Cover Screws

Important – Disclaimer of Liability

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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 Brånemark 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.

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 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.

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™ (IFU1085)
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™ systems (IFU1099)	
Cover Screw Conical Connection WP		WP	NobelActive® (IFU1001) NobelParallel™ CC (IFU1002) 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)	
Cover Screw NobelReplace® NP	Internal Tri-channel	NP	NobelReplace® Tapered Groovy, ReplaceSelect™ (IFU1012)	Unigrip™ (IFU1085)
Cover Screw NobelReplace® RP		RP		
Cover Screw NobelReplace® WP		WP		
Cover Screw NobelReplace® 6.0 mm		6.0		

Table 1 – Cover Screws with Compatible Implants and Screwdrivers

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, 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. gauze, dental dam, or 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

The placement of this device is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, swelling. 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).

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 Conical Connection, internal Tri-Channel and External hex: 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 (ASTM F136, ISO 5832-3) and Diamond Like Carbon (DLC) coating.

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

MR Safety Information for Single Tooth Restoration

MRI Safety Information		
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 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 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.		

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
UK Responsible Person UK RP	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class IIb Devices	CE 2797
UKCA Mark for Class IIb Devices	UK CA 0086

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

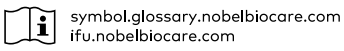
Basic UDI-DI Information

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

Product	Basic UDI-DI Number
Cover Screw Brånemark System® NP Cover Screw Brånemark System® RP Cover Screw Brånemark System® WP	733274700000001336W
Cover Screw Conical Connection 3.0 Cover Screw Conical Connection NP Cover Screw Conical Connection RP Cover Screw Conical Connection WP	733274700000001316S
Cover Screw Nobel Biocare N1™ TCC NP Cover Screw Nobel Biocare N1™ TCC RP	733274700000002116R
Cover Screw NobelReplace®	7332747000000012875

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	