Cover Screws
Instructions for use

Important: Please read.

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Description:

A premanufactured device intended to be directly connected to the endosseous dental implant.

Internal conical connection for: NobelActive®, NobelReplace® CC and NobelParallel™ CC.

Internal tri-channel connection for: NobelReplace®, Replace Select™, NobelSpeedy® Replace, NobelReplace® Platform Shift.

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

Intended use:

Dental implant cover screws are to be used in the upper or lower jaw connected to the endosseous implant to protect the internal threads and implant head during the healing phase.

Indication:

To be used when applicable together with the implant during healing in order to protect the implant platform and internal threads from overgrowth of bone.

Contraindications:

Cover Screw is contraindicated for patients:

– who are medically unfit for an oral surgical procedure.

– in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.

– allergic or hypersensitiv to commercially pure titanium or titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

Cautions:

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

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.

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.

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.

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

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.

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

Handling instructions:

Clinical procedure:

1. Select appropriate cover screw.
2. Connect to implant and hand tighten using Unigrip™ Screwdriver (**A**).

Note: For Brånemark System® cover screw a hex screwdriver should be used for tightening.

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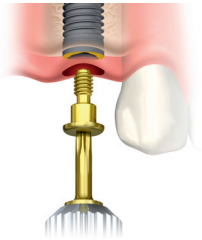

Materials:

Cover Screw for implants with External Hex connection: Commercially pure titanium.

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

Cleaning and sterilization instructions:

Cover Screw is delivered sterile and 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: Cover Screw is a single use product not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

MR safety information:

Note: Only the Conical Connection Wide Platform Cover Screw has 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 product 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-Tesla only.

– Maximum spatial gradient magnetic field of 4000 Gauss/cm or less (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).

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

In non-clinical testing, the image artifact caused by the device extends approximately 30 mm from the product when imaged with a gradient echo pulse sequence a 3 Tesla MRI system.

Should there be no MR symbol on the product label, please note that the product 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 Cleaning and Sterilization and Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines for Nobel Biocare Products including MRI Information" 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.

IFU1016 000 00

CE 0086

Rx Only

Magnetic resonance conditional

Sterile using irradiation

Consult instructions for use

Use-by date

Do not re-use

Batch code

Do not use if package is damaged

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