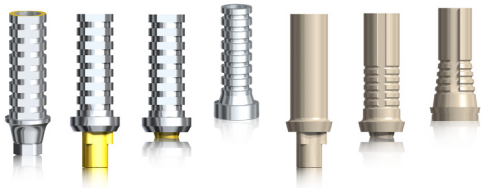
Temporary Abutment Titanium and Plastic, Engaging/Non-Engaging, Temporary Snap Coping Multi-unit Titanium and Temporary Coping Multi-unit Plastic/Titanium

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 or on Multi-unit Abutment/Plus level intended for use as a temporary aid in prosthetic rehabilitation.

Temporary Abutment Titanium Engaging, Temporary Abutment Titanium Non-Engaging:
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.

Temporary Abutment Plastic Engaging, Temporary Abutment Plastic Non-Engaging:
Internal tri-channel connection for: NobelReplace®, Replace Select™ and NobelSpeedy® Replace.

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

Temporary Coping Multi-unit Titanium
For Multi-unit Abutment

Temporary Coping Multi-unit Plastic
For Multi-unit Abutment and Multi-unit Abutment Plus

Temporary Snap Coping Multi-unit Titanium
For Multi-unit Abutment Plus

Note:
Clinical screws are not included with Temporary Abutment Plastic Engaging or Non-engaging nor is Prosthetic screw included with Temporary Coping Plastic.

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.

Indications:

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

The Temporary Abutments and Copings in combination with endosseous implants are indicated for single unit to multiple units screw retained temporary restorations.

Temporary Abutment Engaging Titanium and Plastic are indicated for single unit screw-retained temporary restorations.

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

Temporary Abutment Non-Engaging Titanium and Plastic are indicated for screw-retained multiple temporary restorations, for implants with less than 40° overall divergences to allow path of insertion.

Temporary Snap Coping Multi-unit Titanium, Temporary Coping Multi-unit Titanium and Plastic are indicated for screw retained Multi-unit abutments intended for multiple unit temporary restorations.

The use of Temporary Abutments and Temporary Copings made from plastic is limited to 90 days. For the use of Temporary Abutment Titanium no specific time limit applies.

Contraindications:

It is contraindicated to use Temporary Abutment Engaging Conical Connection 3.0 in other positions then for lateral incisors in the maxilla or central and/or lateral incisors in the mandible. Temporary Abutment Engaging Conical Connection 3.0 is not to be used for multiple unit restorations.

Temporary Abutments and Copings are 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 commercially pure titanium, titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium) or polyetheretherketone (PEEK).

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 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 sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is recommended to use a rubber dam in order to prevent inhalation of loose parts.

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..

The use of Temporary Snap Coping Multi-unit Titanium is limited to 180 days.

Handling instructions:

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

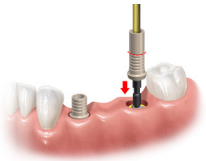
Use a carborundum disk and carbide bur.

Clinical procedure (Chair-side made provisionals):

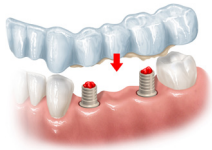
Illustration series illustrates implant level abutments.

1. Connect the Temporary Abutment/Coping (**A**) to the implant and modify the abutment if necessary using copious irrigation.
   Note: Until the Temporary Snap Coping Multi-unit Titanium is secured with the Prosthetic Screw, care should be exercised that the Temporary Snap Coping Multi-unit does not detach from the Multi-unit Abutment Plus (e.g. through pressure from the tongue).
2. Close the screw access hole.
3. Make a temporary restoration using a pre-fabricated mold with suitable temporary crown and bridge material (**B**).

A

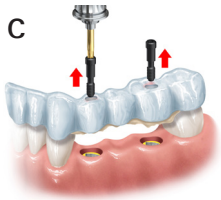


B



4. Drill a hole through the mold, loosen the screw(s) using a Unigrip™ Screwdriver and remove the restoration (**C**).
5. Make final adjustments (**D**).

C



D

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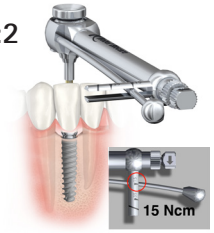
6. Connect the temporary restoration using a Unigrip™ Screwdriver (**E**).

E

Temporary Abutment Titanium: Tighten abutment, except for Conical Connection 3.0, to **35 Ncm** using Unigrip™ Machine Screwdriver and Manual Torque Wrench Prosthetic (**F:1**). For Conical Connection 3.0 tighten abutment to **15 Ncm** using screwdriver and wrench described above (**F:2**).

F:1

F:2



Caution: For 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.

Temporary Snap Coping Titanium: Tighten to **15 Ncm** using Unigrip™ Machine Screwdriver and Manual Torque Wrench Prosthetic.

Temporary Abutment Plastic and Temporary Coping Plastic: Manual tightening only using a Unigrip™ Screwdriver.

Laboratory procedure (laboratory made provisionals):

Laboratory receives an implant or abutment level impression from the clinician.

1. Assemble the impression coping and implant or abutment replica and carefully reposition into the impression.
2. Fabricate a working model with removable gingival material.

Follow step 1–5 from the "Clinical procedure (chair-side made provisionals)" to fabricate a single or multiple unit provisional restoration.

Additional laboratory use (NobelProcera® restoration):

The Temporary Abutment Titanium Engaging/Non-Engaging and Plastic Engaging/Non-Engaging can also be used as a component onto which the dental technician applies wax/pattern resin material to fabricate a diagnostic representation of the framework which he/she desires to receive back as a NobelProcera® CAD/CAM product. To obtain this NobelProcera® CAD/CAM restoration, place this wax-up framework into the Nobel-Procera® or an approved scanner and follow the CAD system software tutorial.

1. Use Temporary Abutment Engaging for NobelProcera® CAD/CAM abutment fabrication.
2. Use Temporary Abutment Non-Engaging or Temporary Coping – for NobelProcera® CAD/CAM implant bridge fabrication.

Materials:

Temporary Abutment Titanium for implants with External hex connection and Internal tri-channel connection: Commercially pure titanium.

Temporary Abutment Titanium for implants with Internal conical connection: Titanium alloy 90% Ti, 6% Al, 4%V.

Temporary Snap Coping Multi-unit Titanium and Temporary Coping Multi-unit Titanium: Commercially pure titanium.

Temporary Abutment Plastic and Temporary Coping Plastic: Polyetheretherketone (PEEK).

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

Cleaning and sterilization:

All temporary abutments and temporary copings are 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.

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

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.

Magnetic Resonance (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.

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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.

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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.

EC REP Authorized representative in the European Community	LOT Batch code	REF Catalogue number	Caution
CE marking	Consult instructions for use	Contains hazardous substances	PHT DEHP 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	
MR Magnetic resonance conditional	Manufacturer	MD Medical device	Non-pyrogenic
NON STERILE Non-sterile	Patient identification	Patient information website	Patient number
SN Serial number	Single sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside

STERILE EO Sterilized using ethylene oxide	STERILE R Sterilized using irradiation	Temperature limit	Tooth number
Upper limit of temperature	STERILE Sterilized using steam or dry heat	UDI Unique Device Identifier	Use-by date

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