Clinical Screws, Abutment Screws, and Prosthetic Screws

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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. Table 1 summarizes the available screws and the compatible Nobel Biocare abutments, frameworks and screwdrivers:

Clinical/Abutment/ Prosthetic Screw	Abutment/Framework	Screwdriver
Clinical Screw CC	Universal Base CC	Unigrip™
	Esthetic Abutment CC	
	Temporary Abutment CC	
	NobelProcera® Abutment Ti CC	
	NobelProcera® Abutment Zr CC	
	NobelProcera® Implant Bridge Ti CC	
	NobelProcera® Implant Bridge Zr CC	
	NobelProcera® Implant Bar Overdenture CC	
	Snappy™ Abutment CC	
	GoldAdapt™ CC	
	Procera Esthetic Abutment CC	
	Narrow Profile Abutment CC	
Omnigrip™ Clinical Screw CC	NobelProcera® Angulated Screw Channel Abutment Zr CC	Omnigrip™
	NobelProcera® HT ML FCZ Implant Crown CC	
	NobelProcera® HT ML FCZ Implant Bridge CC	
	NobelProcera® Zirconia Implant Bridge CC	
Clinical Screw Nobel Biocare N1™ TCC	Universal Abutment TCC	Omnigrip™ Mini
	17°/30° Multi-unit Abutment Xeal™ TCC	
	Temporary Abutment TCC	
	Healing Abutment TCC	
	Esthetic Abutment Nobel Biocare N1™ TCC	
	Titanium Abutment Blank Nobel Biocare N1™ TCC	
Abutment Screw NobelReplace®	Universal Base Tri-channel	Unigrip™
	Esthetic Abutment NobelReplace®	
	Temporary Abutment NobelReplace®	
	NobelProcera® Abutment Ti NobelReplace®	
	NobelProcera® Implant Bridge Ti NobelReplace®	
	NobelProcera® Implant Bar Overdenture NobelReplace®	
	Snappy™ Abutment NobelReplace®	
	GoldAdapt™ NobelReplace®	
	Gold Abutment Bar NobelReplace®	
	Narrow Profile Abutment NobelReplace®	

Screw Ceramic Abutment NobelReplace®	NobelProcera® Abutment Zr NobelReplace® NobelProcera® HT ML FCZ Implant Bridge NobelReplace® NobelProcera® Zirconia Implant Bridge NobelReplace® Procera Esthetic Abutment NobelReplace®	Unigrip™
Abutment Screw Brånemark System®	Universal Base External Hex Esthetic Abutment Brånemark System® Temporary Abutment Brånemark System® NobelProcera® Abutment Ti Brånemark System® NobelProcera® Implant Bridge Ti Brånemark System® NobelProcera® Implant Bar Overdenture Brånemark System® Snappy™ Abutment Brånemark System® GoldAdapt™ Brånemark System® Gold Abutment Brånemark System® CeraOne Abutment Brånemark System®	Unigrip™
Screw Ceramic Abutment Brånemark System®	NobelProcera® Abutment Zr Brånemark System® NobelProcera® HT ML FCZ Implant Bridge Brånemark System® NobelProcera® Zirconia Implant Bridge Brånemark System® Procera Esthetic Abutment Brånemark System®	Unigrip™
Screw Multi-unit Angled Abutment CC	17°/30° Multi-unit Abutment CC	Unigrip™
Clinical Screw Multi-unit Abutment Nobel Biocare N1™ TCC	Straight Multi-unit Abutment Xeal™ TCC	Multi-unit
Screw Multi-unit Angled Abutment NobelReplace®	17°/30° Multi-unit Abutment NobelReplace®	Unigrip™
Screw Multi-unit Angled Abutment Brånemark System®	17°/30° Multi-unit Abutment Brånemark System®	Unigrip™
Prosthetic Screw Multi-unit Abutment	Temporary Coping Multi-unit Abutment NobelProcera® Implant Bridge Ti Multi-unit NobelProcera® Implant Bridge Zr Multi-unit NobelProcera® Implant Bar Overdenture Multi-unit NobelProcera® HT ML FCZ Implant Bridge Multi-unit Gold Coping Multi-unit	Unigrip™
Prosthetic Screw Multi-unit Abutment Omnigrip™ Mini	NobelProcera® Zirconia Implant Bridge Multi-unit	Omnigrip™ Mini
NobelZygoma 0° Angled Multi-unit Abutment Screw	45°/60° Multi-unit Abutment External Hex	Unigrip™
Brånemark System® Zygoma Abutment Screw	NobelProcera® Implant Bridge Zygoma	Unigrip™
Brånemark System® Zygoma Angled Multi-unit Abutment Screw	17° Multi-unit Abutment Brånemark System® Zygoma	Unigrip™

Table 1 – Compatibility of Clinical, Abutment, and Prosthetic Screws with Nobel Biocare Abutments, Frameworks and Screwdrivers

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 2 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.

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 Abutment Screw	DLC	none

Table 2 – Surface Coating and Color Coding for Clinical, Abutment, and Prosthetic Screws

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 to restore chewing function.

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 to restore chewing function.

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.

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 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).

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 Clinical, Abutment, and Prosthetic Screws

Clinical screws, abutment screws and prosthetic screws are components 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, Abutment, 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.

A copy of the Summary of Safety and Clinical Performance document 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 (see Table 1).

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 Table 1) and the Manual Torque Wrench Prosthetic. Refer to Nobel Biocare Instructions for Use (IFU) IFU1098 for information regarding the Manual Torque Wrench Prosthetic.

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.

Materials

- Clinical screws, abutment screws and prosthetic screws: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.

- Certain screws have DLC (Diamond Like Carbon) coating or TiOdize type II anodization (see Table 2).

Sterility and Reusability Information

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.

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 The Clinical Screw Nobel Biocare N1™, Clinical Screw Multi-unit Abutment Nobel Biocare N1™ Clinical Screw CC, Omnigrip™ Clinical Screw CC, Abutment Screw NobelReplace®, Abutment Screw Brånemark System®, Screw Multi-unit Angled Abutment and 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.

The Clinical Screw CC, Omnigrip™ Clinical Screw CC, Abutment Screw NobelReplace®, Abutment Screw Brånemark System®, Screw Multi-unit Angled Abutment and 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.

Cleaning and Sterilization Instructions

The Clinical Screw CC, Omnigrip™ Clinical Screw CC, Abutment Screw NobelReplace®, Abutment Screw Brånemark System®, Screw Multi-unit Angled Abutment and Prosthetic Screw Multi-unit Abutment are delivered non-sterile by Nobel Biocare and are intended for single use. Prior to use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12.

- Sterilization: AAMI ST79 and ISO 17665-1.

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note The Clinical Screw CC, Omnigrip™ Clinical Screw CC, Abutment Screw NobelReplace®, Abutment Screw Brånemark System®, Screw Multi-unit Angled Abutment and Prosthetic Screw Multi-unit Abutment are been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.

2. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.

3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.

4. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 20 seconds until all visible soil is removed.

5. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.

6. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

Note It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying

1. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
4. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
6. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W_{eff}) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C (104°F) / maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly dispose any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 (pre-vacuum cycle); Amsco Century Sterilizer (gravity cycle).

Note It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

1. Seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - EN ISO 11607 and/or DIN 58953-7.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 3 presents examples of suitable sterilization containers, pouches, and wraps.

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch
Pre-vacuum Cycle	SteriCLIN® pouch

Table 3 – Recommended Sterilization Pouches

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 4):

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity cycle[1]	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar[4]
Pre-vacuum cycle[1]	132°C (270°F)	4 minutes	20 minutes	≥2868.2 mbar[4]
Pre-vacuum cycle[2]	134°C (273°F)	3 minutes	20 minutes	≥3042 mbar[5]
Pre-vacuum cycle[3]	134°C (273°F)	18 minutes	20 minutes	≥3042 mbar[5]

Table 4 – Recommended Sterilization Cycles

1 Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

2 Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

3 Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.

4 Saturated steam pressure at 132°C as per required by EN ISO 17665-2.

5 Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/Shipping to Point of Use

The container and/or outer packaging used to transport or ship the processed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Magnetic Resonance (MR) Safety Information

MR Safety Information for Single Tooth Restoration

MRI Safety Information	MR	
Non-clinical testing has demonstrated that Clinical screws Nobel Biocare N1™ TCC, Clinical Screw CC, Omnigrip™ Clinical Screw CC, Abutment Screw NobelReplace®, Abutment Screw Brånemark System®, are 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 Multiple Teeth Configurations

MRI Safety Information	MR	
Non-clinical testing has demonstrated that Clinical Screw Multi-unit Abutments Nobel Biocare N1™ TCC, Screw Multi-unit Angled Abutment, Prosthetic Screw Multi-unit Abutment, NobelZygoma 0° Angled Multi-unit Abutment Screw, Brånemark System® Zygoma Abutment Screw, Brånemark System® Zygoma Angled Multi-unit Abutment Screw are MR conditional. A patient with these devices 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 44.4 T/m (4,440 G/cm).	
RF Excitation	Circularly Polarized (CP).	
RF Transmit Coil Type	Whole body transmit coil.	
Maximum Whole-Body SAR [W/kg]	Inferior to the shoulder: 2.0 W/kg Superior to the shoulder: 0.2 W/kg	Inferior to the navel: 2.0 W/kg Superior to the navel: 0.1 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 2.7 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.	

Single Tooth Configurations Zygoma Implants (applicable only during Zygoma Implant healing phase)

MRI Safety Information	MR	
Non-clinical testing has demonstrated the Screw Multi-unit Angled Abutment, Prosthetic Screw Multi-unit Abutment, NobelZygoma 0° Angled Multi-unit Abutment Screw, Brånemark System® Zygoma Abutment Screw, Brånemark System® Zygoma Angled Multi-unit Abutment Screw are 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, these 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 these 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 1 411 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

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
Clinical Screw CC Clinical Screw Nobel Biocare N1™ TCC Abutment Screw NobelReplace® Abutment Screw Brånemark System® Brånemark System® Zygoma Abutment Screw	73327470000001837D
Omnigrip™ Clinical Screw CC	733274700000018077
Screw Ceramic Abutment NobelReplace® Screw Ceramic Abutment Brånemark System®	733274700000018179
Screw Multi-unit Angled Abutment CC 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 Abutment Screw	73327470000001827B

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

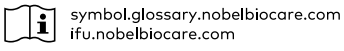
CE mark with Notified Body number

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