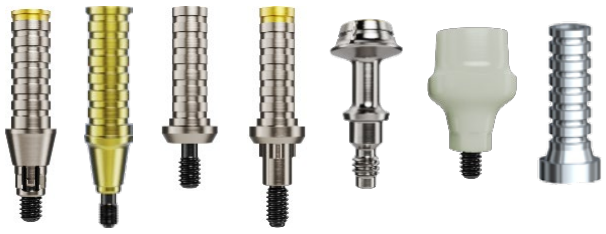
Temporary Abutments and Copings



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Description

Temporary abutments and copings are pre-manufactured 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 Abutments Engaging Conical Connection are available in 3.0/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 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.

Healing Abutment for	Available platforms	Engaging	Non-engaging	Color coding	Available margin heights	Tightening torque	Screwdriver
Conical Connection (CC)	3.0	X	–	None	1.5 mm	15 Ncm	Unigrip™
	NP	X	X	●	1.5 mm 3.0 mm	35 Ncm	
	RP	X	X	●			
	WP	X	X	●			
Tri-oval Conical Connection (TCC)	NP	X	–	● (screw)	1.5 mm 3.0 mm	20 Ncm	Omnigrip™ Mini
	RP	X	–	● (screw)			
Tri-channel	NP	X	X	●	1.5 mm	35 Ncm	Unigrip™
	RP	X	X	●			
	WP	X	X	●			
	6.0	X	X	●			
External Hex	NP	X	X	None	1.5 mm	35 Ncm	Unigrip™
	RP	X	X	None			
	WP	X	X	None			

Table 1 – Temporary Snap Abutments Engaging and Temporary Abutments Engaging/Non-Engaging – Compatible Implant Platforms, Screwdrivers, and Torque Specifications

Slim Temporary Abutments

– Slim Temporary Abutments Conical Connection are available in 3.0, NP and RP platforms, feature a conical connection and can be used with Nobel Biocare's NobelActive®, NobelParallel™ CC and/or NobelReplace® CC implant systems.

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.

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.

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.

Slim Healing Abutment for	Available platforms	Color coding	Available post heights	Tightening torque	Screwdriver
Conical connection (CC)	3.0	None	6.5 mm 7.5 mm	15 Ncm	Unigrip™
	NP	●	6.5 mm 7.5 mm		
	RP	●	6.5 mm 7.5 mm		

Table 2 – Slim Temporary Abutments – Compatible Implant Platforms, Screwdrivers, and Torque Specifications

Temporary Abutment Anatomical PEEK for	Available platforms	Color coding	Available sizes	Tightening torque	Screwdriver
Conical connection (CC)	WP	None	6 x 7 mm 7 x 8 mm	35 Ncm	Unigrip™

Table 3 – Temporary Abutments Anatomical PEEK – Compatible Implant Platforms, Screwdrivers, and Torque Specifications

Temporary coping	MUA connection/platform	Color coding	Tightening torque	Screwdriver
Temporary Snap Coping Multi-unit	CC / NP, RP, WP TCC / NP, RP	None	15 Ncm	Unigrip™
Temporary Coping Multi-unit	Tri-channel / NP, RP, WP External Hex / NP, RP			
Temporary Coping Multi-unit Bmk WP	External Hex / WP			

Table 4 – Temporary Copings Multi-unit and Temporary Snap Copings Multi-unit – Compatible Abutments, Screwdrivers, and Torque Specifications

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.

Cautions

General

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

It is strongly recommended that Nobel Biocare surgical instruments and prosthetic components are used only with Nobel Biocare implants, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory aesthetic 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 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

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

The Nobel Biocare N1™ Base concept is intended to be used by dental health care professionals.

The Nobel Biocare N1™ Base concept is to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Temporary Abutments and Copings

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.

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.

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.

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

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 Titanium, and Temporary Coping Multi-unit are delivered non-sterile by Nobel Biocare and are intended for single use. Prior to use, the devices must be cleaned and sterilized by the user.

Additionally, if any temporary abutment or coping is modified after initial cleaning and sterilization, the device must be cleaned and sterilized again prior to intraoral use.

Temporary Abutments Nobel Biocare N1™ TCC and Temporary Abutments Anatomical PEEK are delivered sterile but if modified during Handling Procedure, must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12.
- Sterilization: AAMI ST79 and ISO 17665-1.

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note The manufacturer's instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note The Temporary abutments and copings have been validated to withstand these cleaning and sterilization procedures.

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Disassemble the screw from the abutment.
2. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.
5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 20 seconds until all visible soil is removed.
6. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single-use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying

1. Disassemble the screw from the abutment.
2. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
5. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W_{eff}) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C (104°F) / maximum 45°C (113°F).
8. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
10. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly dispose any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 (pre-vacuum cycle); Amsco Century Sterilizer (gravity cycle).

Note It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

1. Seal each device in a suitable sterilization pouch.
   The sterilization pouch should fulfill the following requirements:
   - EN ISO 11607 and/or DIN 58953-7.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 5 presents examples of suitable sterilization containers, pouches, and wraps.

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch
Pre-vacuum Cycle	SteriCLIN® pouch

Table 5 – Recommended Sterilization Pouches

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).

3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.

4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 6):

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar[4]
Pre-Vacuum Cycle[1]	132°C (270°F)	4 minutes		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

Table 6 – Recommended Sterilization Cycles

1 Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

2 Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

3 Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.

4 Saturated steam pressure at 132°C as per required by EN ISO 17665-2.

5 Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/Shipping to Point of Use

The container and/or outer packaging used to transport or ship the processed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Magnetic Resonance (MR) Safety Information

MR Safety Information for Single Tooth Restoration

MRI Safety Information		
Non-clinical testing has demonstrated that Temporary Abutments are MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient.		
Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T)
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 58.9 T/m (5,890 G/cm).	
RF Excitation	Circularly Polarized (CP).	
RF Transmit Coil Type	Whole body transmit coil.	
Maximum Whole-Body SAR [W/kg]	Inferior to the neck: 2.0 W/kg Superior to the neck: 0.5 W/kg	Inferior to the xyphoid: 2.0 W/kg Between the xyphoid and neck: 1.0 W/kg Superior to the neck: 0.5 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0°C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 3 T MRI system.	

MR Information for Single Tooth Configurations Zygoma Implants (applicable only during Zygoma Implant healing phase)

MRI Safety Information		
Non-clinical testing has demonstrated the Temporary Coping Multi-unit is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentionned here below. Failure to follow these confitions may result in injury to the patient.		
Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T)
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 58.9 T/m (5,890 G/cm).	
RF Excitation	Circularly Polarized (CP).	
RF Transmit Coil Type	Whole body transmit coil.	
Maximum Whole-Body SAR [W/kg]	Inferior to the shoulders: 2.0 W/kg Superior to the shoulders: 0.2 W/kg	Inferior to the xyphoid: 2.0 W/kg Superior to the xyphoid: 0.2 W/kg

Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0°C after 15 minutes of continuous scanning.
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 2.4 cm from the devices or device assemblies when imaged in a 3 T MRI system.
Caution	Configurations with more than 2 Zygoma implants 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 configurations with more than 2 Zygoma implants in the MR environment is unknown. Scanning a patient who has this configuration may result in patient injury.

Performance Requirements and Limitations

To achieve the desired performance, temporary abutments and copings 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 temporary abutments and copings, 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 1 411 17 Göteborg 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 Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class IIb Devices	CE 2797
UKCA Mark for Class IIb Devices	UK CA 0086

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

The following table lists the Basic UDI-DI information for the devices described in this IFU.

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	7332747000000 1236T
Temporary Copings Multi-unit	
Temporary Copings Multi-unit Bmk WP	

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 / European Union	UK Responsible Person	Authorised Representative in Switzerland	Sterilized using Ethylene Oxide	Sterilized using irradiation	Sterilized using steam or dry heat		
							
Batch code	Catalogue number	Unique Device Identifier	Serial number	Medical device	Magnetic resonance safe		
							
Caution	Magnetic resonance conditional	Non-sterile	Contains hazardous substances	Contains or presence of DEHP phthalate	Contains or presence of natural rubber latex	Contains or presence of phthalate	Contains biological material of animal origin
					Rx only	 symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com	
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	Link to Online Symbols Glossary and IFU Portal	
							
Date of manufacture	Manufacturer	Use-by date	Upper limit of temperature	Temperature limit	Do not resterilize	Do not re-use	Non-pyrogenic
							
Date	Tooth number	Patient number	Patient identification	Health care centre or doctor	Patient information website	EU Importer	Swiss Importer
Double sterile barrier system	Single sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside	Do not use if package is damaged and consult instructions for use	Keep away from sunlight	Keep dry	