Clinical Screws, Abutment Screws, Prosthetic Screws

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Description

Abutment Screw, Prosthetic Screw and Clinical Screw are pre-manufactured devices to be directly connected to the dental abutment or framework, intended for use as an aid in prosthetic rehabilitation.

Clinical 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.

An assortment of Clinical 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.

Table 1 – Compatibility of Clinical, Abutment, and Prosthetic Screws with 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 NobelProcera® HT ML FCZ Implant Crown CC NobelProcera® HT ML FCZ Implant Bridge CC NobelProcera® Zirconia Implant Bridge CC	Omnigrip™
Clinical Screw Nobel Biocare N1™ TCC	Universal Abutment TCC 17°/30° Multi-unit Abutment Xeal™ TCC Temporary Abutment TCC Healing Abutment TCC Esthetic Abutments Nobel Biocare N1™ Titanium Abutment Blank Nobel Biocare N1™ TCC	Omnigrip™ Mini
Abutment Screw NobelReplace®	Universal Base Tri-channel 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®	Unigrip™
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 Abut Screw	17° Multi-unit Abut Brånemark System® Zygoma	Unigrip™
Omnigrip™ Clinical Screw Titanium (CC and Tri-Channel)	Titanium Abutment ASC (CC and Tri-Channel)	Omnigrip™

Clinical Screws Nobel Biocare N1™ TCC are intended for use with NP and RP 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.

Table 2 – 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) ● (NP)
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	DLC	none
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

Note Clinical Screw Nobel Biocare N1™ TCC is color coded to indicate the compatibility with the corresponding Nobel Biocare platform components.

Intended Use

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

Indications for Use

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 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.

Contraindications

It is contraindicated to use clinical 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

- 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).

Warning

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

Cautions

General Cautions

General

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

It is strongly recommended that the Clinical/Abutment/Prosthetic Screws are used only with compatible Nobel Biocare instruments and components. Use of instruments and components that are not intended to be used in combination with the Clinical/Abutment/Prosthetic 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 or appropriate pre- and post-treatment measures 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

Particular caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.

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).

When an abutment with a short gingival margin for clinical use with a compatible dental implant near the crestal bone level is the treatment of choice, consider the following clinical considerations:

- Select an appropriate gingival abutment margin height that maintains biologic width (supracrestal attachment) and suits the patient- and site-specific clinical conditions.
- Use careful clinical technique to avoid subgingival peri-implant cement impaction.
- Provide patient education, focusing on oral hygiene instruction and dental implant home care.
- Provide adjuncts to oral hygiene for effective plaque control, as needed.

After Surgery

Monitor for plaque accumulation, soft tissue inflammation, clinical attachment loss, abutment loosening, and marginal bone loss around the implant during patient maintenance visits.

Consider increasing the frequency of patient maintenance visits for oral examination and prophylaxis, as needed, to improve implant care and/or to monitor for tissue changes that could affect the long-term success of the implant.

Handling Procedure

1. Select the appropriate Clinical 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 with the respective abutment or framework.

3. Tighten the Clinical Screw using the appropriate screwdriver (see Table 1) and the Manual Torque Wrench Prosthetic. Refer to Nobel Biocare Instructions for Use (IFU) IFU1047 for information regarding the Manual Torque Wrench Prosthetic.

Caution Never exceed the recommended maximum tightening torque for the Clinical Screw as stated in the IFU for the associated abutment or framework. Overtightening of the Clinical 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

The Clinical Screw Nobel Biocare N1™ TCC and Clinical Screw Multi-unit Abutment Nobel Biocare N1™ TCC 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™ 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, Omnigrip™ Clinical Screw Titanium CC, Omnigrip™ Clinical Screw Tri-channel, 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.

Caution The Clinical Screw CC, Omnigrip™ Clinical Screw CC, Omnigrip™ Clinical Screw Titanium CC, Omnigrip™ Clinical Screw Tri-channel, 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.

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

Cleaning and Sterilization Instructions

The Clinical Screw CC, Omnigrip™ Clinical Screw CC, Omnigrip™ Clinical Screw Titanium CC, Omnigrip™ Clinical Screw Tri-channel, 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.

Caution Do not deviate from the following reprocessing instructions.

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, Omnigrip™ Clinical Screw Titanium CC, Omnigrip™ Clinical Screw Tri-channel, 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.

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.

Note FDA-cleared washer-disinfectors are to be used for the recommended cleaning parameters.

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. Cydezyme ASP and / or Neodisher Medizym; 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. Cydezyme ASP and / or Neodisher Medizym) 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 discard any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX- 320 and/or Selectomat PL/669-2CL (pre-vacuum cycle); Amsco Century Sterilizer and/or Selectomat PL/669-2CL (gravity cycle).

Note When using Systec HX- 320, Amsco Century Sterilizer, it is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches. When using Selectomat PL/669-2CL, it is recommended to perform sterilization with a maximum load of 2 containers with metal instruments and 2 packages of linen.

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 pouches.

Table 3 – Recommended Sterilization Pouches

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

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:
   - Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure, followed by a minimum drying time of 15 minutes in chamber.
   - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by a minimum drying time of 20 minutes in chamber.

Note FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

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 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		
Non-clinical testing has demonstrated that Clinical screws Nobel Biocare N1™ TCC, Clinical Screw CC, Omnigrip™ Clinical Screw CC, Omnigrip™ Clinical Screw Titanium CC, Omnigrip™ Clinical Screw Tri-channel and 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		
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 Abut 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		
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 Abut 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.

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
Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA

Caution Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

Legal Statements

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
					Rx only		symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com
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	