NobelGuide® Guided Abutments and Guided Titanium Temporary 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 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, it is 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:

NobelGuide® Guided Abutments are expandable titanium abutments that contain a titanium abutment screw with a Unigrip™ fitting. They are designed to be used in conjunction with a Guided Titanium Temporary Coping which has been embedded into a temporary prosthesis intended for intra-oral use, or into a bridge design model which is intended for use in the dental laboratory to facilitate production of a NobelProcera Implant Bridge.

There is space between the Guided Titanium Temporary Coping and Guided Abutment which allows for minor adjustments to the position of the temporary prosthesis or bridge design model relative to the dental implants / implant replicas. When the screw is tightened, the abutment expands and space between the coping and the abutment is filled, which firmly anchors the prosthesis or model to the implant or implant replica, respectively.

Guided Titanium Temporary Copings are available in the NP, RP, and 6.0/WP platforms and are compatible with the respective NobelGuide® Guided Abutments.

There are two versions of NobelGuide® Guided Abutments: Guided Abutments Brånemark System, which are available in the NP, RP, and WP platforms and are compatible with Brånemark System® and NobelSpeedy® Groovy implants, and Guided Abutments NobelReplace®, which are available in the NP, RP, WP, and 6.0 platforms and are compatible with NobelReplace® Tapered, Replace Select™ Tapered, NobelReplace® Straight and Replace Select™ Straight implants.

An abutment screw is co-packed with the NobelGuide® Guided Abutments.

Intended Use / Intended Purpose:

NobelGuide® Guided Abutments and Guided Titanium Temporary Copings:
Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.

Indications:

Nobel Biocare Guided Surgery Tooling is indicated for use to support guided preparation of an osteotomy, to facilitate placement of endosseous dental implants and implant system components intended to restore chewing function.

The following patient prerequisites must be fulfilled:

- Adequate amount and quality of jaw bone.
- Adequate mouth opening (minimum 40 mm) to accommodate guided surgery tooling.

NobelGuide® Guided Abutments:
NobelGuide® Guided Abutments are indicated for use together with an abutment screw and a Guided Titanium Temporary Coping embedded in a dental prosthesis, as an assembly which allows for minor adjustments to the position of the prosthesis relative to the dental implants, in order to facilitate installation of the prothesis on the implants.

Guided Titanium Temporary Copings:
Guided Titanium Temporary Copings are indicated to be embedded into a temporary prosthesis, or into a bridge design model which is subsequently used in the production of a Procera Implant Bridge, for use together with a NobelGuide® Guided Abutment as an assembly which allows for minor adjustments to the position of a temporary prosthesis or bridge design model relative to the dental implants in order to facilitate installation of the prosthesis on the implants.

Contraindications:

It is contraindicated to use NobelGuide® Guided Abutments and Guided Titanium Temporary Copings in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients with inadequate bone volume unless an augmentation procedure can be performed.
- Patients with inadequate mouth opening (minimum 40 mm) to accommodate guided surgery tooling.
- Patients in whom adequate sizes, numbers or desirable position of implants are not achieved to provide safe support of functional or eventually parafunctional loads.
- Patients allergic or hypersensitive to titanium alloy 90% Ti, 6% Al, 4% V, CP titanium, diamond-like carbon (DLC) coating or silicone rubber.

Cautions:

General:
One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) may result in failure.

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

It is strongly recommended that the NobelGuide® Guided Abutments and the Guided Titanium Temporary Coping are used only with compatible Nobel Biocare instruments, components, and prosthetic components. Use of instruments, components, and/or prosthetic components that are not intended to be used in combination with NobelGuide® Guided Abutment or Guided Titanium Temporary Coping can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

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

Before Surgery:
Careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

Special attention must 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.

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

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 or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components

Before performing guided surgery, the surgical template must be carefully inspected and cleared by the clinician performing the surgery. Optimal fit on stone model or in patient's mouth needs to be verified. If in doubt, please contact Nobel Biocare technical support.

At Surgery:
Particular caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

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).

After the implant placement, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

Bending moments: Forces that cause bending moments are known to be the most unfavorable, as they can potentially jeopardize the long-term stability of an implant-supported restoration. In order to decrease bending moments, the distribution of forces should be optimized by cross-arch stabilization, minimizing distal cantilevers, having a balanced occlusion as well as decreased cuspal inclination of the prosthetic teeth.

If modifying the restoration, use copious irrigation and appropriate protection equipment. Avoid inhalation of dust.

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:

- NobelGuide® Guided Abutments and the Guided Titanium Temporary Copings are to be used by dental health care professionals.
- Guided Abutments and Guided Titanium Temporary Copings are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with NobelGuide® Guided Abutments and Guided Titanium Temporary Copings:
Guided Abutments and Guided Titanium Temporary Copings are components 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 NobelGuide® Guided Abutments and Guided Titanium Temporary 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, swelling. During abutment placement or removal, the pharyngeal reflect (gag reflex) may be triggered in patients with a sensitive gag reflex.

Guided Abutments and Guided Titanium Temporary 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, ulcers, 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 Guided Abutments and Guided Titanium Temporary Copings. The SSCP can be obtained at the following website: https://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

https://www.nobelbiocare.com/complaint-form

Handling Procedure:

1. Place the appropriate Guided Abutment into the titanium cylinder of the pre-made prosthesis (A).

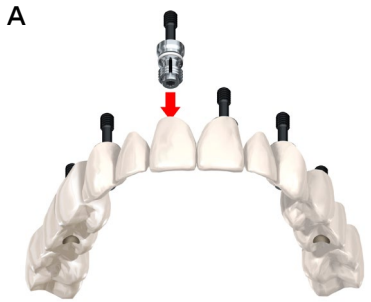


Figure A: Placement of Guided Abutment

2. Insert the prosthesis (B) into the patient's mouth and tighten the Guided Abutment screws by alternating between the left and right side. Finally tighten the abutment screw to 35 Ncm using Screwdriver Machine Unigrip™ and Manual Torque Wrench Prosthetic.

Caution: Never exceed the recommended maximum 35 Ncm-tightening torque for the abutment screw. Overtightening of abutment screws my lead to a screw fracture.

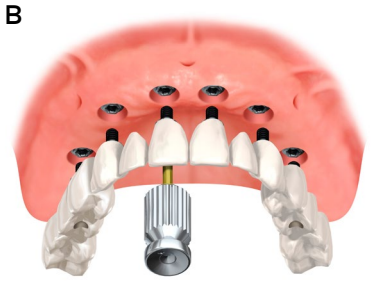


Figure B: Inserting the Prosthesis into the Patient's Mouth

3. Close screw access channel using conventional techniques.

Caution: Ensure abutment screw is re-tightened to 35 Ncm using Screwdriver Machine Unigrip™ and Manual Torque Wrench Prosthetic in the event the prosthesis is removed during recall or maintenance.

For additional information on surgical procedures please consult the procedures manual for the respective implant system available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

For additional information on the NobelGuide® surgical templates and related surgical procedures, please refer to the Instructions for Use NobelGuide® Surgical Template (IFU2001).

Materials:

- Guided Abutment: Titanium alloy (90% Ti, 6% Al, 4% V) 6Al4V ELI according to ASTM F136 and ISO 5832-3 and silicone rubber Silastic 7-6860.
- Abutment screw: Titanium alloy (90% Ti, 6% Al, 4% V) 6Al4V ELI according to ASTM F136 and ISO 5832-3 with diamond-like carbon (DLC) coating.
- Guided Titanium Temporary Coping: Unalloyed Titanium Grade 1 and 4 according to ASTM F67 and IOS 5832-2.

Sterility and Reusability Information:

The Guided Abutment and co-packed abutment screw 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.

The Guided Titanium Temporary Coping is 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: Guided Abutments, abutment screws, and Guided Titanium Temporary Copings are single use devices and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause local or systemic infection.

Cleaning, Disinfection and Sterilization Instructions:

The Guided Titanium Temporary Copings 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.

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, disinfect, and/or dry the device(s) must be strictly followed where applicable.

Note: The Nobel Biocare Guided Surgery Tooling has been validated to withstand these cleaning, disinfection and sterilization procedures.

Initial Treatment at Point of Use Prior to Reprocessing:

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.
3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Note: Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning, disinfection, and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning, Disinfection and Drying (Including Pre-cleaning):

Pre-cleaning:

1. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
2. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
3. 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.
4. 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.
5. 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.
6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning, Disinfection and Drying:

The following washer/disinfector 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 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 (122.0°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. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. 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.
4. 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.
5. 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.
6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) 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).
7. 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.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

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-vaccum 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. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization. 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 7 presents examples of suitable sterilization containers, pouches, and wraps.

Table 7: Recommended Sterilization Pouches

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

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 8):

Table 8: Recommended Sterilization Cycles

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		

[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 reprocessed 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:

Guided Abutments and Guided Titanium Temporary Copings contain metallic materials which can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that these products 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 T/m).
- 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 Guided Abutments and Guided Titanium Temporary 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 the these devices.

Performance Requirements and Limitations:

To achieve the desired performance, the Guided Abutments and Guided Titanium Temporary 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 the Guided Abutments and Guided Titanium Temporary 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 info 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
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

Distributed in Australia by:
Nobel Biocare Australia Pty Ltd
Level 4/7 Eden Park Drive
Macquarie Park, NSW 2114 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 2797
CE Mark for
Class IIb Devices

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.

Product	Basic UDI-DI Number
Guided Titanium Temporary Copings NP/RP/WP/6.0 Guided Abutments Brånemark System NP/RP/WP Guided Abutments NobelReplace NP/RP/WP/6.0	73327470000017176

Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

Authorized representative in the European Community

Batch code

Catalogue number


Caution


CE marking


Consult instructions for use


Contains hazardous substances

Contains or presence of phthalate

Date


Date of manufacture

Do not resterilize

Do not re-use


Do not use if package is damaged

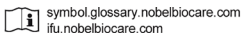

Double sterile barrier system

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional


Manufacturer

Medical device


Non-pyrogenic

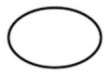
Non-sterile


Patient identification


Patient information website

Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Sterilized using ethylene oxide

Sterilized using irradiation

Temperature limit

Tooth number

Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier

Use-by date