Temporary Abutments and Copings

Important – 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

Temporary abutments and copings are premanufactured dental implant abutments which can be connected to an endosseous dental implant or dental implant abutment to support the placement of a temporary dental prosthesis.

An assortment of temporary abutments and copings are available for use with various Nobel Biocare implant systems.

Temporary Snap Abutments Engaging

– Temporary Snap Abutments Engaging Conical Connection are available in NP/RP/WP platforms and feature a conical connection.

Temporary Abutments Engaging

– Temporary Abutments Engaging Conical Connection are available in 3.0/NP/RP/WP platforms and feature a conical connection.

– Temporary Abutments Nobel Biocare N1™ TCC are available in NP/RP platforms and feature a tri-oval conical connection.

– Temporary Abutments Engaging NobelReplace® are available in NP/RP/WP/6.0 platform and feature an internal tri-channel connection.

– Temporary Abutments Engaging Brånemark System® are available in NP/RP/WP platforms and feature an external hex connection.

Temporary Abutments Non-Engaging

– Temporary Abutments Non-Engaging Conical Connection are available in NP/RP/WP platforms and feature a conical connection.

– Temporary Abutments Non-Engaging NobelReplace® are available in NP/RP/WP/6.0 platform and feature an internal tri-channel connection.

– Temporary Abutments Non-Engaging Brånemark System® are available in NP/RP/WP platforms and feature an external hex connection.

Slim Temporary Abutments

– Slim Temporary Abutments Conical Connection are available in 3.0, NP and RP platforms and feature a conical connection.

Temporary Abutments Anatomical PEEK

– Temporary Abutments Anatomical PEEK Conical Connection are available in WP platform and feature a conical connection.

Temporary Copings Multi-unit and Temporary Snap Copings Multi-unit

– Temporary Snap Copings Multi-unit Titanium are available for Nobel Biocare's Multi-unit Abutments which feature conical connection and/or tri-oval conical connection.

– Temporary Coping Multi-unit are available for Nobel Biocare's Multi-unit Abutments which feature external hex connection and/or internal tri-channel connection.

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

Temporary Abutments Engaging, Temporary Abutments Non-Engaging, Temporary Abutments Anatomical PEEK and Temporary Copings Multi-unit are co-packed with a clinical screw. Refer to Nobel Biocare Instructions for Use (IFU) IFU1057 for information regarding clinical screws. This IFU is available for download at ifu.nobelbiocare.com.

Intended Use/Intended Purpose

Temporary Abutments and Copings

Intended to be connected to an endosseous dental implant to support the placement of a temporary dental prosthesis.

Indications

Temporary Snap Abutments Engaging

Temporary Snap Abutments Engaging are indicated for use with single unit screw-retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days.

Temporary Abutments Engaging

Temporary Abutments Engaging are indicated for use with single unit screw-retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days.

The Temporary Abutment Conical Connection 3.0 is indicated for use with single-unit screw- retained dental prosthesis placed on endosseous dental implants in the lateral incisors in the maxilla, or in the central and/or lateral incisors in the mandible.

Temporary Abutments Non-Engaging

The Temporary Abutment Non-Engaging is indicated for use with multiple unit screw-retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days.

Slim Temporary Abutments

Slim Temporary Abutments are indicated for use with single-unit cement-retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible in the anterior and pre-molar region, for up to 365 days.

Temporary Abutments Anatomical PEEK

Temporary Abutments Anatomical PEEK are indicated for use with single-unit and multiple-unit cement-retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days.

Temporary Copings Multi-unit and Temporary Snap Copings Multi-unit

Temporary/Snap Copings Multi-unit are indicated for use with screw-retained multiple-unit temporary dental prostheses which are placed on Nobel Biocare's Multi-unit Abutments in the maxilla and mandible, for up to 180 days.

Contraindications

It is contraindicated to use temporary abutments and copings in:

– Patients who are medically unfit for an oral surgical procedure.

– Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.

– Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium), DLC (Diamond Like Carbon) or PEEK (Polyetheretherketone).

It is contraindicated to use Slim Temporary Abutments Conical Connection as a base for provisional crowns in the molar region.

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

It is contraindicated to use the Temporary Abutment Conical Connection 3.0 for multiple unit restorations.

Materials

– Temporary Snap Abutments Engaging Conical Connection, Temporary Abutment Engaging Conical Connection, Temporary Abutments Nobel Biocare N1™ TCC, Temporary Abutments Engaging NobelReplace®, Temporary Abutments Engaging Brånemark System®, Temporary Abutments Non-Engaging Conical Connection, Temporary Abutments Non-Engaging NobelReplace®, Temporary Abutments Non-Engaging Brånemark System®, Slim Temporary Abutments Conical Connection, Temporary Snap Copings Multi-unit, and Temporary Copings Multi-unit: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.

– Temporary Abutments Anatomical PEEK: PEEK (Polyetheretherketone).

– Clinical screw: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 with DLC (Diamond Like Carbon) coating.Warnings

Cautions

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

Nobel Biocare surgical instruments and prosthetic components must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Nobel Biocare surgical instruments and prosthetic components can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

It is especially important to achieve proper stress distribution through adaptation and fitting of the crown or bridge by adjusting occlusion to the opposing jaw. In addition, avoid excessive transverse loading forces, particularly in immediate loading cases.

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

Before Surgery

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

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

The device has not been evaluated in pediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended for pediatric patients until the end of the jawbone growth phase has been properly documented.

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, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

At Surgery

Small diameter implants and angled abutments are not recommended for the posterior region.

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. gauze, dental dam, or throat shield).

Never exceed the recommended maximum tightening torque for the clinical/prosthetic screw. Overtightening of abutment may lead to a screw fracture.

After Surgery

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

Intended Users and Patient Groups

Temporary abutments and copings are to be used by dental health care professionals.

Temporary abutments and copings are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Devices in the IFU

Temporary abutments and copings are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with Temporary Abutments and Copings

The placement of these devices is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, and swelling. During abutment placement or removal, the pharyngeal reflex (gag reflex) may be triggered in patients with a sensitive gag reflex.

Temporary abutments and copings are part of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to those associated with teeth, such as retained cement, calculus, mucositis, ulcera, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the Temporary abutments and copings. The SSCP can be obtained at the following website:
ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED)

Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Handling Procedure

Handling Procedure for Temporary Snap Abutments Engaging and Temporary Abutments Engaging/ Non-Engaging

1. Connect the temporary abutment to the implant and check the post height. Modify the abutment if necessary, outside of the patient's mouth. Do not modify the abutment seating area.

Note Temporary abutments should only be exposed to limited occlusal forces by taking the temporary restoration out of the occlusion.

2. After modifying the abutment, it must be cleaned and sterilized prior to further intraoral use, following the instructions in the Cleaning and Sterilization Instructions section.

3. Re-connect the abutment to the implant using the clinical screw and block the screw access hole. For temporary snap abutments, use the snap feature to engage the abutment into the implant.

4. Make a temporary restoration using a pre-fabricated mold with a suitable temporary restoration material, following the instructions by the material manufacturer.

5. For temporary snap abutments: remove the temporary restoration by pulling the crown. Connect the abutment with the restoration to the dedicated protection analog and use the apical drill to create the screw access hole.

6. For temporary abutments without snap feature: drill a hole through the mold, loosen the screw(s) using a dedicated screwdriver and remove the restoration.

7. Make final adjustments to the restoration. Protect the abutment connection while making adjustments using dedicated instruments.

8. Connect the temporary restoration to the implant using the clinical screw and appropriate screwdriver according to Table 1. Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the screwdrivers.

9. Tighten the restoration to the required torque according to Table 1, using the appropriate screwdriver and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare Instructions for Use (IFU) IFU1098 for information regarding the Manual Torque Wrench Prosthetic.

10. It is recommended to verify the final seating using radiographic imaging.

Caution Never exceed the recommended maximum tightening torque for the abutment screw. Overtightening of the abutment may lead to a screw fracture.

11. Block the screw access hole using suitable material, before closing it with composite.

12. If removal of the temporary restoration is needed, open the screw access and untighten the screw using the appropriate screwdriver.

If the abutment cannot be removed, use the Abutment Retrieval Tool. Refer to Nobel Biocare Instructions for Use (IFU) IFU1096 for information regarding Abutment Retrieval Tool.

Note For processing of the temporary restoration in the dental laboratory, a dedicated laboratory screw should be used.

Handling Procedure for Slim Temporary Abutments

1. Connect Slim Temporary Abutment to the implant and check occlusal clearance.

Note Temporary abutments should only be exposed to limited occlusal forces by taking the temporary restoration out of the occlusion.

2. Tighten the abutment to 15 Ncm using the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1085 for information regarding the screwdrivers. Refer to Nobel Biocare IFU1098 for information regarding the torque wrench.

Caution Never exceed 15 Ncm prosthetic tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture (for CC 3.0 and Slim Temporary Abutment).

3. Fabricate a chair side temporary crown.

4. Cement temporary crown onto the slim temporary abutment. If appropriate, splinting to the neighboring teeth can be considered.

5. Remove excess cement.

Handling Procedure for Temporary Abutments Anatomical PEEK

1. Connect the temporary abutment to the implant and check the post height. Modify the abutment if necessary, outside of the patient mouth.

Note Temporary abutments should only be exposed to limited occlusal forces by taking the temporary restoration out of the occlusion.

2. After modifying the abutment, it must be cleaned and sterilized prior to further intraoral use, following the instructions in the Cleaning and Sterilization Instructions section.

3. Cut a small axial flat or groove into the provisional abutment to assist in correct location during cementation.

4. Fabricate a provisional crown/bridge in conventional manner.

5. Contour margins and polish modified area.

6. Tighten the PEEK Temporary Abutment to 35 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1085 for information regarding the screwdrivers. Refer to Nobel Biocare IFU1098 for information regarding the torque wrench.

7. Cement temporary crown/bridge onto the abutment.

8. Remove excess cement.

Handling Procedure for Temporary/Snap Copings Multi-unit

1. Connect the temporary/snap coping to the Multi-unit Abutment and modify it if necessary, using copious irrigation.

Note Until the Temporary/Snap Coping is secured with the Prosthetic Screw, care should be exercised that it does not detach from the Multi-unit Abutment (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 Unigrip™ Screwdriver and remove the restoration. Refer to Nobel Biocare IFU1085 for information regarding the screwdriver.

5. Make final adjustments.

6. Connect and tighten the temporary restoration to 15 Ncm using a Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare IFU1098 for information regarding the torque wrench.

Note If the restoration on Temporary Snap Copings Multi-unit Abutment is cemented, temporary cement should be used.

Sterility and Reusability Information

Temporary Abutments Nobel Biocare N1™ TCC, Slim Temporary Abutments, and Temporary Abutments Anatomical PEEK have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

Warning Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

Temporary Snap Abutments Engaging Conical Connection, Temporary Abutment Engaging Conical Connection, Temporary Abutments Engaging NobelReplace®, Temporary Abutments Engaging Brånemark System®, Temporary Abutments Non-Engaging Conical Connection, Temporary Abutments Non-Engaging NobelReplace®, Temporary Abutments Non-Engaging Brånemark System®, Temporary Snap Copings Multi-unit, and Temporary Coping Multi-unit are delivered non-sterile for single use only. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Caution Temporary abutments and copings are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Note Temporary Snap Abutments Engaging Conical Connection, Temporary Abutment Engaging Conical Connection, Temporary Abutments Nobel Biocare N1™ TCC, Temporary Abutments Engaging NobelReplace®, Temporary Abutments Engaging Brånemark System®, Temporary Abutments Non-Engaging Conical Connection, Temporary Abutments Non-Engaging NobelReplace®, Temporary Abutments Non-Engaging Brånemark System®, and Temporary Abutments Anatomical PEEK Conical Connection must be cleaned and sterilized after performing any modifications to the abutment as described in the Handling Procedure.

Cleaning and Sterilization Instructions

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

Magnetic Resonance (MR) Safety Information

These products are fabricated from a metal material which can be affected by MR energy. For further information refer to Nobel Biocare publication **Magnetic Resonance (MR) Safety Information** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with the devices, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

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

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information

Manufacturer	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
UK Responsible Person UK RP	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
CE Mark for Class IIb Devices	CE 2797
UKCA Mark for Class IIb Devices	UK CA 0086

Note Refer to the product label to determine the applicable conformity marking for each device.

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

Basic UDI-DI Information

Product	Basic UDI-DI Number
Temporary Snap Abutments Engaging CC NP/RP/WP	733274700000017278
Temporary Abutments Engaging CC 3.0/NP/RP/WP	
Temporary Abutments Non-Engaging CC NP/RP/WP	
Temporary Abutments Nobel Biocare N1™ TCC NP/RP	
Temporary Abutments Engaging/Non-Engaging NobelReplace® NP/RP/WP/6.0	
Temporary Abutments Engaging/Non-Engaging Brånemark System® NP/RP/WP	
Slim Temporary Abutments Conical Connection NP/RP/3.0	
Temporary Abutments Anatomical PEEK CC WP	
Temporary Snap Copings Multi-unit	733274700000017278
Temporary Copings Multi-unit	
Temporary Copings Multi-unit Bmk WP	

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.