

Healing Abutments and Healing Caps

Instructions for use



Important: Please read.

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:

A premanufactured dental implant abutment or cap to be directly connected to the endosseous dental implant or abutment intended for use as a temporary aid in prosthetic rehabilitation.

Healing Abutments are made of commercially pure titanium or titanium alloy Ti-6Al-4V. Internal conical connection for: NobelActive®, NobelParallel™ CC and NobelReplace® CC. Internal tri-channel connection for: NobelReplace®, Replace Select™ and NobelSpeedy® Replace.

External hex connection for: Brånemark System® and NobelSpeedy® Groovy.

Healing Cap Multi-unit Abutment is made of titanium alloy Ti-6Al-4V or polybutylene terephthalate (PBT) with a screw of titanium alloy Ti-6Al-4V with DLC (Diamond Like Carbon) coating.

Intended use:

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.

Indications:

The Healing Abutments and Healing Caps are premanufactured 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.

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.

Contraindications:

It is contraindicated placing Healing Abutments and Healing Caps in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are allergic or hypersensitive to commercially pure titanium, titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), polybutylene terephthalate (PBT) or DLC (Diamond Like Carbon) coating.

Cautions:

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

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Special attention has to 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 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.

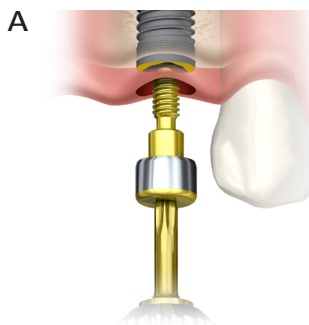
All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Handling procedures:

1. Select appropriate Healing Abutment or Healing Cap and check occlusal clearance.
2. Connect to implant or abutment and tighten using Unigrip™ Screwdriver (A).



For additional information on restorative and dental laboratory procedures please consult treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

Healing Abutment for implants with External hex connection: Commercially pure titanium or titanium alloy 90% Ti, 6% Al, 4%V.

Healing Abutment for implants with Internal conical connection and Internal tri-channel connection: Titanium alloy 90% Ti, 6% Al, 4%V.

Healing Cap Multi-unit Abutment: Polybutylene terephthalate, titanium alloy 90% Ti, 6% Al, 4%V and DLC (Diamond Like Carbon) coating.

Healing Cap Multi-unit Abutment Titanium: Titanium alloy 90% Ti, 6% Al, 4%V.

Cleaning and sterilization instructions:

Healing Abutments and Healing Cap Multi-unit Abutment Titanium are delivered sterile for single use only prior to the labeled expiration date.

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

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.

Healing Cap Multi-unit Abutment made of PBT is delivered non-sterile for single use. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

Warning: Use of non-sterile components may lead to infection of tissues or infectious diseases.

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross contamination.

For USA: Seal single device in a pouch and steam sterilize at 270°F, max 279°F (132°C, max 137°C) for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132°C–135°C, max 137°C (270°F–275°F, max 279°F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134°C–135°C, max 137°C (273°F–275°F, max 279°F) for 3 minutes.

Full set of recommended parameters are provided in "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Magnetic Resonance (MR) safety information:

Note: Only the Conical Connection Wide Platform Healing Abutments have been assessed as MR Conditional.

The other platforms and sizes have not been evaluated for safety and compatibility in the MR environment and have not been tested for heating or migration in the MR environment.

Non-clinical testing has demonstrated that the device is MR conditional. A patient with this device can be safely scanned in a MR system meeting the following 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) 4 W/kg (First Level Controlled Mode).

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of 4.1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 30mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system. Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Should there be no MR symbol on the product label, please note that the device has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.


For additional information on Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Storage and handling:

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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Canada – License Exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription Device – Rx only

Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

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

Rx Only

For prescription use only




Health care centre or doctor



Keep away from sunlight



Keep dry

 symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com

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

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