Temporary Snap Abutment, Engaging/Non-Engaging
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 a temporary aid in prosthetic rehabilitation.

Temporary Snap Abutment Engaging, Temporary Snap Abutment Non-Engaging: Internal conical connection for: NobelActive®, NobelReplace® CC and NobelParallel™ CC.

Intended use:

Temporary Snap Abutments are endosseous dental implant abutments that are designed for single use as a temporary prosthesis during the healing process while the permanent prosthesis is fabricated.

Indications:

The Temporary Snap Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Temporary Snap Abutment can be used for cement retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the Temporary Snap Abutment is not to exceed one hundred and eighty (180) days.

Contraindications:

Temporary Snap Abutments 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).

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 know ledge and experience. For more information, 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.

Temporary Snap Abutments shall be taken out of occlusion and should not be used for full-arch restorations.

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 to shorten the abutment. Minimum height is 4 mm (figure **1**). An angular correction of the abutment or any further adjustments should not be conducted.

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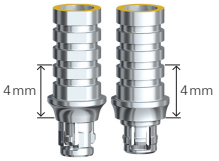

Clinical procedure (Chair-side made provisionals):

1. Connect the Temporary Snap Abutment to the implant and modify the abutment if necessary using copious irrigation.
2. Close the screw access hole.
3. Make a temporary restoration using a pre-fabricated mold with suitable temporary crown and bridge material.
4. Drill a hole through the mold, loosen the screw(s) using a Unigrip™ Screwdriver and remove the restoration.
5. Make final adjustments.
6. Connect the temporary restoration using a Unigrip™ Screwdriver.
7. Tighten abutment to **35 Ncm** using Unigrip™ Machine Screwdriver and Manual Torque Wrench Prosthetic.

Warning: Over tightening of abutment may lead to a screw fracture.

Materials:

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

Cleaning and sterilization:

Temporary Snap Abutments 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.

Manual cleaning, disinfection and drying:
1. Remove debris in lukewarm water and immerse devices in cleaning solution.
2. Scrub with soft bristled nylon brush.
3. Immerse in ultrasonic bath.
4. Rinse and flush with purified or sterile water.
5. Immerse in disinfection solution.
6. Flush internal channels/lumina with disinfection solution.
7. Rinse and flush with purified or sterile water.
8. Dry with compressed air or wipes.

Automated cleaning, disinfection and drying (incl. pre-cleaning):
1. Remove debris in lukewarm water and immerse devices in cleaning solution.
2. Scrub with soft bristled nylon brush.
3. Rinse with tap water.
4. Load devices into thermodisinfector.
5. Run cleaning and disinfection cycle.
6. Run drying cycle.
7. Dry with compressed air or wipes if needed.

Seal single device in a pouch and steam sterilize at 270°F (132°C) for 4 minutes.

Note: FDA cleared sterilization accessories are to be used for the recommended sterilization parameters for wrapping the device supplied non-sterile before user sterilization.

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Method	Moist heat sterilization	
Cycle	Pre-vacuum	Gravity
Temperature	270°F (132°C)	
Exposure time	4 minutes	15 minutes
Pre-vacuum	3 times < 60 mbar	N/A
Drying time	20–30 minutes	15–30 minutes
Cooling time	10 minutes at room temperature	

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Magnetic Resonance (MR) safety information:

The Temporary Snap Abutment has 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 the Temporary Snap Abutment in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage and handling:

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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CE 2797

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

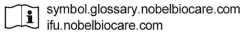

Double sterile barrier system

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



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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