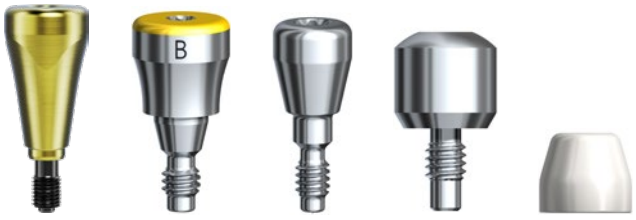
Healing Abutments



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Description

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

Healing Abutments / Healing Screw

- Healing Abutments Nobel Biocare N1™ TCC are available in NP/RP platforms, feature a tri-oval conical connection, and can be used with Nobel Biocare's N1™ TiUltra™ TCC Implant system.
- 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 Brånemark System® Zygoma feature an external hex connection and can be used with Nobel Biocare's Brånemark System® Zygoma 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 Cap Multi-unit Abutment is made of titanium alloy Ti-6Al-4V or polybutylene terephtalate (PBT) with a screw of titanium alloy Ti-6Al-4V with DLC (Diamond Like Carbon) coating.
- 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 table summarizes 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.

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 1 – Healing Abutments – Compatible Implant Platforms and Screwdrivers

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

Table 2 – Healing Screw – Compatible Implant Platforms and Screwdrivers

Healing Abutment Anatomical PEEK for	Available platforms	Color coding	Screwdriver
Conical Connection (CC)	WP	None	Unigrip™

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

Healing abutments which feature tri-oval conical connection and Healing Abutments Anatomical PEEK are co-packed with a clinical screw 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

Healing Abutments for Conical Connection, Healing Screw Replace Select™, Healing Abutments NobelReplace®, Healing Abutments Brånemark System®, Healing Abutments Brånemark System® Zygoma

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

Healing Abutment and Healing Cap is intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue.

Healing Abutments Anatomical PEEK

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

The PEEK Healing Abutment is intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue.

Healing Abutments Nobel Biocare N1™ TCC

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

Indications for use

Healing Abutments for Conical Connection, Healing Screw Replace Select™, Healing Abutments NobelReplace®, Healing Abutments Brånemark System®, Healing Abutments Brånemark System® Zygoma

The Healing Abutments and Healing Caps are pre-manufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for one single tooth to full arch denture procedures.

In addition, for Healing Abutment Conical Connection:

- For internal conical connection implants a specific Healing Abutment Bridge is available.
- The Healing Abutment Bridge is specially designed to avoid any bone to grow on platform and by that prepare for the specially designed Impression Coping Bridge. Using the series of components facilitates the treatment and prepare for an implant level bridge.

Healing Abutments Anatomical PEEK

The Nobel Biocare anatomical PEEK Healing are pre-manufactured, adjustable prosthetic components directly connected to endosseous dental implants and are intended for temporary use up to 180 days as an aid in prosthetic rehabilitation.

Healing Abutments Nobel Biocare N1™ TCC

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.

Contraindications

It is contraindicated to use Healing Abutments, Healing Screw and Healing Caps 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 commercially pure titanium, titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), polybutylene terephtalate (PBT), 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, and 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 the case of bruxism, other parafunctional habits, or unfavorable jaw relationships, reappraisal of the treatment option or appropriate pre- and post-treatment measures 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 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 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 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. gauze, a dental dam, or throat shields).

After Surgery

To secure 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

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

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
www.nobelbiocare.com/complaint-form

Handling Procedure

1. Select the appropriate Healing Abutment, Healing Screw or Healing Cap and check the occlusal clearance.

2. Connect the Healing Abutment, Healing Screw or the Healing Cap to the implant or abutment and hand- tighten using the dedicated screwdriver. See Table 1 and 2 for compatibility. It is recommended to verify the final abutment seating using radiographic imaging.

3. If removal of the abutment is needed, untighten it using the dedicated screwdriver.

4. For abutments featuring the tri-oval conical connection, if the removal is not possible, use the Abutment Retrieval tool. Refer to Nobel Biocare IFU1041 for information regarding the Abutment Retrieval Tool.

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

Handling procedure Healing Abutment 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 IFU1085 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 Healing Screw: Titanium alloy (90% Ti, 6% Al, 4% V) according to ASTM F136 and ISO 5832-3.
- 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.
- Healing Cap Multi-unit Abutment: Polybutylene terephthalate (PBT), titanium alloy 90% Ti, 6% Al, 4% V and DLC (Diamond Like Carbon) coating.
- Healing Abutments Anatomical PEEK: PEEK (Polyetheretherketone).

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 as the device sterility and/or integrity may be compromised.

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 Conical Connection, NobelReplace®, Brånemark System® and Healing Caps

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.

Healing Abutments Nobel Biocare N1™ TCC

MR Safety Information for Single Tooth Restoration

MRI Safety Information		
Non-clinical testing has demonstrated that Healing Abutments Nobel Biocare N1™ TCC s 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 3 T MRI system.	

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 Information

Manufacturer	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 411 17 Göteborg Sweden www.nobelbiocare.com
CE Mark for Class IIb Devices	CE 2797

Note Regarding Canadian Device Licensure, not all products described in the IFU may have a device licence according to Canadian Law.

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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	

symbol.glossary.nobelbiocare.com
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