Procera® Esthetic Abutment
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, 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:

A premanufactured dental implant abutment directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

Internal conical connection for: NobelActive®, NobelReplace® CC and NobelParallel™ CC.

Internal tri-channel connection for: NobelReplace®, Replace Select™ and NobelSpeedy® Replace.

External hex connection for: Brånemark System® and NobelSpeedy® Groovy.

Intended use:

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. The abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructions.

Indications:

Procera® Esthetic Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Procera® Esthetic Abutment Conical Connection is indicated for anterior use.

Contraindications:

Procera® Esthetic Abutment Conical Connection is not indicated for posterior use.

Procera® Esthetic Abutment is contraindicated for patients:

– who are medically unfit for an oral surgical procedure.

– in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.

– allergic or hypersensitiv to zirconia or titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium).

Cautions:

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 instrumentation 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 bisphosphonate 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 **35 Ncm** prosthetic tightening torque for the abutment screw. 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.

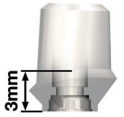
Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

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

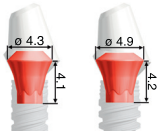
Handling instructions:

Modifications of abutments should be performed using copious water irrigation: Extra-oral modification of abutment is recommended. Use high-speed turbine and a fine diamond drill.

Note: When modifying the abutment, make sure that the thickness of the material is at least 0.9 mm up to a height of 3 mm above the implant level.



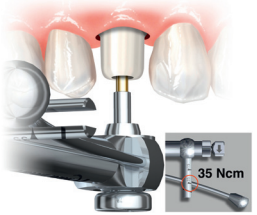
Note: For Procera® Esthetic Abutment Conical Connection; never modify the area of the abutment marked in red, minimum allowed dimension shown.



Clinical procedure:

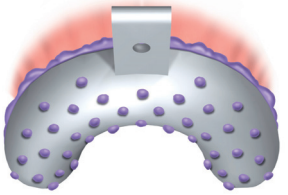
1. Select appropriate abutment and check occlusal clearance.
2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment to **35 Ncm** using Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic (**A**).

A



4. Modify the abutment if necessary using copious irrigation.
5. Take a standard impression (**B**).

B

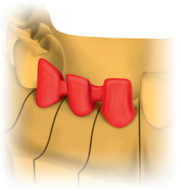


6. Provisionalize after sealing the access hole. Make sure there is no excess cement.

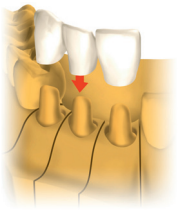
Laboratory procedure:

7. Produce a working model with removable gingival material.
8. Fabricate a crown or bridge with NobelProcera® technique or with conventional casting technique (**C+D**).

C



D



9. Veneer the crown or bridge if applicable.

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Clinical procedure:

10. Remove temporary restoration if applicable.
11. Use the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic to verify the tightening of the abutment to **35 Ncm**.
12. Cement the final crown or bridge using conventional procedures after sealing of access hole (**E**). Make sure there is no excess cement.

E

Caution: Do not use temporary cement when cementing ceramic crowns and bridges due to increased risk of micro fractures.

Materials:

Procera® Esthetic Abutment: Zirconia (zirconium oxide).
Abutment screw: Titanium alloy 90% Ti, 6% Al, 4%V.

Cleaning and sterilization instructions:

Procera® Esthetic Abutment is delivered non-sterile for single use and must be cleaned and sterilized prior to use.

Warning: Use of non-sterile components 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.

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.

MR Safety Information:

Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

For additional information on Magnetic Resonance Imaging, please consult the "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.

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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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.

CE 0086

Rx Only

Consult instructions for use

Use-by date

Do not re-use

LOT

Batch code

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