Cover Screws

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Description

Cover Screws are components that cover the implant platform and prevent 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:

- Internal Conical Connection for: NobelActive®, NobelReplace® CC and NobelParallel™ CC.
- Internal tri-channel connection for: Replace Select™ Tapered.
- External hex connection for: Brånemark System® and NobelSpeedy® Groovy®.
- 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

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.

Indications

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

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.

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) NobelParallel™ CC (IFU1002) NobelReplace® CC (IFU1010)	
Cover Screw Conical Connection RP		RP	NobelActive® (IFU1001) NobelParallel™ CC (IFU1002) NobelReplace® CC (IFU1010) Trefoil™ System (IFU1099)	
Cover Screw Conical Connection WP		WP	NobelActive® (IFU1001) NobelParallel™ CC (IFU1002) NobelReplace® CC (IFU1010)	
Cover Screw NobelReplace® NP	Internal Tri-channel	NP	NobelReplace® Tapered Groovy, ReplaceSelect™ (IFU1012)	
Cover Screw NobelReplace® RP		RP		
Cover Screw NobelReplace® WP		WP		
Cover Screw NobelReplace® 6.0 mm		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	Nobel Biocare N1™ TiUltra TCC (IFU1087)	

Table 1 – Cover Screws with Compatible Implants and Screwdrivers

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.

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).

Caution Tighten the Cover Screw only finger-tight to avoid excessive loads that might damage the Cover Screw parts.

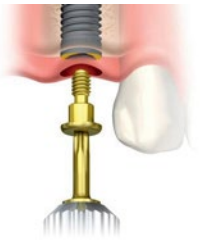


Figure A – Tightening the Cover Screw

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 – Cover Screws with Compatible Abutment Screw Retrieval Instruments

Materials

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

- Cover Screw for implants with Internal Conical Connection, External Hex, Internal tri-channel connection: 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

MR Safety Information for Single Tooth Restoration

MRI Safety Information	MR	
Non-clinical testing has demonstrated that the Cover Screw 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 xyphoid: 2.0 W/kg Between the xyphoid 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.	

MR Safety Information for Single Tooth configuration with Zygoma implants (applicable only during Zygoma Implant healing phase)

MRI Safety Information		
Non-clinical testing has demonstrated the Cover Screw Brånemark System® RP is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentionned here below. Failure to follow these confitions 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 shoulders: 2.0 W/kg Superior to the shoulders: 0.2 W/kg	Inferior to the xyphoid: 2.0 W/kg Superior to the xyphoid: 0.2 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 2.4 cm from the devices or device assemblies when imaged in a 3 T MRI system.	
Caution	Configurations with more than 2 Zygoma implants 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 configurations with more than 2 Zygoma implants in the MR environment is unknown. Scanning a patient who has this configuration may result in patient injury.	
Implant placement with intention to restore at prosthetic level with PIBs or IBOs (multiple tooth restorations): Please consult IFU for NobelProcera® Implant Bridge Titanium and Zirconia, NobelProcera® Crown and Bridge, NobelProcera® HT ML FCZ, and NobelProcera® Implant Bar Overdenture for use as part of a bridge configuration		

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
Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA
CE Mark for Class IIb Devices	CE 2797

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 / 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

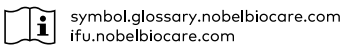
CE mark with Notified Body number

UKCA mark

UKCA mark with Approved Body number

Consult instructions for use

For prescription use only



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