

NobelProcera® Full Contour Zirconia (FCZ) Implant Crown For Nobel Biocare Internal Conical Connection

Instructions for use



Important: Please read.

Disclaimer of liability:

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Description:

Nobel Biocare's FCZ Implant Crown is a customized, CAD/CAM manufactured crown to be placed on an endosseous dental implant. The FCZ Implant Crown is seated and attaches directly to the dental implants and functions as restoration so that no additional abutment is needed. The FCZ Implant Crown is designed and made individually to fulfill the clinical need of the patient. The FCZ Implant Crown is made out of translucent Zirconia, available in several shades, and is delivered with a titanium adapter and an Omnigrip™ clinical screw.

1 FCZ Implant Crown availability and (clinical) screw tightening torque

Connection	Platform	Ncm
Nobel Biocare Internal Conical Connection	NP	35
	RP	35
	WP	35

Important: NobelProcera® FCZ Implant Crown Zirconia and corresponding (clinical) Omnigrip™ screws require special Omnigrip™ screwdrivers.

Intended use:

The NobelProcera® FCZ Implant Crown is intended to be placed in the upper or lower jaw creating a prosthetic device (full contour crown), and to restore the patient's chewing function and esthetics. The NobelProcera® FCZ Implant Crown is individually designed and manufactured to fulfill the clinical need of the patient. The NobelProcera® FCZ Implant Crown is made out of Zirconia and is delivered with a titanium adapter and an Omnigrip™ clinical screw.

Indications:

The NobelProcera® Full Contour Implant Crown is a premanufactured prosthetic component directly connected to endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications:

Treatment of patients with high expected loading conditions of the FCZ Implant Crown, e.g. severe bruxism and / or patients which are known to have allergic reactions to any materials used during the procedure are contraindicated.

Cautions:

NobelProcera® FCZ Implant Crown NP is not recommended for posterior use.

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

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.

Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.

Operating instructions:

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.

Handling procedures:

Laboratory procedure:

Designing the FCZ Implant Crown

Wax-up design:

Scan and import clinical situation into the software:

- If optical wax is not used, the surface needs to be coated with a conventional optical scanning spray.
- Min. and max. constraints are enforced by the software.
- Max. outer constraints are diameter 20mm and a height of 20mm.

CAD design:

- To facilitate correct FCZ Implant Crown rotation, depth and angulation carefully insert an Abutment Position Locator into the Implant Replica.
- Scan and import clinical situation into software.
- Design FCZ Implant Crown.
- Min. and max. constraints are enforced by the software.
- Max. outer constraints are diameter 20mm and a height of 20mm.

Design recommendations:

Although the minimum design shape is controlled by the software the following is a list of basic design recommendations:

- Height max = 20mm & Diameter max 20mm.
- FCZ Implant Crown individual body angulation max 20 degree.

2 Design recommendations per connection type

Platform	Diameter min X mm at implant emergence tapering to Y mm above implant platform
NP	X = 3.9, Y = 3.3
RP	X = 4.3, Y = 3.1
WP	X = 4.7, Y = 3.1

Notes:

- Omnigrip™ Laboratory screws (identified by blue color-coding on entire screw) are available for temporary fixation of the FCZ Implant Crowns – used during the finalization of the restoration within the dental laboratory.

Laboratory finalizing procedures FCZ Implant Crowns:

- 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.
- Adequate polishing of occlusal surface shall be done with any appropriate silicone polishing set intended for polishing zirconia occlusal surface.
- The FCZ Implant Crown is delivered to the laboratory in selected shade. Additional stains can be added to the FCZ Implant Crown 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 Crown 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 crown from Nobel Biocare. After receiving the FCZ Implant Crown from Nobel Biocare this area is veneered with desired dental ceramics, compatible with zirconium oxide (within the CTE value of Zr material) can be used.
- Fluorescent glaze to be applied prior standard firing procedures.
- Clean in an ultrasonic unit.

Clinical procedure:

1. Ensure that adapter is securely attached to the FCZ Implant Crown, then insert the screw into the FCZ Implant Crown, and place the assembly onto the implant.

Notes:

- If adjustments are necessary: Make minor adjustments using diamond impregnated finishing tools with fine grit size, under low pressure and using copious water irrigation. Polish occlusal surface with any appropriate silicone polishing set intended for polishing zirconia occlusal surface.
 - Post placement of the FCZ Implant crown, if it is necessary to remove the restoration for whatever reason from its seating in the oral environment, it may occur that the abutment's metal adapter remains in the implant. If this is the case, the metal adapter can easily be removed with minimal force utilizing Nobel Biocare Abutment Retrieval Instrument Zirconia Conical Connection.
2. Tighten the FCZ Implant Crown with the indicated torque (refer to Table 1: FCZ Implant Crown availability and clinical screw tightening torque) using the Omnigrip™ Screwdriver and corresponding torque wrench. Over tightening may lead to damage of the device or early mechanical failure.
 3. It is recommended to verify the final FCZ Implant Crown seating using appropriate means.
 4. Once the FCZ Implant Crown is inserted into the implant, the defined torque applied and its seating verified 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.

Warning: Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.

Precautions/warning: The clinician is advised to provide regular patient follow up and to inform about good oral hygiene.

Caution: Never exceed **35 Ncm** prosthetic tightening torque for the abutment screw. Over tightening of abutment may lead to a screw fracture.

The FCZ Implant Crowns are delivered with Omnigrip™ screws (identified by blue color-coding on screw head) require the use of the Omnigrip™ screwdriver (identified by blue color-coding – blue ring on driver shaft). The Omnigrip™ screws and screwdriver are not compatible with the Unigrip™ system.

For additional information on restorative and dental laboratory procedures please consult the “Procedures & products” treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

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.

Materials:

FCZ Implant Crown: Yttria-stabilized Zirconium oxide. Adapter for FCZ Implant Crown: Titanium alloy 90% Ti, 6% Al, 4% V. Clinical screws: Titanium alloy 90% Ti, 6% Al, 4% V.

Cleaning and sterilization instructions:

This device is delivered non-sterile and must be cleaned and sterilized prior to use.

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

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

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

Full set of recommended parameters are provided in “Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products” available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

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

Caution: This is a single use product not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause cross contamination.

MRI safety information:

Please note that this product has not been tested for heating or migration in the MR environment.

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

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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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

Rx Only

For prescription use only



Health care centre or doctor



Keep away from sunlight



Keep dry

symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com

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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