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 NobelProcera® FCZ Implant Crown is an individualized, CAD/CAM manufactured crown to be placed on an endosseous dental implant. The NobelProcera® 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. For information specific to the Omnigrip™ Clinical Screws CC NP/RP/WP and Adapters for Zirconia Abutment CC NP/RP/WP, refer to the Nobel Biocare Instructions for Use for the component (IFU1057 and IFU3008).

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 and corresponding Omnigrip™ Clinical Screws CC NP/RP/WP require Omnigrip™ screwdrivers.

Compatible implant Family	Available platform sizes
NobelActive	NP, RP, WP
NobelReplace Conical Connection	NP, RP
NobelReplace Conical Connection PMC	NP, RP
NobelParallel Conical Connection	NP, RP, WP
NobelActive TiUltra	NP, RP, WP
NobelParallel Conical Connection TiUltra	NP, RP, WP
NobelReplace Conical Connection TiUltra	NP, RP

Table 2 – Compatible implant families

	Product Family
Article Description	**NobelProcera® FCZ Implant Crown**
Implant replicas	Implant Replicas Conical Connection
Lab screws	Omnigrip™ Lab Screws CC
Screwdriver	Omnigrip™ Screwdrivers
Protection analogs	Protection Analogs Conical Connection
Abutment retrieval tools	Abutment Retrieval Instruments Zirconia CC

Table 3 – Additional compatible articles

Intended Use / Intended Purpose

The NobelProcera® FCZ Implant Crown is intended to be finalized into a single-unit dental prosthesis, which is connected to an endosseous dental implant to restore chewing function.

Indications

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

Contraindications

It is contraindicated to use NobelProcera® FCZ Implant Crown:

- in Patients who are medically unfit for an oral surgical procedure.
- in Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- in Patients with high expected loading conditions, e.g. parafunctional tendencies such as bruxism and clenching.
- in Patients who are allergic or hypersensitive to Zirconia - Yttria-stabilized tetragonal zirconia polycrystal (Y-TZP), Titanium alloy 90% Ti, 6% Al, 4% V, DLC (diamond like carbon) coating or PEEK.
- with a non-Nobel Biocare manufactured clinical screw.
- for lengths and thicknesses that do not fall within the indicated limits. Refer to the handling procedure for the design constraints.

For contraindications specific to the Omnigrip™ Clinical Screws CC NP/RP/WP and Adapters for Zirconia Abutment CC NP/RP/WP, refer to the Nobel Biocare Instructions for Use for the component (IFU1057 and IFU3008).

Materials

- FCZ Implant Crown: Yttria-stabilized Zirconium oxide according to ISO 13356.
- Adapter for FCZ Implant Crown: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
- Clinical screws: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and DLC (diamond like carbon) coating.

Cautions

General

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

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

NobelProcera® FCZ Implant Crown must only be used with compatible Nobel Biocare instruments and components. Use of instruments or components that are not intended to be used in combination with NobelProcera® FCZ Implant Crown can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method 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.

Before Surgery

Careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

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, 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 until the end of the juvenile 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

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

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).

After the implant installation, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

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.

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

NobelProcera® FCZ Implant Crown is to be used by dental health care professionals.

NobelProcera® FCZ Implant Crown is to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with NobelProcera® FCZ Implant Crown

NobelProcera® FCZ Implant Crown 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 NobelProcera® FCZ Implant Crown

The placement of this device is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, swelling.

During connection or removal of this device the pharyngeal (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 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.

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

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 4 – 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.

Caution Only use clinical screws manufactured by Nobel Biocare when seating the NobelProcera® FCZ Implant Crown. Do not use laboratory screws to seat the NobelProcera® FCZ Implant Crown. The laboratory screws must be utilized in the dental laboratory only and not in patient.

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.

Caution Never exceed the recommended prosthetic tightening torque given by the original manufacturer's Instruction for Use for the clinical screw. Over tightening may lead to screw fracture and/or damage of the restoration.

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.

Sterility and Reusability Information

Caution The NobelProcera® FCZ Implant Crown is delivered non-sterile and must be cleaned and then disinfected and/or sterilized prior to intraoral use following the procedures 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 Do not use device if the packaging has been damaged or previously opened.

The Clinical screw and the Adapter for FCZ Implant Crown are 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.

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

Refer to the following Nobel Biocare IFUs for information regarding the cleaning and sterilization procedures for these instruments:

Component	IFU Number
Clinical Screw	IFU1057
Adapter	IFU3008

Table 5 – Instruments with Cleaning/Sterilization Information in Other IFU

Caution The NobelProcera® FCZ Implant Crown 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.

Cleaning and Sterilization Instructions

Cleaning and sterilization instructions for NobelProcera® supra-constructions that include non-metallic materials, which require cleaning and disinfection and/or sterilization prior to patient contact.

Clean, disinfect, and sterilize the NobelProcera® FCZ Implant Crown according to the dental restorative material manufacturer's instructions prior to use.

Magnetic Resonance (MR) Safety Information

MRI Safety Information		
Non-clinical testing has demonstrated the NobelProcera® FCZ Implant Crown is 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 58.9 T/m (5,890 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	Inferior to the neck: 2.0 W/kg Superior to the neck: 0.5 W/kg	Inferior to the xyphoid: 2.0 W/kg Between the xyphoid and neck: 1.0 W/kg Superior to the neck: 0.4 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 1.9 cm from the devices or device assemblies when imaged in a 3T MRI system.	

Performance Requirements and Limitations

To achieve the desired performance, NobelProcera® FCZ Implant Crown 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 NobelProcera® FCZ Implant Crown, 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 Im/IIa/IIb Devices	UK CA 0086

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

Basic UDI-DI Information

Product	Basic UDI-DI Number
NobelProcera® FCZ Implant Crown	73327470000002106P

Legal Statements

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
					Rx only		symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	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	