

Healing Caps Multi-unit Titanium

Instructions for use



Important: Please read.

Disclaimer of liability:

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Description:

A premanufactured Cap to be directly connected to the Multi-unit Abutment intended for use as a temporary aid in prosthetic rehabilitation to allow healing of the soft tissue.

The Healing Cap Multi-unit Titanium is made of titanium alloy Ti-6Al-4V.

Intended use:

The Healing Cap Multi-unit Titanium is intended to be used as a temporary component to allow healing of the soft tissue.

Indications:

The Healing Cap Multi-unit Titanium are premanufactured prosthetic components to be directly connected to the abutments and are indicated as temporary components.

Contraindications:

It is contraindicated placing Healing Cap Multi-unit Titanium in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are allergic or hypersensitive to commercially titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

Cautions:

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a 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 aesthetic results.

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 information please visit www.nobelbiocare.com.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible 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 procedure:

1. Select appropriate Healing Cap Multi-unit Titanium and check occlusal clearance.
2. Connect to abutment and tighten using Unigrip™ Screwdriver (A).

A



Caution: Never exceed recommended maximum **15 Ncm** tightening torque for the Healing Caps. Overtightening of the Healing Cap Multi-unit Titanium may lead to a screw fracture.

Caution: Blood coagulation between the Healing Cap Multi-unit Titanium and the Multi-unit Abutment can lead to difficult disassembly.

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

Cleaning and sterilization instructions:

The Healing Caps Multi-unit Titanium are delivered sterile for single use only. Do not use after 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 and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.

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

Magnetic Resonance (MR) safety information:

The Healing Cap Multi-unit Titanium has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Healing Cap Multi-unit Titanium in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.


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

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:

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.

For Prescription Use Only. Caution: Federal (United States) law restricts this device to sale by or on the order of a clinician, medical professional or physician.

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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