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 and Temporary Snap Abutment Non-Engaging can be used with internal conical connection implants NobelActive®, NobelReplace® CC and NobelParallel™ CC.

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 Snap Abutment Engaging is indicated for single unit screw-retained temporary restorations.

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

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 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 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 info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. NobelBiocare 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 Abutments is limited to 180 days.

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

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):

1. Connect the Temporary Snap Abutment to the implant and modify the abutment if necessary using copious irrigation.
   Note: Until the Temporary Snap Abutment is secured with the abutment screw, care should be exercised that the Temporary Snap Abutment does not detach from the Implant (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.
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. It is recommended to verify the final seating using radiographic imaging.
   Warning: Over tightening of abutment screw may lead to a screw fracture.

Materials:

Temporary Snap Abutment Engaging and Non-Engaging: Titanium alloy 90% Ti, 6% Al, 4%V.

Cleaning and sterilization:

Temporary Snap Abutment 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 components may lead to infection of tissues or infectious diseases.

Caution: Temporary Snap 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.

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

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:

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 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

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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.

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

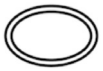
Date

Date of manufacture

Do not resterilize

Do not re-use

Do not use if package is damaged



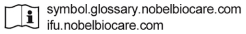
Double sterile barrier system

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

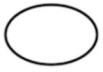
Non-sterile

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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