NobelProcera® Esthetic Zirconia Implant Bridge

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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® Esthetic Zirconia Implant Bridge and NobelProcera® Zirconia Implant Bridge, hereafter called Zirconia Implant Bridge.

Zirconia Implant Bridge is a patient-specific, implant supported screw-retained dental implant bridge 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.

Zirconia Implant Bridge is manufactured from zirconia (Yttria-stabilized 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 Zirconia Implant Bridge from Nobel Biocare, the dental laboratory finalizes the prosthesis per the clinical situation and desired esthetic outcome.

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 Abutments) connections.

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).

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

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

Intended Use/Intended Purpose

NobelProcera® Zirconia Implant Bridge and NobelProcera® Esthetic 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.

Indications

NobelProcera® Zirconia Implant Bridge and NobelProcera® Esthetic Zirconia Implant Bridge

Zirconia implant bridges are patient-matched CAD/CAM implant bridges which are directly connected to endosseous dental implants and/or Nobel Biocare's Multi-unit Abutments and are indicated for use as an aid in prosthetic rehabilitation.

The Implant Bridges are indicated for a bridge span of 2 up to 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 Zirconia Implant Bridges, Clinical/ Prosthetic Screws and Clinical Metal Adapters in:

- Patients who are allergic or hypersensitive to Zirconia (Yttria-stabilized Zirconium oxide), 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

- Zirconia Implant Bridges:
  Yttria-stabilized Zirconium oxide
- 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

Zirconia Implant Bridges are to be used by dental health care professionals.

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

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Devices in the IFU

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 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 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.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the Zirconia Implant Bridge. The SSCP can be obtained at the following website:
ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED)

Notice regarding serious incidents

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

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

Handling Procedure

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.

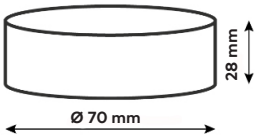

Figure A.1 – NobelProcera® Zirconia Implant bridge, Maximum Dimensions for Outer Shape

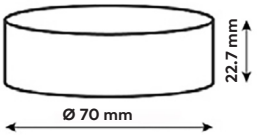

Figure A.2 – NobelProcera® Esthetic Zirconia Implant bridge, Maximum Dimensions for Outer Shape

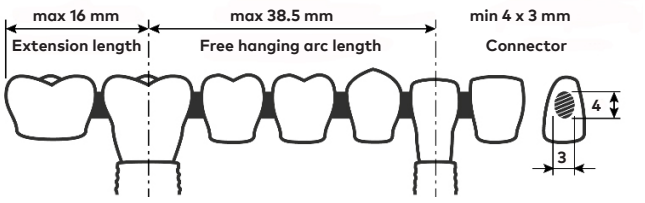

Figure B – Dimensional Requirements for Zirconia Implant Bridge

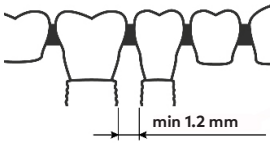

Figure C.1 – NobelProcera® Zirconia Implant bridge, Minimum Distance Between Implants

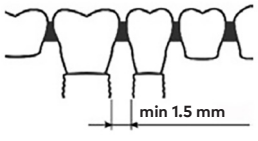

Figure C.2 – NobelProcera® Esthetic Zirconia Implant bridge, Minimum Distance Between Implants

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°

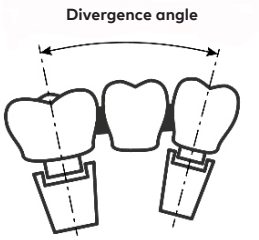

Figure D – Divergence Angle

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

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

After receiving the 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 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 Zirconia 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.

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.

Sterility and Reusability Information

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 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

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

Magnetic Resonance (MR) Safety Information

These products are fabricated from a metal material which can be affected by MR energy. For further information refer to Nobel Biocare publication **Magnetic Resonance (MR) Safety Information** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices 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 devices, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

Storage, Handling and Transportation

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information

Manufacturer	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
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.

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

Basic UDI-DI Information

Product	Basic UDI-DI Number
Metal Adapter Implant Bridge Clinical CC NP/RP/WP	73327470000001667D
NobelProcera® Zirconia Implant Bridge	73327470000002136V
NobelProcera® Esthetic Zirconia Implant Bridge	73327470000002136V

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.