NobelProcera® Zirconia Implant Bridge

Instructions for use

Important – Disclaimer of Liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

NobelProcera® Zirconia Implant Bridges are patient-specific, implant supported screw-retained dental implant bridges which are 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 Bridges are manufactured from zirconia (Yttria-stabilized tetragonal zirconia) and are 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/KaVo-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 Bridges are available for use with Nobel Biocare's Internal Conical Connection, External Hex connection, Internal Tri-Channel connection and MUA (Multi-unit Abutments) connections.

All NobelProcera® Zirconia Implant Bridges are delivered with the compatible clinical screws. NobelProcera® Zirconia Implant Bridges featuring the Internal Conical Connection additionally require a Metal Adapter Implant Bridge CC in the compatible platform size (NP, RP, or WP), which also is delivered with the bridge. Metal Adapters Implant Bridge are designed to protect the connecting surface of implant bridge and facilitate a secure attachment to the implant.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1057 for information regarding clinical screws. This IFU is available for download at ifu.nobelbiocare.com.

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

Intended Use:

NobelProcera® Zirconia Implant Bridges:
Intended to be finalized into a multi-unit dental prosthesis, which is connected to endosseous dental implants to restore chewing function.

Metal Adapters Implant Bridge CC NP/RP/WP:
Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.

Indications:

NobelProcera® Zirconia Implant Bridges:
Implant bridges are 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 Bridges are 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 Bridges are indicated for a bridge span of 2 to up 14 units, on 2 up to 10 implants.

Metal Adapters Implant Bridge CC NP/RP/WP:
Metal Adapters Implant Bridge are 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 Screws and 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.

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

Cautions:

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

It is strongly recommended that Nobel Biocare surgical instruments and prosthetic components are used only with Nobel Biocare implants, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental 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 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 size of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).

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 Bridges are intended to be used by dental health care professionals.

NobelProcera® Zirconia Implant Bridges are intended to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with NobelProcera® Implant Bridges:
NobelProcera® Zirconia Implant Bridges are components of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with NobelProcera® Zirconia Implant Bridges:
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 bridges 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, ulcera, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

Notice regarding serious incidents:
For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
https://www.nobelbiocare.com/complaint-form

Handling Procedure:

NobelProcera® Zirconia Implant Bridges are 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/KaVo-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/KaVo-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 will be enforced within the software, adhering to the maximum dimensions stated in Figures A – D and Table 1.

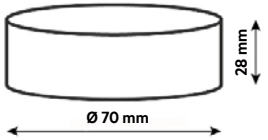

Figure A. Maximum Dimensions for Outer Shape

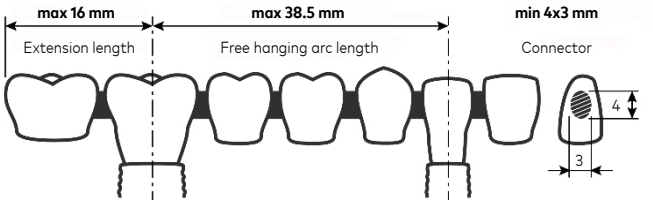

Figure B. Dimensional Requirements for Zirconia Implant Bridge

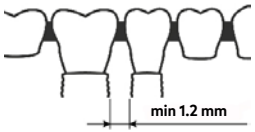

Figure C. Minimum Distance Between Implants

Table 1. Divergence Angle per Platform

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

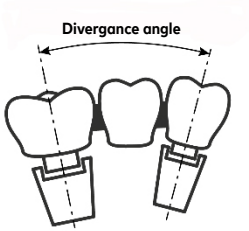

Figure D. Divergence Angle

- 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 2.
- 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.

Table 2. Tightening Torque and Compatible Screwdriver

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

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

Materials:

- NobelProcera® Zirconia Implant Bridges: Yttria-stabilized tetragonal zirconia polycrystal (Y-TZP), according to ISO 13356.
- Metal Adapters Implant Bridge CC NP/RP/WP: Titanium alloy 90% Ti, 6% Al, 4% V, according to ASTM F136.
- Clinical screws: 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:

NobelProcera® Zirconia Implant Bridges are 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.

Metal Adapters Implant Bridge 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.

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

Caution: NobelProcera® Zirconia Implant Bridges and Metal Adapters Implant Bridge CC NP/RP/WP are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

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 finalized NobelProcera® Zirconia Implant Bridge according to the dental restorative material manufacturer's instructions prior to use.

Metal Adapters Implant Bridge CC NP/RP/WP are delivered non-sterile by Nobel Biocare and are 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 Metal Adapters Implant Bridge CC NP/RP/WP have been validated to withstand these cleaning and sterilization procedures.

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 neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

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

Manual Cleaning and Drying:

1. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; 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 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. Cidezyme ASP) 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 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 3 presents examples of suitable sterilization containers, pouches, and wraps.

Table 3: Recommended Sterilization Pouches

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

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

Table 4: Recommended Sterilization Cycles

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

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

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

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

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

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

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

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

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

Magnetic Resonance (MR) Safety Information:

NobelProcera® Zirconia Implant Bridges and Metal Adapters Implant Bridge CC NP/RP/WP contain metallic materials which can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that these devices are unlikely to impact patient safety under the following MRI conditions:

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

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

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

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

Note: Although the non-clinical testing demonstrates that NobelProcera® Zirconia Implant Bridges and Clinical Adapters are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to support a claim of MR Safe or MR Conditional for these devices.

Performance Requirements and Limitations:

To achieve the desired performance, The 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 The 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:
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411 17 Göteborg
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CE 2797
CE Mark for
Class IIb Devices

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

Basic UDI-DI Information:

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

Product	Basic UDI-DI Number
NobelProcera® Zirconia Implant Bridges	7332747000000 2136V
Metal Adapters Implant Bridge Clinical Conical Connection NP/RP/WP	7332747000000 1667D

Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

Authorized representative in the European Community

Batch code

Catalogue number


Caution


CE marking


Consult instructions for use


Contains hazardous substances

Contains or presence of phthalate

Date


Date of manufacture


Do not resterilize


Do not re-use


Do not use if package is damaged


Double sterile barrier system

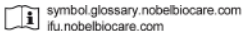
Rx Only

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional


Manufacturer

Medical device


Non-pyrogenic

Non-sterile


Patient identification


Patient information website


Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Sterilized using ethylene oxide

Sterilized using irradiation


Temperature limit


Tooth number


Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier


Use-by date