera® Zirconia Implant Bridge according to the dental restorative material manufacturer's instructions prior to use.

Metal Adapter Implant Bridge Clinical CC NP/RP/WP 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 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 Metal Adapter Implant Bridge Clinical CC NP/RP/WP has been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following processing 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 of 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum of 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum of 2 minutes rinsing with cold desalinated 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 20 seconds 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. Cydezyme ASP; maximum of 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 an 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_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP) 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 20 ml 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: Systec HX-320 (pre-vacuum cycle); Amsco Century Sterilizer (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 4 presents examples of suitable sterilization pouches.

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

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 Multiple Teeth Configurations

MRI Safety Information		
Non-clinical testing has demonstrated the NobelProcera® Zirconia Implant Bridge and clinical adapter 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 44.4 T/m (4,440 G/cm).	
RF Excitation	Circularly Polarized (CP).	
RF Transmit Coil Type	Whole body transmit coil.	
Maximum Whole-Body SAR [W/kg]	Inferior to the shoulders: 2.0 W/kg	Inferior to the navel: 2.0 W/kg
	Superior to the shoulders: 0.2 W/kg	Superior to the navel: 0.1 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 2.7 cm from the devices or device assemblies when imaged in a 3 T MRI system.	
Caution	Configurations with more than 2 Zygoma implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of configurations with more than 2 Zygoma implants in the MR environment is unknown. Scanning a patient who has this configuration may result in patient injury.	
Implant placement with intention to restore at prosthetic level with PIBs or IBOs (multiple tooth restorations): Please consult IFU for NobelProcera® Implant Bridge Titanium and Zirconia, NobelProcera® Crown and Bridge, NobelProcera® HT ML FCZ, and NobelProcera® Implant Bar Overdenture for use as part of a bridge configuration.		

Performance Requirements and Limitations

To achieve the desired performance, NobelProcera® Zirconia Implant Bridge and clinical adapter 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 Implant Bridge and clinical adapter, 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 Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
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 Refer to the product label to determine the applicable conformity marking for each device.

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
Metal Adapter Implant Bridge Clinical CC NP/RP/WP	73327470000001667D
NobelProcera® Zirconia Implant Bridge	73327470000002136V

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	