# Cover Screws
## Instructions for use

### Important – 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:

Cover screws are a component that covers the implant platform and prevents tissue overgrowth during the healing phase of the implant. The threaded portion of the Cover Screw fits inside the internal thread of the implant, while the head of the Cover Screw covers the top surface of the implant (the implant head).

Cover screws are intended to be used with the following implant systems:

- Cover screws which feature an Internal Conical Connection (CC) can be used with Nobel Biocare's NobelActive™, NobelParallel™ CC, NobelReplace® CC implant and Trefoil™ systems.
- Cover screws which feature a Tri-oval Conical Connection (TCC) can be used with Nobel Biocare's Nobel Biocare N1™ TiUltra TCC implant system.
- Cover screws which feature an external hexagon connection can be used with Nobel Biocare's Branemark System® NobelZygoma and NobelSpeedy® Groovy implant systems.

The Cover Screw N1™ TCC features two parts, the main body and the internal screw.

Table 1 presents a summary of the available cover screws and the corresponding compatible implant systems and screwdrivers, including references to the associated Nobel Biocare Instructions for Use (IFU). These IFUs are available for download at ifu.nobelbiocare.com.

**Table 1: Cover Screws with Compatible Implants and Screwdrivers**

| Cover Screw | Connection Type | Implant Platform | Implant System | Screwdriver |
|---|---|---|---|---|
| Cover Screw Branemark System® NP | External Hex | NP | Branemark System® (IFU1015)<br>NobelSpeedy® Groovy (IFU1007) | Cover Screw Driver Branemark System Hexagon (IFU1085) |
| Cover Screw Branemark System® RP | | RP | Branemark System® (IFU1015)<br>NobelSpeedy® Groovy (IFU1007)<br>NobelZygoma 0° (IFU1051) | |
| Cover Screw Branemark System® WP | | WP | Branemark System® (IFU1015)<br>NobelSpeedy® Groovy (IFU1007) | |
| Cover Screw Conical Connection 3.0 | Conical Connection | 3.0 | NobelActive™ (IFU1001)<br>NobelParallel™ CC (IFU1002)<br>NobelReplace® CC (IFU1010) | Unigrip (IFU1085) |
| Cover Screw Conical Connection NP | | NP | NobelActive™ (IFU1001)<br>NobelParallel™ CC (IFU1002)<br>NobelReplace® CC (IFU1010) | |
| Cover Screw Conical Connection RP | | RP | NobelActive™ (IFU1001)<br>NobelParallel™ CC (IFU1002)<br>NobelReplace® CC (IFU1010)<br>Trefoil™ systems (IFU1099) | |
| Cover Screw Conical Connection WP | | WP | NobelActive™ (IFU1001)<br>NobelParallel™ CC (IFU1002)<br>NobelReplace® CC (IFU1010) | |
| Cover Screw Nobel Biocare N1™ TCC NP | Tri-Oval Conical Connection | NP | Nobel Biocare N1™ TiUltra TCC (IFU1087) | Omnigrip Mini (IFU1085) |
| Cover Screw Nobel Biocare N1™ TCC RP | | RP | Nobel Biocare N1™ TiUltra TCC (IFU1087) | |

### Intended Use/Intended Purpose:

Cover Screws:
Intended to be temporarily connected to an endosseous dental implant to protect the implant connection interface during bone healing.

### Indications:

Cover screws are indicated for use with implants placed in the maxilla, mandible, or zygomatic bone, as per the indications for the respective implant system.

### Contraindications:

It is contraindicated to use cover screws in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients allergic or hypersensitive to commercially pure titanium or titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium) and DLC (Diamond Like Carbon) coating.

For contraindications specific to the implants, refer to the applicable Nobel Biocare IFU per Table 1.

### Cautions:

**General:**
Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.

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

It is strongly recommended that cover screws are used only with compatible Nobel Biocare instruments and components. Use of instruments or components that are not intended to be used in combination with cover screws can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

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.

**Before Surgery:**
Careful psychological and physiological evaluation followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

Special attention must 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, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

The device has not been evaluated in paediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jaw bone growth phase has been properly documented.

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

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

**At Surgery:**
Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).

After the implant placement, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

**After Surgery:**
To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform the patient about appropriate oral hygiene.

### Intended Users and Patient Groups:

Cover screws are to be used by dental health care professionals.

Cover screws are to be used in patients subject to dental implant treatment.

### Clinical Benefits and Undesirable Side Effects:

**Clinical Benefits Associated with Cover Screws:**
Cover screws are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored

**Undesirable Side Effects Associated with Cover Screws:**
During placement of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex. During the submerged healing period, bone may grow over the cover screw. In some cases, cover screws may get exposed prematurely.

**Notice regarding serious incidents:**
For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

**Nobel Biocare AB**
https://www.nobelbiocare.com/complaint-form

## Surgical Procedure and Handling Procedure:

1. Select the appropriate cover screw based on the implant connection and platform type (see Table 1).
2. Connect the cover screw to the implant and hand tighten using a Unigrip™ Screwdriver, a Driver Branemark System Hexagon or an Omnigrip Mini as indicated in Table 1, depending on the connection type (see Figure A).

**Caution:** Tighten the cover screw only finger-tight to avoid excessive loads that might damage the cover screw parts.

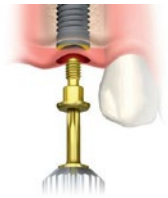

**Figure A: Tightening the Cover Screw**

3. To remove the cover screw, untighten the screw by hand using the appropriate screwdriver referenced in Table 1.
4. In the event the cover screw becomes stuck or is broken, abutment screw retrieval instruments can be used. Refer to Table 2 for the compatible instruments and Nobel Biocare IFU1043 for further details.

**Table 2: Cover Screws with Compatible Abutment Screw Retrieval Instruments**

| Cover Screw | Abutment Screw Retrieval Instruments |
|---|---|
| Cover Screw Branemark System® NP | Abutment Screw Retrieval Reverse Drill CC 3.0/NP<br>Abutment Screw Retrieval Instrument CC 3.0 |
| Cover Screw Branemark System® RP | Abutment Screw Retrieval Reverse Drill CC RP/WP/6.0<br>Abutment Screw Retrieval Instrument RP/WP/6.0 |
| Cover Screw Branemark System® WP | Abutment Screw Retrieval Reverse Drill CC RP/WP/6.0<br>Abutment Screw Retrieval Instrument RP/WP/6.0 |
| Cover Screw Conical Connection 3.0 | Abutment Screw Retrieval Reverse Drill 3.0/NP<br>Abutment Screw Retrieval Instrument CC 3.0/NP & TCC NP/RP |
| Cover Screw Conical Connection NP | Abutment Screw Retrieval Reverse Drill 3.0/NP<br>Abutment Screw Retrieval Instrument CC 3.0/NP & TCC NP/RP |
| Cover Screw Conical Connection RP | Abutment Screw Retrieval Reverse Drill CC RP/WP/6.0<br>Abutment Screw Retrieval Instrument RP/WP/6.0 |
| Cover Screw Conical Connection WP | Abutment Screw Retrieval Reverse Drill CC RP/WP/6.0<br>Abutment Screw Retrieval Instrument RP/WP/6.0 |
| Cover Screw Nobel Biocare N1™ TCC NP | Abutment Screw Retrieval Reverse Drill CC 3.0/NP & TCC NP/RP<br>Abutment Screw Retrieval Instrument CC 3.0/NP & TCC NP/RP |
| Cover Screw Nobel Biocare N1™ TCC RP | Abutment Screw Retrieval Reverse Drill CC 3.0/NP & TCC NP/RP<br>Abutment Screw Retrieval Instrument CC 3.0/NP & TCC NP/RP |

## Materials:

- Cover Screws: Titanium Alloy 90% Ti, 6% Al, 4% V (ASTM F136, ISO 5832-3).
- Cover Screws for Nobel Biocare N1 Implant System: Titanium Alloy 90% Ti, 6% Al, 4% V and Diamond Like Carbon (DLC) coating (ASTM F136, ISO 5832-3).

## Sterility and Reusability Information:

Cover Screws have been sterilized using irradiation and are intended 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 as the device sterility and/or integrity may be compromised.

**Caution:** Cover Screws are a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

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

## Magnetic Resonance (MR) Safety Information:

Cover screws contain metallic materials which can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that cover screws are unlikely to impact patient safety under the following MRI 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) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

**Note:** Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Under the conditions defined above, these devices are expected to produce a maximum temperature rise of 4.1°C (39.4°F) after 15 minutes of continuous scanning.

In the non-clinical testing, the image artifact caused by the devices extends approximately 30 mm from the devices when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

**Note:** Although the non-clinical testing demonstrates that cover screws are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to support a claim of MR Safe or MR Conditional for the cover screws.

## Performance Requirements and Limitations:

To achieve the desired performance, cover screws must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with cover screws, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

## Facilities and Training:

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

## 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:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

## Manufacturer and Distributor Information:

**Manufacturer:**
Nobel Biocare AB
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411 17 Göteborg
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CE 2797
CE Mark for
Class IIb Devices

**Notice Regarding Canadian Device Licensure:** Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

## Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

| Product | Basic UDI-DI Number |
|---|---|
| Cover Screw Branemark System® NP<br>Cover Screw Branemark System® RP<br>Cover Screw Branemark System® WP | 73327470000001336W |
| Cover Screw Conical Connection 3.0<br>Cover Screw Conical Connection NP<br>Cover Screw Conical Connection RP<br>Cover Screw Conical Connection WP | 73327470000001316S |
| Cover Screw Nobel Biocare N1™ TCC NP<br>Cover Screw Nobel Biocare N1™ TCC RP | 73327470000002116R |

**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

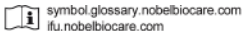
Rx Only

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



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