NobelProcera® Zirconia 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:

The NobelProcera® Zirconia Bridge is an individualized cement retained dental restoration manufactured from translucent zirconia material.

The NobelProcera® Zirconia Bridge is intended to be a replacement for natural teeth. After finalizing the NobelProcera® Zirconia Bridge in the dental laboratory, it is cemented or bonded on prepared teeth or artificial abutments by a clinician, to provide a natural tooth like appearance and to restore chewing functionality in the patient's mouth.

To achieve esthetics and required value and chroma of the surrounding natural teeth the NobelProcera® Zirconia Bridge is suitable for cut-back (veneering) or stain and glaze techniques.

The design of the NobelProcera® Zirconia Bridge is determined in a dental laboratory, hospital or dental practice by scanning, designing and ordering the bridge using DTX Studio Lab or supported third party CAD systems. The bridge, once ordered, is sent electronically to one of NobelProcera's centralized milling centers for fabrication.

Intended Use/Intended Purpose:

NobelProcera® Zirconia Bridge is intended for use as an aid in prosthetic rehabilitation.

Indications:

NobelProcera® Bridge is indicated for use as core structure of an artificial prosthesis for partially edentulous patients in need of prosthetic oral reconstruction in order to restore chewing function.

NobelProcera® Bridge is indicated for use as a bridge that is cemented on natural teeth or artificial abutments.

Contraindications:

It is contraindicated to use NobelProcera® Zirconia Bridge in:

- Patients who have parafunctional tendencies, for example bruxism and/or clenching.
- Patients who are allergic or hypersensitive to Zirconia: zirconium dioxide Y-TZP.
- Cases with lengths that exceed the maximum limits (**table 2**) and minimum thickness as indicated (**table 1**).

Cautions:

General:

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

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. For more information please visit www.nobelbiocare.com.

It is especially important to achieve proper stress distribution through adaptation and fitting of the Bridge, by adjusting the occlusion to the opposing jaw. In addition, avoid excessive transverse loading forces, particularly in immediate loading cases.

In general, 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 jawbone growth phase has been properly documented.

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. rubber dam, a throat shield).

When designing the Bridge make sure to maintain minimum edge thickness and wall thickness.

If necessary, make minor adjustments using diamond impregnated finishing tools with fine grit size under low pressure and using copious water irrigation, use copious irrigation and appropriate protection equipment. Avoid inhalation of dust.

If the Bridge requires modification, make sure that the minimum wall thickness as detailed in **Table 1** and **2** is maintained even after polishing.

If the Bridge requires modification, make sure that the minimum edge thickness of 0.1 mm is maintained even after polishing.

The connector dimension of a multi-unit bridge depends on the distance between the supporting teeth/abutments, see **table 2** defining the minimum requirements that must be met.

The NobelProcera® Zirconia Bridge should be designed to fit into a disc of 70 mm × height 20 mm, see figure B.

To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after treatment and to inform the patient about appropriate oral hygiene.

The minimal wall thickness of the final product must not be lower than the values defined in **Table 1**.

Table 1

	Anterior min	Pre-Molar min	Molar min
Occlusal Area	0.6 mm	0.6 mm	0.6 mm
Circular Area	0.6 mm	0.6 mm	0.6 mm

Table 2: Product constraints: further shown in **Figure A**

Type/position	Length [mm] a = Arc length e = Extension length	Minimum connector and cross section height × width (mm)/area (mm^2)
Free hanging arc, Any position	0.8 < a ≤ 21.0	4.0 × 2.5 / 8
	21.0 < a ≤ 38.5	4.0 × 3.0 / 9.4
Extension, Any position	e ≤ 16.0	

Fiaure A

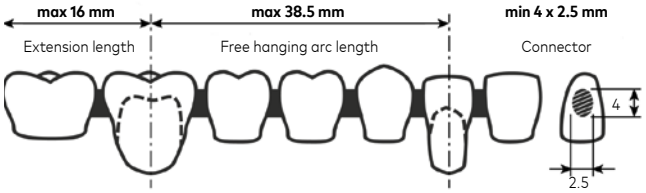
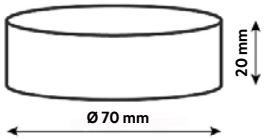


Figure B



Handling Procedure:

Clinical Procedure:

1. Preparation of tooth or abutment:

- Eliminate sharp edges, undercuts and grooves.
- Provide sufficient (minimum 1.5 – 2 mm) occlusal/incisal reduction.
- Provide adequate space for the bridge (see **table 1** and **2**).
- Avoid sharp angles on the occlusal surface.
- Avoid creating a deep fossa/cavity.
- Avoid preparations that are excessively tapered or too close to parallel.
- The ideal total occlusal convergence is 6 – 10°.

2. Impression taking:

- Take an impression; digital or conventional of the tooth or abutment, following the implant manufacturer's guidelines, the impression material manufacturer's guidelines, and/or Intra Oral scanner manufacturer's guidelines.
- Send the physical or digital impression to the laboratory.

3. Shade selection:

- Determine the required shade according the 'VITA classical' shade scale and communicate to laboratory.

Laboratory procedure:

1. Scan and design:

- Scan and import/import the clinical situation into the software using a NobelProcera® scanner or an approved 3rd party system.
- Once imported, open relevant CAD module and design your bridge, following the instructions in the software tutorial, according to the patient's clinical needs. If a cut- back if performed in the software, make sure to not have any undercuts or sharp corners.
- Send the scan data file with shade information to a Nobel Biocare production facility by clicking on the order button in the software.

2. Finalization steps:

- After receiving the bridge check precision of fit on the definitive model and check proximal and occlusal contact points.
- If necessary, make minor adjustments using diamond impregnated finishing tools with fine grit size under low pressure and using copious water irrigation.
- Make sure that the minimum wall and product constraints as detailed in **Table 1** and **2** are maintained even after minor adjustments are made.
- Make sure that the minimum edge thickness of 0.1 mm is maintained even after minor adjustments are made.
- Finalize the NobelProcera® Zirconia Bridge according to conventional procedures by applying the desired glaze and/or stain material intended for zirconia within the CTE (coefficient thermal expansion) value of zirconia material. It is recommended that the guidelines of the stain and glaze manufacturer are followed when finalizing the Bridge.

– Alternative, if NobelProcera® Zirconia Bridge has a partial cutback design, according to conventional procedures, apply dental ceramic compatible with zirconia oxide within the CTE (coefficient thermal expansion) value of zirconia material.

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

– Fluorescent glaze is to be applied prior to standard firing procedures.

– Adequate polishing of occlusal surface should be done with an appropriate silicone polishing set intended for polishing zirconia occlusal surfaces.

– Thereafter clean in ultrasonic unit.

Clinical procedure:
Procedure to be carried out in the dental practice, following delivery of the Bridge from the dental laboratory.

– After receiving the bridge check the fit, if adjustments are necessary make minor adjustments using diamond impregnated finishing tools with fine grit size, under low pressure and using copious water irrigation. Then polish the occlusal surface with an appropriate silicone polishing set intended for polishing zirconia surfaces.

– Following conventional procedures, cement or bond the Bridge using material intended for cementing or bonding zirconia.

– It is recommended that the guidelines of the cement or bonding agent manufacturer's guidelines are followed, when cementing or bonding the Bridge to the natural tooth or implant abutment.

– Cementation or bonding: gently seat the Bridge on the tooth or implant abutment and check both the occlusion and the interproximal contacts. The Bridge should be in adequate occlusion.

Note: If it is necessary to remove the restoration use cross-cutting burs with copious irrigation to avoid overheating. If rotating instruments are used for removal, eye protection must be used.

Caution: Do not use temporary cement when cementing ceramic Bridges due to increased risk of micro fractures. Whenever using cement to retain a restoration, it is recommended to remove any excess in order to avoid sub-mucosal cement remains.

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

Product constraints
The final outer product design must fit in a cylinder of ∅ 18.5 mm and height of 14 mm

Materials:

NobelProcera Zirconia Bridge – is a zirconium dioxide Y-TZP used for manufacturing dental prosthesis.

Physical Properties:

Coefficient thermal expansion (CTE) (25 – 500°C): 10.7 (±0.2) x $10^{-6}K^{-1}$.

Sterility and reusability information:

NobelProcera® Zirconia Bridge is delivered non-sterile and is intended for single use only. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Caution: NobelProcera® Zirconia 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.

Warning: Do not use device if the packaging has been damaged or previously opened.

Cleaning and Sterilization Instructions:

NobelProcera® Zirconia Bridge 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 NobelProcera® Zirconia Bridge has 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 1 minute until all visible soil is removed.
4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 30 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 1 minute to remove all cleaning solution.
6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe..

Automated Cleaning and Drying:
The following washer was used in the Nobel Biocare validation: Miele G7836 CD.

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 0.1 % neutralizing agent (e.g. Neodisher Z) in cold deionized water.
   - Draining.
   - Minimum 2 minutes rinsing with cold deionized 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, discoloration, pitting, or cracks and properly discard any devices that fail the inspection.

Manual Cleaning and Drying:

1. Immerse device for a minimum of 5 minutes in a sterile 0.9 % NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 30 s 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. 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 1 min until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 30 seconds to remove all cleaning solution.
6. Immerse the device in an ultrasonic bath (e.g. Bandelin : frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5 % enzymatic cleaning agent (e.g. 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 20ml syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 30 seconds to remove all cleaning agent.
9. Repeat cleaning steps if needed.
10. 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 3 presents examples of suitable sterilization containers, pouches, and wraps.

Table 3: Recommended Sterilization Pouches

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

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

Table 4: Recommended Sterilization Cycles

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

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

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

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

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

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

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

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

Magnetic Resonance (MR) Safety Information:

The NobelProcera Zirconia Bridge has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of NobelProcera Zirconia Bridge in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

Warning: Do not use device if the packaging has been damaged or previously opened.

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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Distributed in USA by:
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Caution: Federal (United States) law restricts this device to sale by or on the order of a dentist or a physician.

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Prescription Device – Rx only
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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 Union

Batch code

Catalogue number


Caution


CE marking

CE mark with Notified Body number


Consult instructions for use


Contains hazardous substances

Implantation date


Date of manufacture

Do not resterilize

Do not re-use


Do not use if package is damaged

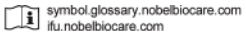

Double sterile barrier system

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

Contains or presence of DEHP phthalate

Contains or presence of phthalate

Contains or presence of natural rubber latex

Magnetic resonance safe

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