Healing Abutments
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, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

Healing abutments are premanufactured dental implant abutments which can be directly connected to the endosseous dental implant to support healing of the surrounding soft tissue.

Healing Abutments:

- Healing Abutments 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
- Healing Abutments Bridge 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
- Healing 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.
- Healing Abutments 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.
- Healing Abutments Brånemark System® are available in NP/RP/WP platforms, feature an external hex connection and can be used with Nobel Biocare's Branemark System and/or NobelSpeedy Groovy implant systems.
- Healing Abutments Brånemark System® Zygoma feature an external hex connection and can be used with Nobel Biocare's Brånemark System® Zygoma implant system.
- Healing Abutments NobelZygoma 0° feature an external hex connection and can be used with Nobel Biocare's NobelZygoma 0° implant system.

Slim Healing Abutments:

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

Healing Abutments Anatomical PEEK:

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

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

Table 1: Healing Abutments – Compatible Implant Platforms and Screwdrivers

Healing Abutment for	Available platforms	Color coding	Screwdriver
Conical connection (CC)	3.0 NP RP WP	none O O O	Unigrip
Tri-oval conical connection (TCC)	NP RP	O (screw) O (screw)	Omnigrip mini
Tri-channel	NP RP WP 6.0	O O O O	Unigrip
External Hex	NP RP WP	none none none	Unigrip

Table 2: Slim Healing Abutments – Compatible Implant Platforms and Screwdrivers

Slim Healing Abutment for	Available platforms	Color coding	Screwdriver
Conical connection (CC)	3.0 NP RP	none O O	Unigrip

Table 3: Healing Abutments Anatomical PEEK – Compatible Implant Platforms and Screwdrivers

Healing Abutment Anatomical PEEK for	Available platforms	Color coding	Screwdriver
Conical connection (CC)	WP	none	Unigrip

Healing abutments which feature tri-oval conical connection and Healing Abutments Anatomical PEEK are co-packed with a clinical screw. Refer to Nobel Biocare Instructions for Use (IFU) IFU1057 for information regarding clinical screws. This IFU is available for download at ifu.nobelbiocare.com.

Intended Use/Intended Purpose:

Healing Abutments:

Intended to be temporarily connected to an endosseous dental implant or implant abutment, to support healing of the surrounding soft tissue.

Indications:

Healing abutments are indicated for use with endosseous dental implants or implant abutments in the maxilla or mandible for supporting single tooth to full arch denture procedures.

Healing abutments Nobel Biocare N1™ TCC are indicated for use for up to 180 days.

Healing Abutments Bridge Conical Connection are additionally indicated to prevent growth of bone on the implant platform to support placement of an Impression Coping Bridge.

Healing Abutments Anatomical PEEK Conical Connection are adjustable abutments which are indicated for use for up to 180 days with endosseous dental implants in the maxilla or mandible, for supporting single tooth to full arch denture procedures.

Contraindications:

It is contraindicated to use healing abutments 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 (titanium, aluminum, vanadium), DLC (Diamond Like Carbon), or PEEK (Polyetheretherketone).

Cautions:

General:

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for 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 esthetic results.

Before Surgery:

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.

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.

At Surgery:

Because of the small size 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 Surgery:

To secure the 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:

Healing abutments are to be used by dental health care professionals.

Healing abutments are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Healing Abutments:

- Healing abutments 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 Healing Abutments:

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.

Healing abutments 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

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

Handling Procedure for Healing Abutments and Slim Healing Abutments:

1. Select appropriate abutment and check occlusal clearance.
2. Connect the abutment to implant and hand-tighten using dedicated screwdriver. See **Table 1** or **Table 2** for compatibility. Refer to Nobel Biocare IFU 1085 for information regarding the screwdriver. It is recommended to verify the final abutment seating using radiographic imaging.

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

3. If removal of the abutment is needed, untighten it using dedicated screwdriver.
4. For abutments featuring tri-oval conical connection, if the removal is not possible, use the Abutment Retrieval tool. Refer to Nobel Biocare IFU1096 for information regarding the Abutment Retrieval Tool.

Handling Procedure for Healing Abutments Anatomical PEEK:

1. Select appropriate abutment and check occlusal clearance.
2. If necessary, adjust the abutment height using a rotary instrument (e.g. carbide or acrylic bur). The tissue facing axial contours of the abutment may be modified to achieve the desired shape. If axial modification is done, polishing with silicone points or similar methods is recommended.
3. Connect to implant and hand-tighten using Unigrip™ screwdriver. Refer to Nobel Biocare IFU 1085 for information regarding the screwdriver. It is recommended to verify the final abutment seating using radiographic imaging.
4. If removal of the abutment is needed, untighten the screw using dedicated screwdriver.
5. If the abutment cannot be removed, use the Abutment Retrieval tool. Refer to Nobel Biocare IFU1096 for information regarding the Abutment Retrieval Tool.

Materials:

- Healing Abutments and Slim Healing Abutments: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- Healing Abutments Anatomical PEEK: PEEK (Polyetheretherketone) according to SPE 130322.
- Clinical screws: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.

Sterility and Reusability Information:

Healing abutments have been sterilized using irradiation and are intended for single use. Do not use after the labeled expiration date.

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

Caution: Healing abutments 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.

Magnetic Resonance (MR) Safety Information:

Healing abutments which contain metallic materials can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that these healing abutments 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 the metallic healing abutments 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, healing abutments 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 healing abutments, 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:

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 IIa Devices

Notice Regarding Canadian License Exemption: 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
Healing Abutments Conical Connection 3.0/NP/RP/WP	73327470000001236T
Healing Abutments Bridge Conical Connection NP/RP/WP	
Healing Abutments Nobel Biocare N1™ TCC NP/RP	
Healing Abutments NobelReplace NP/RP/WP/6.0	
Healing Abutments Brånemark System NP/RP/WP	
Brånemark System® Zygoma Healing Abutments	
Slim Healing Abutments Conical Connection 3.0/NP/RP	
Healing Abutments Anatomical PEEK Conical Connection 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

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

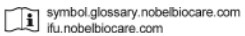

Double sterile barrier system

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