Healing Abutments, Healing Screws

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 and Healing Screws 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 Screws

- Healing Abutments Conical Connection are available in 3.0/NP/RP/WP platforms and feature a conical connection. They are available with different emergence profiles and anodization types.
- Healing Abutments Bridge Conical Connection are available in NP/RP/WP platforms and feature a conical connection. Healing Abutments Bridge Conical Connection are to be used exclusively for bridges.
- Healing Abutments Nobel Biocare N1™ TCC are available in NP/RP platforms and feature a tri-oval conical connection.
- Healing Abutments NobelReplace® are available in NP/RP/WP and 6.0 platform and feature an internal tri-channel connection.
- Healing Screw Replace Select is available in NP/RP platforms and feature an internal tri-channel connection.
- Healing Abutments Brånemark System® are available in NP/RP/WP platforms and feature an external hex connection.
- Healing Abutments Brånemark System® Zygoma feature an external hex connection.

Slim Healing Abutments

- Slim Healing Abutments Conical Connection are available in 3.0/NP/RP platforms and feature a conical connection.

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

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

Intended Use/Intended Purpose

Healing abutments/healing screws

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

Indications

Healing abutments and healing screws 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.

Contraindications

It is contraindicated to use healing abutments and healing screws 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).

Materials

- Healing abutments and healing screws and Slim Healing Abutments: Titanium alloy Ti-6Al-4V (90 wt.% titanium, 6 wt.% aluminum, 4 wt.% vanadium) according to ASTM F136 and ISO 5832-3.
- Clinical screws for Healing Abutments Nobel Biocare N1 TCC: Titanium alloy Ti-6Al-4V (90 wt.% titanium, 6 wt.% aluminum, 4 wt.% vanadium) according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating. The average composition of the coating (DLC) of 1 to 4 µm thick is around: 73 wt.% tungsten (W), 23 wt.% carbon (C), and 4 wt.% nickel (Ni).

Cautions

General

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

Healing Abutments and Healing Screws must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Nobel Biocare's Healing Abutments and Healing Screws can lead to product 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.

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.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

All components, instruments and tooling used during the clinical and/or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

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 gauze, a dental dam, or 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 and healing screws are to be used by dental health care professionals.

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

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Devices in the IFU

Healing abutments and healing screws 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 and Healing Screws

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 and healing screws 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.

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 Healing abutments and healing screws

1. Select appropriate abutment and check occlusal clearance.

2. Connect the abutment to implant and hand-tighten using dedicated screwdriver. Refer to Nobel Biocare IFU1085 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 screw 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.

Sterility and Reusability Information

Healing abutments and healing screws 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 as the device sterility and/or integrity may be compromised.

Caution Healing abutments and healing screws 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

These products are fabricated from a metal material which can be affected by MR energy. For further information refer to Nobel Biocare publication **Magnetic Resonance (MR) Safety Information** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices 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 devices, 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 Göteborg 411 17 Sweden www.nobelbiocare.com
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CE Mark for Class IIb Devices	CE 2797
UKCA Mark for Class IIb Devices	UK CA 0086

Note Refer to the product label to determine the applicable conformity marking for each device.

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

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 Screws	

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.