### NobelProcera® and Procera® Abutment Titanium and Zirconia

**Instructions for use**

**Important:** Please read.

**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, it is 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:**

A individuated dental implant abutment directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitation. The NobelProcera®/Procera® Abutment is designed and made individually to fit the individual requirements for each patient.

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<th>Connection</th>
<th>Platform</th>
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<td>Zirconia r x h</td>
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* Zirconia solution consists of Zirconia body and a small titanium insert (MZ adapter) with implant interface that is cemented into zirconia component.

**Only available Zr ASC (Angulated Screw Channel).**

**Intended use:**

- Nobel Biocare’s NobelProcera®/Procera® Abutment Titanium/Zirconia is a customized dental abutment. The abutment attaches directly to the endosseous dental implant with a clinical screw and provides a platform for restoration.

- The NobelProcera®/Procera® Abutment Titanium/Zirconia is designed and made individually to fit the individual requirements for each patient.

- The NobelProcera®/Procera® Abutment Titanium/Zirconia is made out of Titanium/Zirconia and selected Zirconia abutments are delivered with a Titanium adapter.

**Indications:**

Nobel Biocare’s NobelProcera®/Procera® Abutment Titanium/Zirconia is indicated for the treatment of partially edentulous patients requiring prosthetic devices and/or endosseous implants to restore chewing function.

**Contraindications:**

- Treatment of patients with high expected loading conditions of the implant crown, e.g. severe bruxism and/or patients.

NobelProcera® and Procera® Abutment full zirconia for NobelActive®, NobelReplace® CC and NobelParallel® CC implants are not indicated for posterior use.

NobelProcera® Abutment Conical Connection 3.0 and NobelProcera® Abutment Camlog 3.3 are contraindicated to use in other positions than for lateral incisors in the maxilis or central and/or lateral incisors in the mandible.

- NobelProcera® Abutment Conical Connection 3.0 is not to be used for multiple unit restorations.

- This product is contra-indicated for patients who are allergic or hypersensitive surgical grade titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium) (Ti6Al4V ELI) in accordance to ASTM F136.

- This product is contra-indicated for patients who are allergic or hypersensitive to Yttria-stabilized Zirconiumoxide (Y-TZP).

**Cautions:**

Nobel Procera® Abutment Zirconia NP is not recommended for posterior use.

- Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene. All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumention does not damage implants or other components.

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 bisphosphate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

Never exceed the recommended maximum prosthetic tightening torque for the abutment screw (see clinical procedure). Overtightening of abutment may lead to a screw fracture. Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

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 procedure:**

**Clinical procedure:**

**Impression taking:**

1. Take a conventional open or closed tray impression, following the implant manufacturers and the impression material manufacturers guidelines. Alternatively, take an intra-oral scan following the manufacturer’s guidelines of the implant.

2. Send the physical or digital impression to the laboratory.

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**Laboratory procedure:**

1. Conventional model fabrication from an impression: Assemble the impression coping to a working model with removable gingival material.

2. Scan and import/import the clinical situation into the software using a NobelProcera® Scanner (or an approved NobelProcera® System), according to the tutorial found within the software.
If desktop scanner is used:
   2A. NobelProcera®/Procera® Abutment:
      – Select and carefully mount the appropriate abutment position locator to facilitate the correct depth and orientation of the implant into the NobelProcera® (or a NobelProcera® approved software), prior to designing the abutment (A).
   If desktop or intra-oral scanner is used:
      – Once imported, open the relevant CAD module and design your restoration, follow the instruction in the software tutorial, according to the patient’s clinical needs whilst ensuring to provide adequate support for veneering material or crown/bridge retention.
      – Send scan data file to Nobel Biocare production facility by clicking on the order button in the software.

If desktop scanner is used:
2B. NobelProcera®/Procera® Wax-up Abutment:
   – Wax-up the abutment to provide adequate retention/ support for the veneering material (veneering material is cemented directly onto the abutment).
   – Carefully mount the wax-up abutment onto the wax-up platform and place into the NobelProcera® (or a NobelProcera® approved) scanner prior to designing the abutment.
   – Once imported, open the relevant CAD module and design your restoration, follow the instruction in the software tutorial, according to the patient’s clinical needs whilst ensuring to provide adequate support for veneering material or crown/bridge retention.
   – Send scan data file to Nobel Biocare production facility by clicking on the order button in the software.

Note: If optical wax is not used – the surface needs to be coated with a conventional optical scanning spray.

3. Upon return check for precision of fit on the definitive model.
4A. NobelProcera®/Procera® Abutment Zirconia:
   – If necessary, make minor adjustments using diamond impregnated finishing tools with fine grit size under low pressure and using copious water irrigation.
   – Proper surface finishing is mandatory if minor adjustments on the sintered abutment were made.
   – Sandblast using max. one bar of pressure utilizing 110 μm aluminum oxide.

4B. NobelProcera®/Procera® Abutment Titanium:
   – If necessary, make minor adjustments, with a carbide bur. Rubber wheels are recommended to be used for the collar part.
   Caution: For CADwax-up designed abutments the maximum abutment dimensions specified in Table 1 must be followed.
   Caution: When designing/preparing NobelProcera®/Procera® Abutment Zirconia, make sure that the thickness of the ceramic material is at least 0.9 mm. This thickness limit is applicable up to a height of 3 mm above implant level (B).
   Caution: For NobelProcera®/Procera® Abutment Conical Connection NVP/1P, never modify the area of the abutment marked in dark (shown C). Do not modify the abutment below the dimensions shown (C).
   Design Constraints:
      – Height min = 4 mm above implant platform to allow sufficient prosthetic retention.
      – Height max = 15 mm.
      – Diameter min = 4.4 mm at implant emergence tapering to 2.8 mm and 1.9 mm above implant platform.
      – Diameter max = 16 mm.
      – Angulation = max. angulation 20 degrees.

5. For single tooth screw retained restorations, it is possible to apply dental ceramics (veneering material) directly onto the abutment.
   If a cement retained crown or bridge is required, follow the current workflow for the separate fabrication of this restoration. Please refer to NobelProcera® Instructions for Use Crown & Bridge and software tutorials, for the fabrication of this restoration.
   Thereafter clean in ultrasonic unit.
   Apply veneering material directly onto the coping or bridge following the veneering material manufacturers guidelines.

Applicable for: NobelProcera® Straumann Bone Level, Straumann Std/Std Plus and Astra Tech Abutment Zirconia
Procedure: Cementation of MZ adapter to zirconia abutment
   – To facilitate the mounting, mark the position of the lobs on the implant connection before bonding (G).
   – Gently sandblast the retention area of the MZ adapter and the zirconia abutment (H) using max 0.2 bar pressure utilizing 50 – 110 μm aluminum oxide.

6. Connect the abutment onto the implant (D). It is recommended the original implant manufacturers prosthetic tooling and torque are applied to the screw.
For NobelProcera®/Procera® Abutments the abutment should be torqued to 35 Ncm using Unigrip™ Machine Screwdriver and Manual Torque Wrench Preshoc (E), except for Conical Connection 3.0 where the abutment should be torqued to 15 Ncm (refer to Table 2).
Caution: For all NobelProcera®/Procera® Abutments never exceed 35 Ncm prosthetic tightening torque apart from Conical Connection 3.0 never exceed 15 Ncm tightening torque for the clinical screw.
Caution: Always use current instructions from corresponding implant supplier regarding torque and tools.

Cleaning and sterilization instructions:
This device is delivered non-sterile for single use 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–136°C (273°F–278°F) for 3 minutes.
Full set of recommended parameters are provided in “Cleansing & 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.
Waring: 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 device has not been evaluated for safety and compatibility in the MR environment. This device 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.
Manufacturer: Nobel Biocare AB, Box 5190, 402 26 Västra Hamngatan 1, 411 17 Göteborg, Sweden.
Phone: +46 31 81 88 00. Fax: +46 31 16 31 52. www.nobelbiocare.com

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.

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