Healing Abutments, Healing Screws

Important – Disclaimer of Liability

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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 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 Screw Replace Select is available in NP and RP platforms, feature an internal tri-channel connection and can be used with Replace Select TC.
- Healing Abutments 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. The RP can be used with NobelZygoma.
- Healing Abutments Brånemark System® Zygoma feature an external hex connection and can be used with Nobel Biocare's Brånemark System® Zygoma 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.

Table1 – Healing Abutments – Compatible Implant Platforms and Screwdrivers

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

Table 2 – Healing Screws - Compatible Implant Platforms and Screwdrivers

Healing Screw for	Available platforms	Color coding	Screwdriver
Tri-channel	NP	●	Unigrip™
	RP	●	

Table 3 – Slim Healing Abutments – Compatible Implant Platforms and Screwdrivers

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

Table 4 – 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/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.

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 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) or PEEK (Polyetheretherketone).

Materials

– Healing abutments and healing screws 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).

– Clinical screws for Healing Abutments Nobel Biocare N1 TCC and for Healing Abutments Anatomical PEEK: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.

Cautions

General

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

Nobel Biocare surgical instruments and prosthetic components 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 surgical instruments and prosthetic components 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 Healing abutments and healing screws

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
https://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.
   See Table 1 or Table 2 for compatibility. 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.

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.

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

MR Safety Information for Single Tooth Restoration

MRI Safety Information		
Non-clinical testing has demonstrated that healing abutments and healing screws 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 3T MRI system.	

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

MRI Safety Information		
Non-clinical testing has demonstrated the Brånemark System® Zygoma Healing Abutment, Healing Abutment Bmk Syst RP (when used with Zygoma) 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.	
Implant placement with intention to restore at prosthetic level with PIBs or IBOs (multiple tooth restorations): Please consult IFU for NobelProcera® Implant Bridge Titanium and Zirconia, NobelProcera® Crown and Bridge, NobelProcera® HT ML FCZ, and NobelProcera® Implant Bar Overdenture for use as part of a bridge configuration		

Performance Requirements and Limitations

To achieve the desired performance, healing abutments and healing screws 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 Information

Manufacturer	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 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 Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
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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.

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

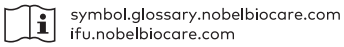
Basic UDI-DI Information

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 Abutments Anatomical PEEK Conical Connection WP	
Healing Screws	

Legal Statements

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
 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	