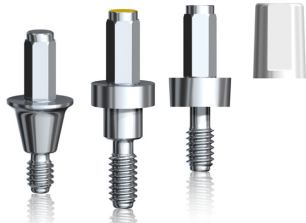


Immediate Temporary Abutment

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.

The Immediate Temporary Abutment comes co-packed with a temporary plastic coping. 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 Immediate Temporary Abutments in combination with endosseous implants are indicated for single unit cement retained temporary restorations.

Indications:

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

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

Contraindications:

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

Immediate Temporary 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) 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.

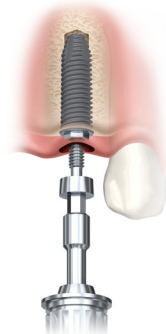
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Handling instructions:

Clinical procedure:

1. Connect appropriate abutments (A) and check occlusal clearance.

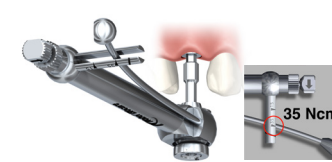
A



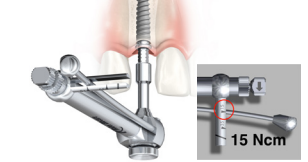
2. Tighten the abutment, except for Immediate Temporary Abutment Conical Connection 3.0, to **35 Ncm** using Screwdriver Machine Multi-Unit and Manual Torque Wrench prosthetic. (B:1)

For Immediate Temporary Abutment Conical Connection 3.0 tighten abutment to **15 Ncm** using Machined Multi-Unit screwdriver and wrench as described above. (B:2)

B:1

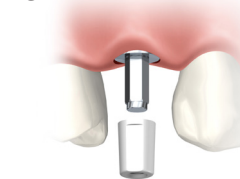


B:2



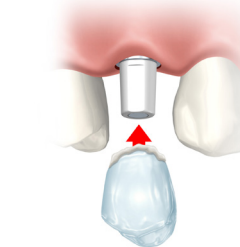
3. Adjust the height of the abutment post if applicable using copious irrigation.
4. Try in plastic coping and check occlusal clearance (C). If abutment post height has been adjusted, perform corresponding adjustment also on the plastic coping.

C



5. Fabricate a chair side temporary crown with usual methods.
6. Cement temporary crown (D). Remove any excess cement.

D



Caution: Do not use plastic temporary coping with polyurethane cements. The cement will not cure.

7. Check occlusion.

Materials:

Immediate Temporary Abutment: Titanium alloy 90% Ti, 6% Al, 4%V.
Plastic coping: Polycarbonate.

Cleaning and sterilization instructions:

Immediate Temporary Abutment is delivered sterile and for single use only prior to the labeled expiration date.

Warning: Do not use device if the packaging has been damaged or previously opened.

Caution: Immediate Temporary Abutment is a single use product not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

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 for Nobel Biocare Products including MRI Information" 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.

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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