Clinical Screws, Abutment Screws, Prosthetic 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

Clinical screws, abutment screws and prosthetic screws are pre-manufactured dental implant screws designed to fix dental prostheses or dental implant system components such as implant abutments and implant healing abutments to an endosseous dental implant or to another abutment.

An assortment of clinical screws, abutment screws and prosthetic screws are available for use with different prostheses or implant system components, depending on the dental implant platform or connection type.

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.

Clinical screws, abutment screws and prosthetic screws are intended for use with 3.0, NP, RP, WP or 6.0 platform sizes; the specific screw used must have the same platform size as the implant or abutment.

Refer to Table 1 for an overview of the coatings and/or color coding applied where applicable.

Note The Omnigrip™ Clinical Screw CC and Clinical Screw Nobel Biocare N1™ TCC are color coded to indicate the compatibility with the corresponding Nobel Biocare platform components.

Table 1 – Surface Coating and Color Coding for Clinical, Abutment, and Prosthetic Screws

Clinical/Abutment/Prosthetic Screw	Coating	Color Coding
Clinical Screw CC	none (NP) DLC (3.0, RP, WP)	none
Omnigrip™ Clinical Screw CC	none (NP) DLC (RP, WP)	●
Clinical Screw Nobel Biocare N1™ TCC	DLC	● (NP) ● (RP)
Abutment Screw NobelReplace®	none (NP) TiOdize (RP, WP, 6.0)	none
Screw Ceramic Abutment NobelReplace®	none (NP) TiOdize (RP, WP, 6.0)	none
Abutment Screw Brånemark System®	DLC	none
Screw Ceramic Abutment Brånemark System®	none (NP) DLC (RP, WP)	none
Screw Multi-unit Angled Abutment CC	DLC	none
Clinical Screw Multi-unit Abutment Nobel Biocare N1™ TCC	DLC	none
Screw Multi-unit Angled Abutment NobelReplace®	DLC	none
Screw Multi-unit Angled Abutment Brånemark System®	DLC	none
Prosthetic Screw Multi-unit Abutment	DLC	none
Prosthetic Screw Multi-unit Abutment Omnigrip™ Mini	DLC	none
NobelZygoma 0° Angled Multi-unit		
Abutment Screw	DLC	none
Brånemark System® Zygoma Abutment Screw	DLC	none
Brånemark System® Zygoma Angled Multi-unit Abut Screw	DLC	none
Omnigrip™ Clinical Screw Titanium (CC and Tri-Channel)	none (NP) DLC (RP)	none
Temporary Prosthetic Screw Multi-unit Abutment	none	none

Intended Use/Intended Purpose

Clinical Screws, Abutment Screws, and Prosthetic Screws

Intended for use to fasten dental implant system components to a dental implant or to another component.

Indications

Clinical and Abutment Screws

Clinical and Abutment Screws are indicated for use to secure a dental abutment or framework to a dental implant in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.

Prosthetic Screw

Prosthetic screws are indicated for use to secure a dental abutment or framework to a dental abutment or base in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.

Temporary prosthetic screws are indicated for use to secure a temporary framework to a dental abutment in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation, for up to 180 days.

Contraindications

It is contraindicated to use clinical screws, abutment screws and prosthetic screws in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are contraindicated for treatment with Nobel Biocare implants or restorative components.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), DLC (diamond like carbon) coating.

For contraindications specific to the abutment or framework, refer to the Nobel Biocare Instructions for Use for the component.

Materials

Screw Ceramic Abutment NobRpl (NP, RP/WP/6.0), Screw Ceramic Abutment (NobRpl NP, Bmk Syst NP), Omnigrip™ Clinical Screw (CC NP, Titanium CC NP, Ti Tri-ChannelNP), Brånemark System® Zygoma Abutment Screw, Temporary Prosthetic Screw Multi-unit Abutment and Clinical Screw Conical Connection NP

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.% Aluminum, 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).

Abutment Screw Brånemark System, Clin Screw Multi-unit Abut Nobel Biocare N1 TCC, Clinical Screw Nobel Biocare N1™ TCC, Clinical Screw Conical Connection, Prosthetic Screw Multi-unit, NobelZygoma™ 0° Angled Multi-unit Abutment Screw, Brånemark System® Zygoma Angled Multi-unit Abutment Screw, Screw Ceramic Abutment (Bmk Syst RP, Bmk Syst WP, NobRpl RP/WP/6.0), Omnigrip™ Clinical Screw (CC RP/WP, Titanium CC RPWP, Ti Tri-Chn RP/WP/6.0), Screw Multi-unit Angled Abutment (Bmk Syst, NobRpl, Conical Connection)

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.% Aluminum, 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.

Cautions

General

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

Clinical screws, abutment screws, and prosthetic screws must only be used with compatible Nobel Biocare instruments and components. Use of instruments and components that are not intended to be used in combination with the clinical screw, abutment screw or prosthetic screw 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 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 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

Small diameter implants and angled abutments are not recommended for the posterior region.

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).

Intended Users and Patient Groups

Clinical screws, abutment screws, and prosthetic screws are to be used by dental health care professionals.

Clinical screws, abutment screws, and prosthetic 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

Clinical screws, abutment screws and prosthetic 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 clinical screws, abutment screws and prosthetic screws

The placement of these devices is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, and swelling. During screw placement or removal, the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Clinical screws, abutment screws and prosthetic screws are part of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to those associated with teeth, such as retained cement, calculus, mucositis, ulcera, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

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 clinical screws, abutment screws and prosthetic 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

Handling Procedure

1. Select the appropriate clinical screw, abutment screw, or prosthetic screw for the abutment or framework.

2. Following conventional procedures insert the screw into the abutment or framework and place the assembly onto the implant or abutment.

Refer to Nobel Biocare Instructions for Use (IFU) of the associated abutment or framework for handling procedures specific for use of the clinical screw, abutment screw or prosthetic screw with respective abutment or framework.

3. Tighten the clinical screw, abutment screw or prosthetic screw using the appropriate screwdriver (see compatibility IFU and the Manual Torque Wrench Prosthetic). Refer to Nobel Biocare Instructions for Use (IFU) IFU1098 for information regarding the Manual Torque Wrench Prosthetic.

Note the tightening torque of the Temporary Prosthetic Screw is 15 Ncm.

Caution Never exceed recommended maximum tightening torque for the clinical screw, abutment screw or prosthetic screw as stated in the IFU for the associated abutment or framework. Overtightening of the clinical screw, abutment screw and prosthetic screw may lead to a screw fracture and/or damage of the component.

Caution Laboratory screws must not be used to place the finalized restoration in order to avoid damaging the bridge.

Sterility and Reusability Information

Warning Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

The Clinical Screw Nobel Biocare N1™ and Clinical Screw Multi-unit Abutment Nobel Biocare N1™ have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

Caution The Clinical Screw Nobel Biocare N1™ and Clinical Screw Multi-unit Abutment Nobel Biocare N1™ 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.

The Clinical Screw CC, Omnigrip™ Clinical Screw CC, Abutment Screw NobelReplace®, Abutment Screw Brånemark System®, Screw Multi-unit Angled Abutment, Omnigrip™ Clinical Screw Titanium CC, Omnigrip™ Clinical Screw Tri-channel,Prosthetic Screw Multi-unit Abutment and Temporary Prosthetic Screw Multi-unit Abutment are delivered non-sterile and are intended for single use only. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Caution The Clinical Screw CC, Omnigrip™ Clinical Screw CC, Abutment Screw NobelReplace®, Abutment Screw Brånemark System®, Screw Multi-unit Angled Abutment, Omnigrip™ Clinical Screw Titanium CC, Omnigrip™ Clinical Screw Tri-channel, Prosthetic Screw Multi-unit Abutment and Temporary Prosthetic Screw Multi-unit Abutment 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.

Cleaning and Sterilization Instructions

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

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

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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
Clinical Screw CC	73327470000001837D
Clinical Screw Nobel Biocare N1™ TCC Abutment Screw NobelReplace® Abutment Screw Brånemark System® Brånemark System® Zygoma Abutment Screw	
Screw Ceramic Abutment Bmk Syst RP	733274700000018077
Screw Ceramic Abutment NobRpl RP/WP/6.0 Screw Ceramic Abutment NobRpl NP Screw Ceramic Abutment Bmk Syst WP Screw Ceramic Abutment Bmk Syst NP	
Screw Ceramic Abutment NobelReplace® Screw Ceramic Abutment Brånemark System®	733274700000018179
Screw Multi-unit Angled Abutment CC	73327470000001827B
Clinical Screw Multi-unit Abutment Nobel Biocare N1™ TCC Screw Multi-unit Angled Abutment NobelReplace® Screw Multi-unit Angled Abutment Brånemark System® Prosthetic Screw Multi-unit Abutment Prosthetic Screw Multi-unit Abutment Omnigrip™ Mini NobelZygoma 0° Angled Multi-unit Abutment Screw Brånemark System® Zygoma Angled Multi-unit Abut Screw	
Omnigrip™ Clinical Screw CC	73327470000002066Y
Omnigrip™ Clinical Screw Titanium CC Omnigrip™ Clinical Screw Titanium Tri-Channel Omnigrip™ Clinical Screw Titanium (CC & Tri-Channel)	

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.