

Cover Screws



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 an internal tri-channel connection can be used with Nobel Biocare's NobelReplace® Tapered Groovy® and Replace Select™ implant systems.
- Cover Screw which feature an External hex connection can be used with Nobel Biocare's Brånemark System®, NobelZygoma and NobelSpeedy® Groovy® implant systems.
- Cover Screws which feature a Tri-oval Conical Connection (TCC) can be used with Nobel Biocare's N1™ -TiUltra™ TCC Implant system.

The Cover Screw Nobel Biocare 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.

Intended Use / Intended Purpose

Dental Implant Cover Screws

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.

Cover screw Nobel Biocare N1™

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

Indications

Dental Implant Cover Screws

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.

Cover Screw	Connection Type	Implant Platform	Implant System	Screwdriver
Cover Screw Brånemark System® NP	External Hex	NP	Brånemark System® (IFU1015) NobelSpeedy® Groovy® (IFU1007)	Cover Screw Driver Brånemark System® Hexagon (IFU1085)
Cover Screw Brånemark System® RP		RP	Brånemark System® (IFU1015) NobelSpeedy® Groovy® (IFU1007) NobelZygoma 0° (IFU1051)	
Cover Screw Brånemark System® WP		WP	Brånemark System® (IFU1015) NobelSpeedy® Groovy® (IFU1007)	
Cover Screw Conical Connection 3.0	Conical Connection	3.0	NobelActive® (IFU1001)	Unigrip™ (IFU1058)
Cover Screw Conical Connection NP		NP	NobelActive® (IFU1001)	
Cover Screw Conical Connection RP		RP	NobelParallel™ CC (IFU1002) NobelReplace® CC (IFU1010)	
Cover Screw Conical Connection WP		WP		
Cover Screw NobelReplace® NP	Internal Tri-channel	NP	Replace Select™, NobelReplace® Tapered Groovy® (IFU1012)	
Cover Screw NobelReplace® RP		RP		
Cover Screw NobelReplace® WP		WP		
Cover Screw NobelReplace® 6.0		6.0		
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		

Table 1 – Cover Screws with Compatible Implants and Screwdrivers

Cover Screws Nobel Biocare N1™

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 static and dynamic 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.

Cover screws must only be used 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, and 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 pediatric/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 successful treatment. Sterilized instruments not only safeguard 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. gauze, a dental dam, or throat shields).

After the implant placement, the surgeon's evaluation of bone quality and primary stability will determine when the 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

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 Brånemark System® Hexagon or an Omnigrip™ Mini as indicated in Table 1, depending on the connection type (see Figure A).

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

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.

Cover Screw	Abutment Screw Retrieval Instruments
Cover Screw Brånemark System® NP	Abutment Screw Retrieval Reverse Drill 3.0/NP Abutment Screw Retrieval Instrument 3.0/NP
Cover Screw Brånemark System® RP	Abutment Screw Retrieval Reverse Drill RP/WP/6.0 Abutment Screw Retrieval Instrument RP/WP/6.0
Cover Screw Brånemark System® WP	Abutment Screw Retrieval Reverse Drill RP/WP/6.0 Abutment Screw Retrieval Instrument RP/WP/6.0
Cover Screw Conical Connection 3.0	Abutment Screw Retrieval Reverse Drill CC 3.0/NP & TCC NP/RP Abutment Screw Retrieval Instrument CC 3.0/NP & TCC NP/RP
Cover Screw Conical Connection NP	Abutment Screw Retrieval Reverse Drill CC 3.0/NP & TCC NP/RP Abutment Screw Retrieval Instrument CC 3.0/NP & TCC NP/RP
Cover Screw Conical Connection RP	Abutment Screw Retrieval Reverse Drill RP/WP/6.0 Abutment Screw Retrieval Instrument RP/WP/6.0
Cover Screw Conical Connection WP	Abutment Screw Retrieval Reverse Drill RP/WP/6.0 Abutment Screw Retrieval Instrument RP/WP/6.0
Cover Screw NobelReplace® NP	Abutment Screw Retrieval Reverse Drill 3.0/NP Abutment Screw Retrieval Instrument 3.0/NP
Cover Screw NobelReplace® RP	Abutment Screw Retrieval Reverse Drill RP/WP/6.0 Abutment Screw Retrieval Instrument RP/WP/6.0
Cover Screw NobelReplace® WP	Abutment Screw Retrieval Reverse Drill RP/WP/6.0 Abutment Screw Retrieval Instrument RP/WP/6.0
Cover Screw NobelReplace® 6.0	Abutment Screw Retrieval Reverse Drill RP/WP/6.0 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 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 Abutment Screw Retrieval Instrument CC 3.0/NP & TCC NP/RP

Table 2 – Compatible Abutment Screw Retrieval Instruments

Materials

- Cover Screws for the Nobel Biocare N1™ Implant System: Titanium Alloy 90% Ti, 6% Al, 4% V (ASTM F136, ISO 5832-3). and Diamond Like Carbon (DLC) coating.
- Cover Screw Conical Connection, Internal Tri-channel Connection and External Hex implants: Titanium alloy 90% Ti, 6% Al, 4% V.

Sterility and Reusability Information

Cover Screws have been sterilized using irradiation and are intended for single. 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 single use products 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 a non-sterile device may lead to infection of tissues or infectious diseases.

Magnetic Resonance (MR) Safety Information

Cover screws Brånemark System®, Cover Screw Conical Connection and Cover Screws NobelReplace®

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.

Cover Screws Nobel Biocare N1™ TCC

MR Safety Information for Single Tooth Restoration

MR Safety Information



Non-clinical testing has demonstrated that the Cover Screw Nobel Biocare N1™ TCC is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient.

Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T)
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 58.9 T/m (5,890 G/cm).	
RF Excitation	Circularly Polarized (CP).	
RF Transmit Coil Type	Whole body transmit coil.	
Maximum Whole-Body SAR [W/kg]	Inferior to the neck: 2.0 W/kg Superior to the neck: 0.5 W/kg	Inferior to the xiphoid: 2.0 W/kg Between the xiphoid and neck: 1.0 W/kg Superior to the neck: 0.5 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0 °C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 3 T MRI system.	

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
PO Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

CE Mark for Class IIb Devices

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

EN All rights reserved.

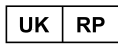
Nobel Biocare, the Nobel Biocare logotype and all other trademarks used in this document are, if nothing else is stated or is evident from the context in a certain case, trademarks of Nobel Biocare. Product images in this folder are not necessarily to scale. All product images are for illustration purposes only and may not be an exact representation of the product.

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 / European Union



UK Responsible Person



Authorised Representative in Switzerland



Sterilized using Ethylene Oxide



Sterilized using irradiation



Sterilized using steam or dry heat



Batch code



Catalogue number



Unique Device Identifier



Serial number



Medical device



Magnetic resonance safe



Caution



Magnetic resonance conditional



Non-sterile



Contains hazardous substances



Contains or presence of DEHP phthalate



Contains or presence of natural rubber latex



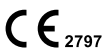
Contains or presence of phthalate



Contains biological material of animal origin



CE mark



CE mark with Notified Body number



UKCA mark



UKCA mark with Approved Body number



Consult instructions for use



For prescription use only



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

Link to Online Symbols Glossary and IFU Portal



Date of manufacture



Manufacturer



Use-by date



Upper limit of temperature



Temperature limit



Do not resterilize



Do not re-use



Non-pyrogenic



Date



Tooth number



Patient number



Patient identification



Health care centre or doctor



Patient information website



EU Importer



Swiss Importer



Double sterile barrier system



Single sterile barrier system



Single sterile barrier system with protective packaging inside



Single sterile barrier system with protective packaging outside



Do not use if package is damaged and consult instructions for use



Keep away from sunlight



Keep dry