Healing Abutments and Healing Caps
Instructions for use

Important: Please read.

Disclaimer of liability:
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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 terephtalate (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 terephtalate (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**).

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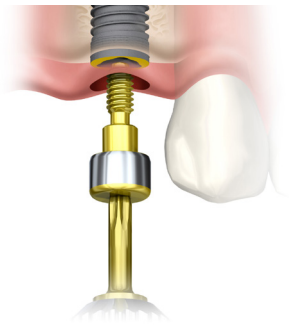

For additional information on restorative and dental laboratory procedures please consult treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

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 terephtalate, 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.

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In non-clinical testing, the image artifact caused by the device extends approximately 30 mm 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.

Manufacturer: Nobel Biocare AB, Box 5190, 402 26
Västra Hamngatan 1, 411 17 Göteborg, Sweden.
Phone: +46 31 81 88 00. Fax: +46 31 16 31 52. www.nobelbiocare.com

CE 2797

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

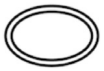
Date


Date of manufacture


Do not resterilize


Do not re-use


Do not use if package is damaged

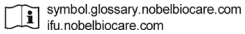

Double sterile barrier system

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

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