

NobelProcera® Angulated Screw Channel Abutment Zirconia 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® ASC Abutment Zirconia is an individualized dental abutment. The abutment attaches directly to the endosseous dental implants and provides a platform for restoration. The NobelProcera® ASC Abutment Zirconia is designed and made individually to fit the individual requirements for each patient. The NobelProcera® ASC Abutment Zirconia is delivered with a titanium adapter and an Omnigrip[™] clinical screw.

Adapter for Zirconia Ab (CC) NP/RP/WP are inserted into the NobelProcera® ASC Abutment Zirconia to act as the interface for all CC (Conical Connection) implant interfaces.

 $\label{eq:table_table} Table 1-NobelProcera^{\otimes} Angulated Screw Channel (ASC) Abutment Zirconia availability and (clinical) screw tightening torque$

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

Important NobelProcera® ASC Abutment Zirconia and corresponding (clinical) Omnigrip™ screws require Omnigrip™ screwdrivers.

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to <u>ifu.nobelbiocare.com</u>.

Intended Use/Intended Purpose

Nobel Biocare's NobelProcera® ASC Abutment Zirconia is a customized dental abutment. The abutment is seated and attached directly to the endosseous dental implant and provides a platform for restoration. The NobelProcera® ASC Abutment Zirconia is individually designed and manufactured to fulfill the clinical need of each patient. The NobelProcera® ASC Abutment Zirconia is made out of Zirconia and is delivered with a titanium adapter and an Omnigrip™ clinical screw.

Indications

Adapter for Zirconia Ab CC NP: same as intended purpose.

The NobelProcera® Angulated Screw Channel Abutment 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, e.g. severe bruxism and/or patients, which are known to have allergic reactions to any materials used during the procedure are contraindicated.

Materials

- ASC Abutments Zirconia: Yttria-stabilized Zirconiumoxide.
- Adapter for ASC abutment: Titanium alloy 90% Ti, 6% Al, 4% V.
- Clinical screws: Titanium alloy 90% Ti, 6% Al, 4% V.

Cautions

 $\mathsf{NobelProcera}^{\otimes}\mathsf{ASC}$ Abutment Zirconia NP is not recommended for posterior use.

Intended Users and Patient Groups

NobelProcera® ASC Abutment Zirconia are to be used by dental health care professionals.

 $\mathsf{NobelProcera}^{\otimes}\mathsf{ASC}$ Abutment Zirconia are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Devices in the IFU

NobelProcera® ASC Abutment Zirconia are 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® ASC Abutment Zirconia

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 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

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 <u>www.nobelbiocare.com</u>.

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.

Instructions for dental laboratory

NobelProcera® CAD abutment design

Scan and import clinical situation into software:

- Select and carefully mount appropriate NobelProcera® abutment position locator to facilitate the correct depth and orientation of the implant into the frontend software, prior to designing the abutment.
- Scan the clinical situation and the abutment position locators using a NobelProcera[®] scanner (or an approved NobelProcera[®] System), according to the tutorial found within the software.
- Once scanned, open the abutment CAD module and design your abutment, follow the instructions in the software tutorial, according to the patient's clinical needs whilst ensuring to provide adequate support for veneering material or crown retention.
- When designing the abutment it is recommended to avoid designs where the margin height is higher than 4 mm in combination with abutment body angulations above 30 degrees.

NobelProcera® Wax-up abutment 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.
- Design abutment to provide adequate crown retention or support for veneering material.

Design recommendations

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

- Height min. = 4 mm above implant platform to allow sufficient prosthetic retention.
- Height max. = 20 mm and diameter max 20 mm.
- Max. outer constraints are diameter 16 mm and a height of 15 mm.
- Min and Max constraints are enforced by the software.
- Once abutment is designed, dispatch order to NobelProcera® production plant.

Please refer to Table 2 for further design recommendations.

Table 2 – Design recommendations for the angulation of Zirconia abutment

Recommended max angulation degree			
Margin height	Recommendation for max upper body angulation		
0 mm	59°		
1 mm	51°		
2 mm	44°		
3 mm	37°		
4 mm	31°		
5 mm	27°		
6 mm	24°		
7 mm	22°		
8 mm	19°		

Note Omnigrip[™] laboratory screws (identified by blue colorcoding on entire screw) are available for temporary fixation of the abutments – used during the finalization of the restoration within the dental laboratory.

Finalizing procedures NobelProcera® ASC Abutments Zirconia

- If necessary, make minor adjustments with diamond bur or flex disc with fine grit size under low pressure and with copious water irrigation.
- Proper surface finishing is mandatory if minor adjustments on the sintered frameworks were made.
- Sandblast using max. one bar of pressure utilizing 110 μm aluminum oxide, at an approximate distance of 10 mm.
- Clean in an ultrasonic unit.
- For single tooth screw-retained restorations it is possible to apply dental ceramics (veneering material) directly onto the abutment.

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

 If a cement retained crown or bridge is required, follow the current workflow for the separate fabrication of this restoration. Please refer to NobelProcera® Crown and Bridge Instructions For Use, and software tutorials, for the fabrication of this restoration.

Clinical procedure

1. Ensure that adapter is securely attached to the abutment, then insert the screw into the abutment, and place the assembly onto the implant. It is recommended to verify the final abutment seating using appropriate means.

Note Post placement of the abutment, if it is necessary to remove the abutment 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.

- Tighten the clinical screw in the abutment to 35 Ncm, using the corresponding Nobel Biocare torque wrench and Omnigrip[™] Screwdriver.
- 3. Once the abutment is inserted into the implant, its seating verified and the defined torque applied, using conventional procedures the screw access hole of the screw retained crown can be sealed. Alternatively, if a final crown or bridge is to be cemented conventional procedures are to be followed and any excess cement removed.

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 ASC Abutments 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. 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.

Sterility and Reusability Information

The Nobel Biocare's NobelProcera® ASC Abutment Zirconia 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.

The Clinical screw and the Adapter for ASC abutment NP/RP/WP 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 IFU for information regarding the cleaning and sterilization procedures for the Clinical Screw (Table 3):

Table 3 – Instruments with Cleaning/Sterilization Information in Other IFU

Component	IFU Number
Clinical Screw	IFU1057

Caution The NobelProcera® Angulated Screw Channel Abutments, Adapter for ASC abutment NP/RP/WP and clinical screws are single use products 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

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to <u>ifu.nobelbiocare.com</u>

Magnetic Resonance (MR) Safety Information

These products are fabricated from a metal material which can be affected by MR energy. For further information refer to Nobel Biocare publication **MRI Safety Information** by navigating to <u>ifu.nobelbiocare.com</u>

Performance Requirements and Limitations

To achieve the desired performance, the devices 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 the devices, 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 <u>www.nobelbiocare.com</u>.

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 <u>www.nobelbiocare.com</u>
UK Responsible Person	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 TEE 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.

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

Basic UDI-DI Information

 Product
 Basic UDI-DI Number

 NobelProcera® Angulated Screw Channel Abutment Zirconia
 7332747000001677F

 Adapter for Zirconia Abutments
 74000001677F

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

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to <u>ifu.nobelbiocare.com</u>