

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



## 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

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.

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

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

**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.

## 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.

## 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](http://www.nobelbiocare.com).

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications.

## 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 20 mm and a height of 20 mm.

#### 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 20 mm and a height of 20 mm.

#### Design recommendations

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

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

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

Table 2 – Design recommendations per connection type

**Note** 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.

**Caution** If modifying the restoration, use copious irrigation and appropriate protection equipment. Avoid inhalation of dust.

**Note** 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.

**Note** 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 (loses 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 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 and 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](http://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.

## 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](http://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.

## Magnetic Resonance (MR) 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, Handling and Transportation

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.

# Manufacturer and Distributor Information

---

**Manufacturer**

Nobel Biocare AB  
PO Box 5190, 402 26  
Västra Hamngatan 1  
Göteborg  
411 17  
Sweden  
[www.nobelbiocare.com](http://www.nobelbiocare.com)

---

**CE Mark for Class IIa/IIb Devices**

---

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.

**Note** Refer to the product label to determine the applicable conformity marking for each device.

## Legal Statements

EN All rights reserved.

Nobel Biocare, the Nobel Biocare logotype and all other trademarks used in this document are, if nothing else is stated or is evident from the context in a certain case, trademarks of Nobel Biocare. Product images in this folder are not necessarily to scale. All product images are for illustration purposes only and may not be an exact representation of the product.

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