NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge and framework

Instructions for use

Important: Please read.

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, it is 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® HT ML (High Translucent Multi Layer) FCZ (full contour zirconia) Implant Bridge is an individualized full contour, implant supported screw-retained dental implant bridge manufactured from high translucent multi-layered zirconia, for the partially dentate and edentulous patients.

NobelProcera® HT ML (High Translucent Multi Layer) FCZ (full contour zirconia) Implant Bridge is available on Nobel Biocare's Internal Conical Connection, Internal Tri-Channel connection, External Hex connection and MUA (Multi-unit Abutments).

NobelProcera® HT ML (High Translucent Multi Layer) FCZ (full contour zirconia) Implant Bridge on Nobel Biocare's Internal Conical Connection comprises of clinical metal adapters and Omnigrip™ clinical screws which are delivered with the product. On MUA the prosthetic clinical screws are included with the product. For External Hex and Internal Tri-Channel Unigrip™ clinical screws are delivered with the product.

NobelProcera® HT ML (High Translucent Multi Layer) zirconia framework Implant Bridge is an individualized implant supported screw-retained dental implant bridge manufactured from high translucent multi-layered zirconia, for the partially dentate and edentulous patients.

NobelProcera® HT ML (High Translucent Multi Layer) zirconia framework Implant Bridge is available on Nobel Biocare's Internal Conical Connection, External Hex connection, Internal Tri-Channel connection and MUA (Multi-unit Abutments).

NobelProcera® HT ML (High Translucent Multi Layer) zirconia framework Implant Bridge on Internal Conical Connection comprises of clinical metal adapters and Omnigrip™ clinical screws which are delivered with the product. On MUA the prosthetic clinical screws are included with the product. For External Hex and Internal Tri-Channel the clinical screws are delivered with product.

Note: For Internal Conical Connection laboratory metal adapters and Omnigrip™ laboratory screws are available.

The NobelProcera® HT ML (High Translucent Multi Layer) Implant Bridge (FCZ and framework) is intended for patients missing several teeth – from 2 to 5 units. The design of the Zr (zirconia) Implant Bridge FCZ (full contour zirconia) and framework is determined in a dental laboratory, hospital or dental practice by scanning, designing and ordering the restoration using the NobelProcera® system (NobelDesign) or supported third party CAD systems. The restoration, once ordered is sent electronically to one of NobelProcera's centralized milling centers for fabrication.

A

Maximum tightening torques
Implant and MUA (Multi Unit Abutment) level

Clinical Screw	Nominal tightening torque
Implant level (clinical screw)	35 Ncm
MUA level (prosthetic screw)	15 Ncm

Intended use:

The NobelProcera® HT ML FCZ (full contour zirconia) and framework Implant Bridge 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 clinical screws and provides a platform for restoration.

The NobelProcera® HT ML FCZ (full contour zirconia) and framework Implant Bridge are designed and made individually to fit the individual requirements for the patient.

Clinical metal adapters are intended to be inserted into the zirconia implant bridge (FCZ and framework) to act as the interface for all CC (conical connection) implant interfaces between implant bridge and implant.

Laboratory metal adapters are intended to be inserted into the zirconia implant bridge (FCZ and framework) to act as the interface for all CC (conical connection) implant interfaces between implant bridge and implant replica, for laboratory use only.

Indications:

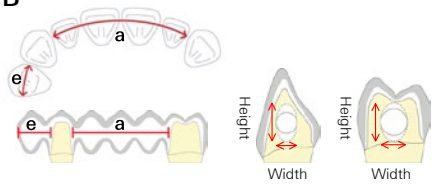
The NobelProcera® HT ML FCZ (full contour zirconia) and framework Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

Clinical metal adapters are indicated for long term clinical support of CC restorations (both FCZ and framework) as a connection between implant and zirconia.

Laboratory metal adapters are indicated for short term support of CC restorations (both FCZ and framework) as a connection between implant replica and zirconia during lab procedures.

The NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge and framework should be designed to fit into a bloc of 20.5 mm (height) x 16.8 mm (width) x 56 mm (length). The connector dimension of a multi-unit framework depends on the distance between the implant seats (see table below and illustrations under **B** illustrating and defining the minimum requirements that must be met).

B



B

Product constraints

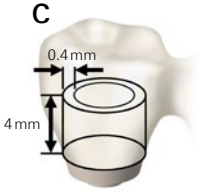
Type/position	Length [mm] a = Arc length e = Extension length	Minimum connector and cross section height x width (mm)/ ∅ (mm)
Free hanging arc, Any position	0.8 < a ≤ 21.0	4.0 x 2.5 / ∅ = 4.95
	21.0 < a ≤ 35.0	4.0 x 3.0 / ∅ = 5.95
Extension, Any position	e ≤ 10.0	

– A minimum material thickness of 0.4 mm from the seating surface for a height of 4 mm is required (**C**).

Generally the minimum zirconia material thickness supported is 0.4 mm.

Implant seats which are closer than 1.2 mm to each other cannot be produced.

C



Contraindications:

The NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge and NobelProcera® HT ML zirconia framework Implant Bridge are contraindicated in:

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

– Cases with lengths that exceed the maximum limits and minimum thickness as indicated.

– Patients who are allergic or hypersensitive to Zirconia – Yttria-stabilized tetragonal zirconia polycrystal (6 to 8Y-TZP), CP Titanium or Titanium alloy 90% Ti, 6% Al, 4% V.

It is contraindicated to use screws and screwdrivers different than indicated – Omnigrip™ for conical connection and Unigrip™ for all other connections.

It is contraindicated to use HT ML Implant Bridge without the clinical metal adapter on the conical connection interfaces.

NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge and framework on Internal Conical Connection, Internal Tri-Channel and External Hex with an implant divergence higher than 20° between all implants are contraindicated.

NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge and framework on MUA (Multi Unit Abutments) with an implant divergence higher than 40° between all implants are contraindicated.

If there is a mix between Implant level and MUA (Multi Unit Abutment) NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge and framework, an implant divergence higher than 20° between all implants is contraindicated.

It is contraindicated to use separating discs, sharp diamond-burs and/or anything causing sharp grooves and/or sharp edges on the NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge and framework.

It is contraindicated, to make any modifications to the seating area of the NobelProcera® HTML FCZ (full contour zirconia) Implant Bridge or the NobelProcera® HTML Implant Bridge framework or the metal adapters as this may affect/hinder its strength or fit.

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Warnings:

Do not use laboratory metal adapter or laboratory screw in patient.

Cautions:

General:

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

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Before surgery:

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

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

All instruments and tooling used in surgery 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.

After surgery:

To secure the long term treatment outcome the practitioner/clinician is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Handling procedures:

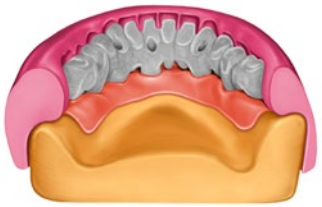
Clinical procedure:

Take a conventional impression using open or closed tray impression coping according to standard clinical procedures for restorative operations.

Laboratory procedure:

Fabricate a working model with removable gingival material following standard conventional laboratory procedures.

Fabricate a verification jig following standard conventional laboratory procedures.



Clinical procedure:

Verify using standard clinical procedures for restorative operations that the master model and patient's clinical situation are the same.

Laboratory procedure:

Select and carefully mount the appropriate model position locators onto the master model to facilitate the capturing of the correct depth and orientation of the implant into the front-end software, prior to designing the implant bridge.

Scan the definitive cast with pre-mounted model position locators using a NobelProcera® scanner (or an approved Nobel Biocare® System) and optionally the diagnostic tooth set-up, according to the tutorial found within the software.

Once scanned, open the relevant CAD module and design your implant bridge, following the instructions in the software tutorial, according to the patient's clinical needs.

Note: Ensure prior to scanning that the scanning position locators are seated flat and securely on the implant replicas.

Send scan and design data file to Nobel Biocare production facility.

Upon return check for precision of fit on the definitive cast.

Recommendations:

Regularly check scanning position locators for damage and imperfections under a loupe or microscope.

Confirm they fit properly onto the implant replicas.

Regularly inspect the threads for damage or cross-threading.

Clean position locators and replicas in ultrasonic unit and remove any foreign material (e.g. CAD spray, finger oils, stone chips/dust).

After receiving the NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge or NobelProcera® HT ML zirconia framework Implant Bridge from Nobel Biocare production facility:

Finishing procedure for NobelProcera® HT ML Implant Bridge framework:

If necessary, make minor adjustments using diamond impregnated finishing tools with fine grit size, under low pressure and using copious water irrigation.

When adjustments are made near to the connection (to implant/metal adapter) protection analogues must be utilized.

Adhere to minimum dimensions described above (illustrations **A**, **B** and **C**).

Apply dental ceramic compatible with zirconium oxide (within the CTE (coefficient thermal expansion) value of Zr material).

For long-term clinical success please follow the recommendations and handling instructions of the veneering material manufacturer.

Laboratory metal adapters (if applicable) and laboratory screws must be utilized in the dental lab only and not in patient.

Finishing procedure for NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge:

If necessary, make minor adjustments using diamond impregnated finishing tools with fine grit size under low pressure and using copious water irrigation.

Adhere to minimum dimensions described above (illustrations **A**, **B** and **C**).

Adequate polishing of occlusal surface must be done with any appropriate silicone polishing set intended for polishing zirconia occlusal surface.

The NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge is delivered to the laboratory in selected shade. Additional stains can be added to NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge to achieve the desired final color. Ceramic staining material compatible with zirconium oxide (within the CTE value of Zr material) can be used.

If desired, the FCZ Implant Bridge can be individualized using the cut back method. This is done by reducing the buccal surface. Check that no occluding surface is impacted prior to ordering the implant bridge from Nobel Biocare. After receiving the FCZ Implant Bridge from Nobel Biocare the reduced area is veneered with desired dental ceramics, compatible with zirconium oxide (within the CTE value of Zr material).

For long-term clinical success please follow the recommendations and handling instructions of the veneering material manufacturer.

Caution: Do not exceed the maximum firing temperature of 930°C/1706°F. Exceeding this guideline will result in the risk of material color change.

Fluorescent glaze to be applied prior standard firing procedures.

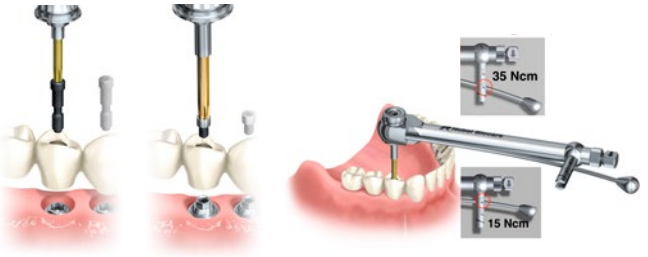
Clean in an ultrasonic unit.

Clinical procedure:

Seat the NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge or NobelProcera® HT ML zirconia framework Implant Bridge onto implants and carefully insert clinical screws and clinical metal adapter, if applicable. Using Manual Torque Wrench Prosthetic apply recommended screw tightening torque as described in Table **A**.

Seat NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge or NobelProcera® HT ML zirconia framework Implant Bridge onto Multi unit Abutments and carefully insert clinical prosthetic screws. Using Manual Torque Wrench Prosthetic apply recommended screw tightening torque (as described in Table **A**).

Caution: Never exceed **35 Ncm** prosthetic tightening torque for the clinical screw and **15 Ncm** for Multi-unit Abutment clinical prosthetic screw. Over tightening may lead to screw fracture and/or damage of the restoration and/or the implant/MUA.



It is recommended to verify the final NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge and/or NobelProcera® HT ML zirconia framework Implant Bridge seating using appropriate means.

Once the NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge or NobelProcera® HT ML zirconia framework Implant Bridge is installed, the defined torques applied and the seating of the product is verified, then use conventional procedures to seal the screw access hole.

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 (looses gloss), polish as described above.

Materials:

HT ML FCZ (full contour zirconia) Implant Bridge and framework zirconia: Yttria-stabilized tetragonal zirconia polycrystal (6 to 8Y-TZP).

Adapter for HT ML FCZ (full contour zirconia) Implant Bridge and framework (only on conical connection): Titanium alloy 90% Ti, 6% Al, 4% V.

Clinical and laboratory screws: Titanium alloy 90% Ti, 6% Al, 4% V, CP Ti.

Cleaning and sterilization instructions:

The NobelProcera® HT ML FCZ (full contour zirconia) Implant Bridge and NobelProcera® HT ML zirconia framework Implant Bridge including clinical metal adapter and clinical screw are delivered non-sterile for single use. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

The laboratory adapter and laboratory screw are delivered non-sterile and intended for re-use in the dental lab.

For USA: Seal single device in a pouch and steam sterilize at 270 °F, max 279 °F (132 °C, max 137 °C) for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132 °C–135 °C, max 137 °C (270 °F–275 °F, max 279 °F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134 °C–135 °C, max 137 °C (273 °F–275 °F, max 279 °F) for 3 minutes.

Full set of recommended parameters are provided in "Cleaning and Sterilization Guidelines including Magnetic Resonance Imaging Information of Nobel Biocare Products" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Warning: Do not use device if products or/and the packaging have been damaged.

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

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Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Clinical re-use could cause cross contamination. This is applicable for Implant Bridge (both FCZ and framework), clinical metal adapters and clinical screws.

Laboratory adapters and laboratory screws are reusable in the dental lab.

Magnetic Resonance (MR) safety information:

The device 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 the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage and handling:

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

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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CE 2797

Canada – License Exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription Device – Rx only
Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

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

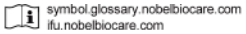

Double sterile barrier system

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

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