Esthetic Abutment
Instructions for use

Important: Please read.

Disclaimer of liability:
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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.

Plastic Temporary Copings are available for Esthetic Abutment for Internal tri-channel connection and External hex connection.

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:

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.

Esthetic Abutment Conical Connection 3.0 is indicated for use in the treatment of missing maxillary lateral incisors or in the mandibular central and lateral incisors.

Contraindications:

It is contraindicated to use Esthetic Abutment Conical Connection 3.0 in other positions than for lateral incisors in the maxilla or central and/or lateral incisors in the mandible.

Esthetic Abutment Conical Connection 3.0 is not to be used for multiple unit restorations.

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 commercially pure titanium, titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium) or polycarbonate.

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 (**15 Ncm** for NobelActive® 3.0). 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:

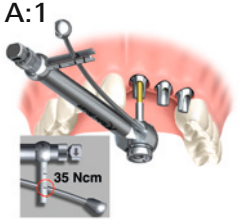
Modifications of abutments could be performed using copious water irrigation. Extra-oral modification of abutment is recommended.

Use a carborundum disk and carbide bur.

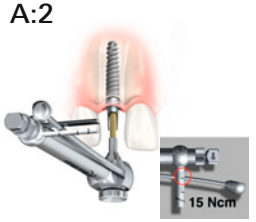
Clinical procedure:

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, except for Esthetic Abutment Conical Connection 3.0, to **35 Ncm** using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (**A:1**). For Esthetic Abutment Conical Connection 3.0 tighten abutment to **15 Ncm** using screwdriver and wrench as described above (**A:2**).

A:1



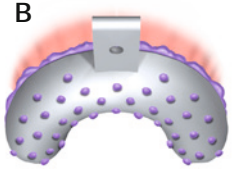
A:2



Caution: For Esthetic Abutment Conical Connection 3.0. Never exceed **15 Ncm** prosthetic tightening torque for the abutment screw. Over tightening of abutment may lead to a screw fracture.

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. A plastic temporary coping could be used.

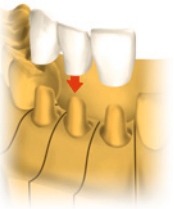
Caution: Do not use Plastic Temporary coping with polyurethane cements. The cement will not cure.

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**). For Esthetic Abutment the plastic copings could be used as burn-out patterns (**E**).

C

D



E

9. Veneer the crown or framework if applicable.

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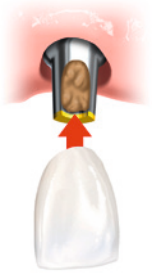
Clinical procedure:

10. Remove temporary restoration if applicable.
11. Use the Unigrip™ Screwdriver and Manual Torque Wrench prosthetic to verify the tightening of the abutment. For Esthetic Abutment Conical Connection 3.0 tighten to **15 Ncm** (**A:2**) and for the other Esthetic Abutments tighten to **35 Ncm** (**A:1**).
12. Cement the final crown or framework using conventional procedures after sealing of access hole (**F**). Make sure there is no excess cement.

F



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

Materials:

Esthetic Abutment for implants with External hex connection: Commercially pure titanium.

Esthetic Abutment for implants with Internal conical connection and Internal tri-channel connection: Titanium alloy 90% Ti, 6% Al, 4%V.

Abutment screw: Titanium alloy 90% Ti, 6% Al, 4%V.

Plastic coping: Polycarbonate.

Cleaning and sterilization instructions:

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:

Note: Only the Conical Connection Wide Platform abutments have been assessed as MR Conditional. The other platforms and sizes have not been evaluated for safety and compatibility in the MR environment and have not been tested for heating or migration in the MR environment.

Non-clinical testing has demonstrated that the product is MR conditional. A patient with this device can be safely scanned in a MR system meeting the following conditions:

– Static magnetic field of 1.5-Tesla and 3-Tesla only.

– Maximum spatial gradient magnetic field of 4000 Gauss/cm or less (40 T/m).

– Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

Under the scan conditions defined above, the product is expected to produce a maximum temperature rise of 4.1° C after 15 minutes of continous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 30 mm from the product when imaged with a gradient echo pulse sequence a 3 Tesla MRI system.

Should there be no MR symbol on the product label, 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.

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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Rx Only

MR
Magnetic resonance conditional

Consult instructions for use

Do not re-use

LOT
Batch code

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