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).

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

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to 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 respective Nobel Biocare Implant Systems.

Materials

Cover Screws for implants with Internal Conical Connection, Internal Tri-Channel and External Hex connection

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Cover Screws for Nobel Biocare N1 Implant System

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value). Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing carbon coating, containing tungsten carbide and carbon with chromium interlayer between substrate and Diamond like Carbon coating.

Plug: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

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 and/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 Devices in the IFU

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.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the cover screws. The SSCP can be obtained at the following website: ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED)

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/or Handling Procedure

1. Select the appropriate cover screw based on the implant connection and platform type.

2. Connect the cover screw to the implant and hand tighten using a Unigrip™ Screwdriver, a Driver Brånemark System® Hexagon or an Omnigrip™ Mini, 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.

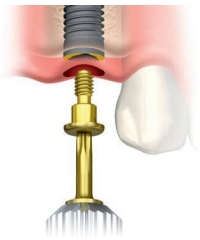

Figure A – Tightening the Cover Screw

3. To remove the cover screw, untighten the screw by hand using the appropriate screwdriver.

4. In the event the cover screw becomes stuck or is broken, abutment screw retrieval instruments can be used. Refer to Table 1 for the compatible instruments and Nobel Biocare IFU1043 for further details.

Table 1 – Cover Screws with Compatible Abutment Screw Retrieval Instruments

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

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.

Magnetic Resonance (MR) Safety Information

These products are fabricated from a metal material which can be affected by MR energy. For further information refer to Nobel Biocare publication **Magnetic Resonance (MR) Safety Information** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices 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 the devices, 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 Göteborg 411 17 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 Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
CE Mark for Class IIb Devices	CE 2797
UKCA Mark for Class IIb Devices	UK CA 0086

Note Refer to the product label to determine the applicable conformity marking for each device.

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

Product	Basic UDI-DI Number
Cover Screw Brånemark System® NP Cover Screw Brånemark System® RP Cover Screw Brånemark System® WP	733274700000013 36W
Cover Screw Conical Connection 3.0 Cover Screw Conical Connection NP Cover Screw Conical Connection RP Cover Screw Conical Connection WP	733274700000013 16S
Cover Screw Nobel Biocare N1™ TCC NP Cover Screw Nobel Biocare N1™ TCC RP	733274700000021 16R
Cover Screw NobelReplace®	733274700000022 26W

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.