

# Cover Screws

## Instructions for use



### Important: Please read.

#### Disclaimer of liability:

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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 hypersensitive 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](http://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.

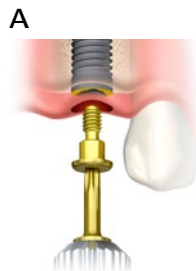
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

#### 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.



#### 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 and Zygoma implants: 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:

Cover Screws have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Cover Screws in the MR environment is unknown. Scanning a patient who has may result in patient injury.

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](http://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.

CE 0086

Rx Only

STERILE R

Sterile using irradiation



Consult instructions for use



Use-by date



Do not re-use

LOT

Batch code



Do not use if package is damaged

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