

Narrow Profile 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.

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 Narrow Profile Abutments in combination with endosseous implants are indicated for single unit cement retained crowns when space is limited.

Indications:

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

Narrow Profile Abutment Conical Connection 3.0 is indicated for use in the treatment of missing single maxillary lateral incisor or in the mandibular central and lateral incisor.

Contraindications:

Narrow Profile Abutment is not to be used for multiple unit restorations.

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

Narrow Profile 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 hypersensitive to 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 (**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.

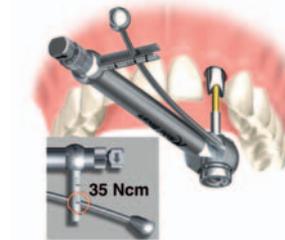
Use a carborundum disk and carbide bur.

Clinical procedure:

1. Connect and tighten the abutment and check for occlusal clearance. It is recommended to verify the final abutment seating using radiographic imaging.
2. Tighten the abutment, except for Narrow Profile Abutment Conical Connection 3.0, to **35 Ncm** using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (**A:1**). For Narrow Profile Abutment Conical Connection 3.0 tighten abutment to **15 Ncm** using screwdriver and wrench described above (**A:2**).

Caution: For Narrow Profile 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.

A:1

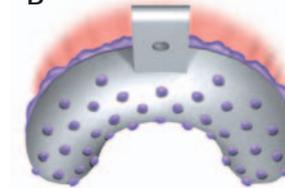


A:2



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

B



5. Provisionalize after sealing the access hole (**E**). Make sure there is no excess cement.

Laboratory procedure:

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

C



D



8. Veneer the crown if applicable.

Clinical procedure:

9. Remove temporary restoration if applicable.
10. Use the Unigrip™ Screwdriver and Manual Torque Wrench prosthetic to verify the tightening of the abutment. For Narrow Profile Abutment Conical Connection 3.0 tighten to **15Ncm** and for the other Narrow Profile Abutments tighten to **35Ncm (A:1 and A:2)**.
11. Cement the final crown 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 due to increased risk of micro fractures.

Materials:

Narrow Profile Abutment and Abutment Screw: Titanium alloy 90% Ti, 6% Al, 4%V.

Cleaning and sterilization instructions:

Narrow Profile 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



Do not re-use



Batch code

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