NobelProcera® Angulated Screw Channel Abutment Zirconia For Nobel Biocare Internal Conical Connection

Instructions for use

Important: Please read.

Disclaimer of liability:
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Description:

Nobel Biocare's NobelProcera® ASC Abutment Zirconia is a customized 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 made out of Zirconia and is delivered with a titanium adapter and an Omnigrip™ clinical screw.

1 NobelProcera® 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 special Omnigrip™ screwdrivers.

Intended use:

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:

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.

Caution:

NobelProcera® ASC Abutment Zirconia NP is not recommended for posterior use.

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.

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 front-end 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.

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 color-coding 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.

2. 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.

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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 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 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:

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.

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 that must not 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.

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

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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