Temporary Abutments and Copings

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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, feature a conical connection and can be used with Nobel Biocare's NobelActive®, NobelParallel™ CC and/or NobelReplace® CC implant systems.

Temporary Abutments Engaging

– Temporary Abutment Engaging Conical Connection 3.0 is available in the 3.0 platform, features a conical connection and can be used with Nobel Biocare's NobelActive® implant system.

– Temporary Abutments Nobel Biocare N1™ TCC are available in NP/RP platforms and feature a tri-oval conical connection and can be used with Nobel Biocare's Nobel Biocare N1™ implant system.

– Temporary Abutments Engaging NobelReplace® are available in NP/RP/WP and 6.0 platform, feature an internal tri-channel connection and can be used with Nobel Biocare's NobelReplace®, Replace Select™ and/or NobelSpeedy® Replace™ implant systems.

– Temporary Abutments Engaging Brånemark System® are available in NP/RP/WP platforms, feature an external hex connection and can be used with Nobel Biocare's Brånemark System® and/or NobelSpeedy® Groovy® implant systems.

Temporary Abutments Non-Engaging

– Temporary Abutments Non-Engaging Conical Connection are available in NP/RP/WP platforms, feature a conical connection and can be used with Nobel Biocare's NobelActive®, NobelParallel™ CC and/or NobelReplace® CC implant systems.

– Temporary Abutments Non-Engaging NobelReplace® are available in NP/RP/WP and 6.0 platform, feature an internal tri-channel connection and can be used with Nobel Biocare's NobelReplace®, Replace Select™ and/or NobelSpeedy® Replace implant systems.

– Temporary Abutments Non-Engaging Brånemark System® are available in NP/RP/WP platforms, feature an external hex connection and can be used with Nobel Biocare's Brånemark System® and/or NobelSpeedy® Groovy® implant systems.

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.

Temporary Abutments Anatomical PEEK

– Temporary Abutments Anatomical PEEK Conical Connection are available in WP platform, feature a conical connection and can be used with Nobel Biocare's NobelActive® and/or NobelParallel™ CC implant systems.

– The following tables summarize the implant platforms which are compatible with the various temporary abutments and copings, including the specifications for tightening torque, required screwdrivers, and other key information for each type of temporary abutment and coping, based on their connection type.

Table 1 – Temporary Snap Abutments Engaging, Temporary Abutments Engaging/ Non-Engaging – Torque Specifications

Temporary Abutment for	Available Platforms	Tightening Torque
Conical connection (CC)	3.0	15 Ncm
	NP RP WP	35 Ncm
Tri-oval conical connection (TCC)	NP RP	20 Ncm
Tri-channel	NP RP WP 6.0	35 Ncm
External Hex	NP RP WP	35 Ncm

Table 2 – Temporary Abutments Anatomical PEEK – Torque Specifications

Temporary Abutment Anatomical PEEK for	Tightening torque
Conical connection (CC)	35Ncm

Table 3 – Temporary Copings Multi-unit and Temporary Snap Copings Multi-unit – Torque Specifications

Temporary coping	Tightening torque
Temporary Snap Coping Multi-unit	15 Ncm
Temporary Coping Multi-unit	
Temporary Coping Multi-unit Bmk WP	

Temporary Snap Abutments Engaging, Temporary Abutments Engaging, Temporary Abutments Non-Engaging and Temporary/ Snap Copings Multi-unit, Temporary Abutments Anatomical PEEK 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.

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.

Intended Use

Temporary Abutments and Copings

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

The PEEK Temporary Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. It is indicated for single and multiple unit cement retained temporary restorations.

Indications for Use

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

Temporary Coping Multi-unit Titanium is indicated for screw retained Multi-unit abutments intended for multiple unit temporary restorations.

For Temporary Abutment Titanium and Temporary Coping Titanium no specific time limit applies.

Temporary Abutments Nobel Biocare N1™ TCC 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 Nobel Biocare anatomical PEEK Temporary Abutments are premanufactured, adjustable prosthetic components directly connected to endosseous dental implants and are intended for temporary use up to 180 days as an aid in prosthetic rehabilitation.

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 static and dynamic loads.

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

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 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®, 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.

– Anatomical PEEK Healing and Temporary Abutment:
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.

Cautions

General 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.

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 jaw bone growth phase has been properly documented.

In general, implant placement and prosthetic design must accommodate individual patient conditions.

In the case of bruxism, other parafunctional habits, or unfavorable jaw relationships, reappraisal of the treatment option or appropriate pre- and post-treatment measures may be considered.

At Surgery

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, a dental dam, or throat shields).

Never exceed the recommended maximum tightening torque for the clinical/prosthetic screw. Overtightening of the 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.

Handling Procedure

Handling Procedure for Temporary Abutments Engaging/Non-Engaging

1. Connect the Temporary Abutment to the implant using the appropriate screwdriver according to Table 1 and check the post height. Modify the abutment, if necessary, outside of the patient's mouth. Do not modify the abutment seating area.

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 the 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.

9. Tighten the restoration to the required torque according to Table 1, using the appropriate screwdriver and the Manual Torque Wrench Prosthetic. Refer to Nobel Biocare Instructions for Use (IFU) IFU1047 for information regarding the Manual Torque Wrench Prosthetic.

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.

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.

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

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

12. If the abutment cannot be removed, use the Abutment Retrieval Tool. Refer to Nobel Biocare Instructions for Use (IFU) IFU1041 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 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.

5. Make final adjustments.

6. Connect and tighten the temporary restoration to 15 Ncm using a Unigrip™ Screwdriver and Manual Torque Wrench prosthetic.

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

Handling procedure PEEK Temporary Abutment

The Nobel Biocare Anatomical PEEK Temporary Abutment may be used for cement retained provisional restorations.

1. Select appropriate temporary abutment. Height may be adjusted by use of a rotary instrument (e.g. carbide or acrylic bur).

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

3. Construct a provisional crown/bridge in conventional manner. It is important to remove and replace the provisional crown/bridge at least once prior to final setting of the restorative material to avoid difficulty in removing the crown/bridge once the restorative material has set.

4. Contour margins and polish modified area.

5. Tighten the PEEK Temporary Abutment to 35 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic.

Cement provisional crown/bridge onto PEEK Abutment with preferred temporary cement. Care should be taken to ensure that all excess cement is completely removed.

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 and Temporary Coping 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 NobelProcera® 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.

Sterility and Reusability Information

Temporary Abutments Nobel Biocare N1™ TCC and PEEK Temporary abutments 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 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 Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

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 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® 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 **MRI Safety Information** by navigating to ifu.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

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Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA

Caution Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

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.