Temporary Abutments and Copings

Instructions for use

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 uses 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 consult 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 to bear responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising therefrom. 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 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 Non-Engaging:
Temporary Abutments Non-Engaging 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.

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

<table>
<thead>
<tr>
<th>Healing Abutment for</th>
<th>Available platforms</th>
<th>Conical connection (CC)</th>
<th>Tri-oval conical connection (TCC)</th>
<th>External Hex</th>
<th>Non-engaging</th>
<th>Engagement</th>
<th>Color coding</th>
<th>Available margin heights</th>
<th>Tightening torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N/ O</td>
<td></td>
<td>N/ O</td>
<td>X</td>
<td>X</td>
<td>O (screw)</td>
<td>(screw)</td>
<td>15 Ncm</td>
<td>Unigrip</td>
</tr>
<tr>
<td>Slim Temporary Abutments:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 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.</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Table 2: Slim Temporary Abutments – Compatible Implant Platforms, Screwdrivers, and Torque Specifications

<table>
<thead>
<tr>
<th>Slim Healing Abutment for</th>
<th>Available platforms</th>
<th>Color coding</th>
<th>Available post heights</th>
<th>Tightening torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
<td>none</td>
<td>6.5 mm</td>
<td>75 mm</td>
<td>15 Ncm</td>
<td>Unigrip</td>
</tr>
</tbody>
</table>
| Table 3: Temporary Abutments Anatomical PEEK – Compatible Implant Platforms, Screwdrivers, and Torque Specifications

<table>
<thead>
<tr>
<th>Healing Abutment Anatomical PEEK for</th>
<th>Available platforms</th>
<th>Color coding</th>
<th>Available post heights</th>
<th>Tightening torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP</td>
<td>none</td>
<td>6 x 7 mm</td>
<td>6 x 8 mm</td>
<td>35 Ncm</td>
<td>Unigrip</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Temporary coping</th>
<th>MUA connection/platform</th>
<th>Color coding</th>
<th>Tightening torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary Snap Coping Multi-unit</td>
<td>CC/NP/RP/RP</td>
<td>none</td>
<td>35 Ncm</td>
<td>Unigrip</td>
</tr>
<tr>
<td>Temporary Coping Multi-unit</td>
<td>Tri-channel/NP/RP/RP</td>
<td>External Hex/NP/RP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporary Coping Multi-unit</td>
<td>Basket-WP</td>
<td>External Hex/WP</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 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.

Temporary Abutments Non-Engaging: Temporary Abutments 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 single unit or 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 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.
and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area.

During abutment placement or removal, the pharyngeal reflex (gag reflex) may be triggered in some patients with a sensitive gag reflex.

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

Before Surgery:

- Manual hard tissue or soft tissue deficits may yield a compromised aesthetic 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.
- Special attention is 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, pro-facial radiotherapy, strep. 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 characteristics. 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. a throat shield).
- Never exceed the recommended maximum tightening torque for the clinical/prosthetic screw.
- For temporary abutments without snap feature: drill a hole through the mold, loosen the screw(s) using a dedicated screwdriver and remove the restoration.
- For temporary abutments with snap feature: drill a hole through the mold, loosen the screw(s) using a dedicated screwdriver and remove the restoration.

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.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Temporary Abutments and Copings:

- Temporary abutments and copings are a component of a 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, mucosa, ulcer, soft tissue hypertrophy, saliva and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

Note:

- Temporary abutments 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 screw: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.

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.

Clinical screw: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.

Temporary Abutments and Copings are single use products and must not be reused. Use of non-sterile devices may lead to infection of tissues or infectious diseases.

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

Temporary Snap Copings Engaging Conical Connection, Temporary Abutments Engaging Brånemark System®, Temporary Abutments Nobel Biocare N1™ TCC, Temporary Abutments Engaging NobelReplace™, Temporary Abutments Engaging Brånemark System®, Temporary Abutments Non-Engaging Brånemark System®, 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 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.

Temporary Snap Copings Engaging Conical Connection, Temporary Abutments Engaging Brånemark System®, Temporary Abutments Non-Engaging Brånemark System®, 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.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program of 11 individual devices.

6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Pre-cleaning:

Automated Cleaning and Drying (Including Pre-cleaning):

Note: where applicable.

equipment and accessories used to clean and/or dry the device(s) must be strictly followed as set forth by the manufacturer. Proper cleaning and drying is essential to 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.

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

Automated Cleaning and Drying:

The following 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 sew 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.
   - Pre-cleaning:
     - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Medicated).
     - Draining.
     - Minimum 3 minutes neutralization with cold desalinated water.
     - Draining.
     - Minimum 5 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. Vacuum dry if necessary.

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

Sterilization:

The following steam sterilizers were used in the Nobel Biocare validation: Systex HK-320 (pre-vacuum cycle), Amso Century Sterilizer (gravity cycle).

Note: It is recommended to perform sterilization with a maximum load of 11 devices individually sterilized 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 the sterilization packaging to mechanical damage.

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

<table>
<thead>
<tr>
<th>Method</th>
<th>Recommended Sterilization Pouch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum Cycle</td>
<td>SPS Medical Self-Seal sterilization pouch</td>
</tr>
<tr>
<td>SterilINA® pouch</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Minimum Temperature</th>
<th>Minimum Sterilization Time</th>
<th>Minimum Drying Time (in Chamber)</th>
<th>Minimum Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum Cycle</td>
<td>132°C (270°F)</td>
<td>15 minutes</td>
<td>20 minutes</td>
<td>≥2868.2 mbar*</td>
</tr>
<tr>
<td>Pre-vacuum Cycle</td>
<td>134°C (273°F)</td>
<td>3 minutes</td>
<td>3 minutes</td>
<td>≥3042 mbar*</td>
</tr>
<tr>
<td>Pre-vacuum Cycle</td>
<td>136°C (279°F)</td>
<td>18 minutes</td>
<td>18 minutes</td>
<td>≥3042 mbar*</td>
</tr>
</tbody>
</table>

* Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^-6 in accordance to EN ISO 11607-1.

1 Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.
2 Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/LD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.
3 Saturation steam pressure at 132°C as per required by EN ISO 17665-2.
4 Saturation 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 265, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standards. 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.

Container and Transportation/Shipping to Point of Use:

The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the stability 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:

Temporary abutments and copings which contain metallic materials can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that these temporary abutments and copings are unlikely to impact patient safety under the following MRI conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 Tm).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

Note: Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Under the conditions defined above, these devices are expected to produce a maximum temperature rise of 4.1°C (39.4°F) after 15 minutes of continuous scanning.

In the non-clinical testing, the image artifact caused by the devices extends approximately 30 mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Note: Although the non-clinical testing demonstrates that the metallic temporary abutments and copings are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to support a claim of MR Safe or MR Conditional for these products.

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 devices 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:

Safety 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.
Notice Regarding Canadian Device Licensure: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Basic UDI-DI Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary Snap Abutments Engaging CC NP/RP/WP</td>
<td>733274700000017279</td>
</tr>
<tr>
<td>Temporary Abutments Engaging CC 3.0/NP/RP/WP</td>
<td></td>
</tr>
<tr>
<td>Temporary Abutments Non-Engaging CC NP/RP/WP</td>
<td></td>
</tr>
<tr>
<td>Temporary Abutments Nobel Biocare N1™ TCC NP/RP</td>
<td></td>
</tr>
<tr>
<td>Temporary Abutments Engaging/Non-Engaging NobelReplace NP/RP/WP</td>
<td></td>
</tr>
<tr>
<td>Temporary Abutments Engaging/Non-Engaging Brånemark System® NP/RP/WP</td>
<td></td>
</tr>
<tr>
<td>Slimi Temporary Abutments Conical Connection NP/RP/3.0</td>
<td></td>
</tr>
<tr>
<td>Temporary Abutments Anatomical PEEK CC WP</td>
<td></td>
</tr>
<tr>
<td>Temporary Snap Copings Multi-unit</td>
<td>73327470000001238T</td>
</tr>
<tr>
<td>Temporary Copings Multi-unit</td>
<td></td>
</tr>
<tr>
<td>Temporary Copings Multi-unit Brmk WP</td>
<td></td>
</tr>
</tbody>
</table>

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.

- **EC REP**: Authorized representative in the European Community
- **LOT**: Batch code
- **REF**: Catalogue number
- **Caution**: Contains hazardous substances, contains or presence of phthalate
- **Date**: Do not re-sterilize, do not re-use
- **Rx Only**: Double sterile barrier system, for prescription use only
- **For health care centre or doctor**: Keep away from sunlight, keep dry
- **Ingredient**: Link to Online Symbols Glossary and IFU Portal
- **Non-sterile**: Magnetic resonance conditional
- **Manufacturer**: Medical device, non-pyrogenic
- **Patient identification**: Patient information website, Patient number
- **Single sterile barrier system**: Single sterile barrier system with protective packaging inside
- **Single sterile barrier system with protective packaging outside**: Unique Device Identifier, Use-by date

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