

NobelProcera® Zirconia Implant Bridge



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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-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) / MUA Plus connections.

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

This IFU covers following products; NobelProcera® Zirconia Implant Bridges and its Clinical Metal Adapters and Prosthetic Screws.

Intended Use

The NobelProcera® Zirconia Implant Bridges are customized dental implant bridges. The implant Bridge attaches directly to the endosseous dental implants and/or onto Nobel Biocare's Multi-unit Abutments with prosthetic screws and provides a platform for restoration.

The NobelProcera® Zirconia Implant Bridges are designed and made individually to fit the individual requirements for the patient. NobelProcera® Zirconia Implant Bridges are indicated for a bridge span of 2 to up 14 units, on 2 up to 10 implants.

Clinical Metal Adapters are intended to be inserted into the zirconia implant bridge (full contour and framework) to act as the interface for all CC (conical connection) implant interfaces between implant bridge and implant.

Indications for Use

The NobelProcera® Zirconia Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

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.

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.

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 Clinical 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 clinical/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.

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 that must be followed are stated below in Figures A – D and Table 1.

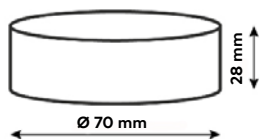


Figure A – Maximum Dimensions for Outer Shape

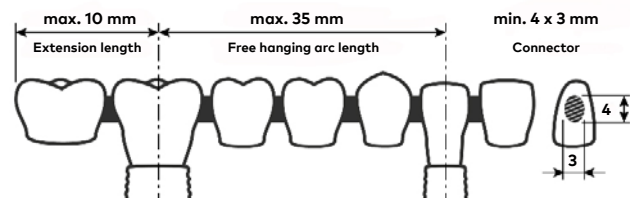


Figure B – Dimensional Requirements for Zirconia Implant Bridge

Note If the free hanging arc length is 21 mm or less, connector sizes may be as small as 4 x 2.5 mm.

Note A minimum material thickness of 0.4 mm is required.

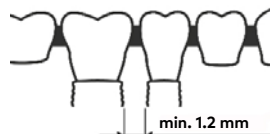


Figure C – Minimum Distance Between Implants

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

Table 1 – Divergence Angle per Platform

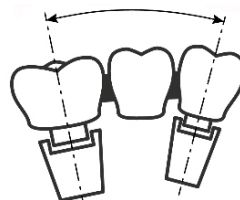


Figure D – Divergence Angle

- 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 and Multi-unit Abutment, the clinical/prosthetic 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 $10.5-11 \times 10^{-6} \text{ K}^{-1}$) 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 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/prosthetic 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/prosthetic 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.

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 2 – Tightening Torque and Compatible Screwdriver

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.
- Clinical Metal Adapters: Titanium alloy 90% Ti, 6% Al, 4% V, according to ASTM F136.

- Clinical/Prosthetic 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 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

NobelProcera® Zirconia Implant Bridge and Metal Adapter Implant Bridge Clinical CC NP/RP/WP are 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 NobelProcera® Zirconia Implant Bridge and 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 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 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 for the Metal Adapter Implant Bridge Clinical CC or Minimum of 3 minutes neutralization with 0.1% neodisher Z for the NobelProcera® Zirconia Implant Bridge.
 - 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.

Note FDA-cleared washer- disinfectors are to be used for the recommended cleaning parameters.

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 30 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 / Neodisher Medizym ; 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 1 minute 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_{eff}) containing an 0.5% enzymatic cleaning agent (e.g., Cydezyme ASP / Neodisher Medizym) 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 30 seconds to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Note Neodisher Medizym was used in the validation of the NobelProcera® Zirconia Implant Bridge.

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 and/or Selectomat PL/669-2CL (pre-vacuum cycle); Amsco Century Sterilizer and/or Selectomat PL/669-2CL (gravity cycle).

Note When using Systec HX-320, Amsco Century Sterilizer, it is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches. When using Selectomat PL/669-2CL, it is recommended to perform sterilization with a maximum load of 2 containers with metal instruments and 2 packages of linen.

Note Sterilizer Selectomat PL/669-2CL was used in the validation of the NobelProcera® Zirconia Implant Bridge.

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 pouches.

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

Table 3 – Recommended Sterilization Pouches

Note Sterilization pouch Steriking pouch (Wipak) was used in the validation of the NobelProcera® Zirconia Implant Bridge.

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:
 - Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure, followed by drying for a minimum of 30 minutes in chamber.
 - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by drying for a minimum of 20 minutes in chamber.

Note FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

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.			

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
Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA

Caution Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

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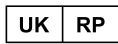
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Symbols Glossary

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 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



[symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com](https://symbol.glossary.nobelbiocare.com/ifu.nobelbiocare.com)

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