NobelGuide® Guided 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, it is 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:

Guided Abutment
An expandable titanium abutment with a titanium screw with Unigrip™ fitting, which is to be placed in the guided titanium temporary coping of the pre-made prosthetic reconstruction and fitted onto the installed implants in the mouth of the patient.

The guided titanium temporary coping, embedded in the prosthetic reconstruction together with the guided abutment allow for a little play in order to make the prosthetic reconstruction fit. This space is filled when the guided abutment expands during the tightening of the screw, firmly anchoring the prosthetic reconstruction to the implant.

Guided Abutment Brånemark System
The Guided Abutment Brånemark System is compatible with Brånemark System® and NobelSpeedy® Groovy implants.

Guided Abutment NobelReplace
The Guided Abutment NobelReplace is compatible with NobelReplace® Tapered, Replace Select™ Tapered, NobelReplace® Straight and Replace Select™ Straight implants.

The Guided Abutment comes with a co-packed abutment screw.

Guided Titanium Temporary Coping
The Guided Titanium Temporary Coping is used as a standardized interface between the Guided Abutment, which fits into the interior geometry of the Guided Titanium Temporary Coping, and the prosthetic reconstruction. The Guided Titanium Temporary Coping is intended to be embedded into either a temporary prosthesis or into a bridge design model to be used in the production of a Procera Implant Bridge.

Intended use:

The NobelGuide® guided surgery system is intended to transfer a treatment planning done by the clinician into a physical/clinical reality. The system is intended to facilitate implant installation with high predictability and contribute to better restoration of these implants placed in both mandible and maxilla.

Indications:

The guided surgery concept is indicated for the treatment of edentulous and partially edentulous jaws (including patients missing a single tooth) for placement of implant fixtures, if indicated in combination with immediate function to restore esthetics and functionality (e.g. masticatory, speech). The following prerequisites must be fulfilled:

– Adequate amount jawbone.
– The quality of jawbone must be judged as adequate.
– Adequate mouth opening (minimum 40 mm) to accommodate guided surgery tooling.
– Exclusion of compromised diseases in conflict with dental implant treatment.
– Adequate compliance.

Contraindications:

It is contraindicated to use Guided Abutments and Guided Titanium Temporary Coping in:

– Patients who are medically unfit for an oral surgical procedure.
– Patients with inadequate bone volume unless an augmentation procedure can be performed.
– Patients in whom adequate sizes, numbers or desirable position of implants are not achieved to provide safe support of functional or eventually parafunctional loads.
– Patients who are allergic or hypersensitive to titanium alloy 90% Ti, 6% Al, 4% V, CP titanium or silicone rubber.
– The specific Guided Abutments are not to be used on implants which are not compatible with the specific Guided Abutment implant interface.

Cautions:

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

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 information please visit www.nobelbiocare.com.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

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.

Pre-operative hard tissue or soft tissue defects may yield a compromised esthetic result or unfavorable implant angulations.

All instruments and tooling used during procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient.

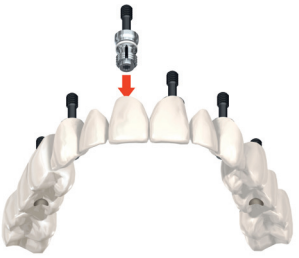
To secure the long term treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Handling procedure:

Clinical procedure:

1. Place the appropriate Guided Abutment into the titanium cylinder of the pre-made prosthesis (**A**).

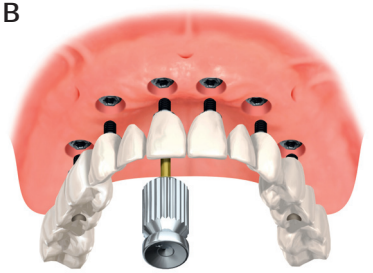
A



2. Insert the prosthesis (**B**) into the patient's mouth and tighten the Guided Abutment screws by alternating between the left and right side. Finally tighten the abutment screw to **35 Ncm** using Screwdriver Machine Unigrip™ and Manual Torque Wrench Prosthetic.

Caution: Never exceed the recommended maximum **35 Ncm**-tightening torque for the abutment screw. Overtightening of abutment screws my lead to a screw fracture.

B



3. Close screw access channel using conventional techniques.

Caution: Ensure abutment screw is re-tighten to **35 Ncm** using Screwdriver Machine Unigrip™ and Manual Torque Wrench Prosthetic in the event the prosthesis is removed during recall or maintenance.

Materials:

Guided Abutment: Titanium alloy 90% Ti, 6% Al, 4% V and silicone rubber.

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

Guided Titanium Temporary Coping: CP Titanium.

Cleaning and sterilization instructions:

The Guided Abutment is delivered sterile for single use only. Do not use after the labeled expiration date.

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

Caution: The Guided Abutment is a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross contamination.

The Guided Titanium Temporary Coping is delivered non-sterile for single use only. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Caution: The Guided Titanium Temporary Coping is a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.

Clean the device using manual or automated cleaning, disinfect and dry the device following instructions in Cleaning and Sterilization Guidelines available at www.nobelbiocare.com/sterilization.

Inspect and seal the single device in a pouch and steam sterilize, both the gravity cycle (saturated steam) and pre-vacuum (forced air removal) cycle can be applied, using the following parameters:

For USA: Steam sterilization 270°F (132°C) for 4 minutes when using pre-vacuum method and 15 minutes when using the gravity method. Dry for 20 to 30 minutes when using pre-vacuum method and 15 to 30 minutes when using the gravity method.

For outside USA: Temperature 132°C (270°F), max 137°C (279°F) for 3 minutes (up to 20 minutes). Dry for 10 minutes in chamber.

Alternative UK: Temperature 134°C (273°F), max 137°C (279°F) for 3 minutes (up to 20 minutes). Dry for 10 minutes in chamber.

Magnetic resonance (MR) safety information:

The Guided Abutment and the Guided Titanium Temporary Coping have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Guided Abutment and of the Guided Titanium Temporary Coping in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage, handling and transportation:

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation 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 (United States) law restricts this device to sale by or on the order of a clinician, medical professional or physician.

CE 0086

Rx Only

Sterilized using irradiation

Non-sterile

Do not resterilize


Caution


Consult instructions for use


Use-by date


Do not re-use

Batch code


Do not use if package is damaged

Catalogue number

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