

# Cover Screws

## 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, they are 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 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.

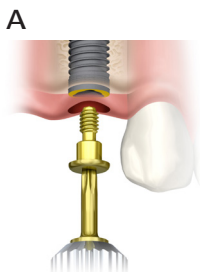
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

#### 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.

**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 re-sterilize



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](https://symbol.glossary.nobelbiocare.com)  
[ifu.nobelbiocare.com](https://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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