NobelProcera® Angulated Screw Channel Abutment Zirconia For Nobel Biocare Internal Conical Connection

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

Nobel Biocare's NobelProcera® ASC Abutment Zirconia is an individualized dental abutment. The abutment attaches directly to the endosseous dental implants and provides a platform for restoration. The NobelProcera® ASC Abutment Zirconia is designed and made individually to fit the individual requirements for each patient. The NobelProcera® ASC Abutment Zirconia is delivered with a titanium adapter and an Omnigrip™ clinical screw.

Adapter for Zirconia Ab (CC) NP/RP/WP are inserted into the NobelProcera® ASC Abutment Zirconia to act as the interface for all CC (Conical Connection) implant interfaces.

Connection	Platform	Ncm
Nobel Biocare Internal Conical Connection	NP	35
	RP	35
	WP	35

Table 1 – NobelProcera® Angulated Screw Channel (ASC) Abutment Zirconia availability and (clinical) screw tightening torque

Important NobelProcera® ASC Abutment Zirconia and corresponding (clinical) Omnigrip™ screws require Omnigrip™ screwdrivers.

Compatible implant Family	Available platform sizes
NobelActive®	NP, RP, WP
NobelReplace® Conical Connection	NP, RP
NobelReplace® Conical Connection PMC	NP, RP
NobelParallel™ Conical Connection	NP, RP, WP
NobelActive® TiUltra™	NP, RP, WP
NobelParallel™ Conical Connection TiUltra™	NP, RP, WP
NobelReplace® Conical Connection TiUltra™	NP, RP

Table 2 – Compatible Implant Families

	Product Family
Article Description	**NobelProcera® ASC Abutment Zirconia**
Implant replicas	Implant Replicas Conical Connection
Lab screws	Omnigrip™ Lab Screws CC
Screwdriver	Omnigrip™ Screwdrivers
Protection analogs	Protection Analogs Conical Connection
Abutment retrieval tools	Abutment Retrieval Instruments Zirconia CC

Table 3 – Additional compatible articles

Intended Use / Intended Purpose

NobelProcera® Angulated Screw Channel Abutment Zirconia and Adapter

Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.

Indications

Adapter for Zirconia Ab CC NP: same as intended purpose.

The NobelProcera® Angulated Screw Channel Abutment is a premanufactured prosthetic component directly connected to endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications

It is contraindicated to use Nobel Biocare's NobelProcera® ASC Abutment Zirconia (CC) NP/ RP/ WP:

- in patients who are medically unfit for an oral surgical procedure.
- in patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- in patients with high expected loading conditions, e.g. parafunctional tendencies such as bruxism and clenching.
- in patients who are allergic or hypersensitive to Yttria-stabilized Zirconiumoxide and Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium).
- with non-Nobel Biocare manufactured clinical screws.
- for lengths and thicknesses that do not fall within the indicated limits.

For contraindications specific to the implant or restorative component, refer to the Nobel Biocare or 3rd party manufacturer's Instructions for Use for the component.

Materials

- Adapter for ASC abutment NP/RP/WP: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.
- NobelProcera® ASC Abutment Zirconia: Yttria-stabilized Zirconiumoxide.
- Clinical screws: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136 and ISO 5832-3.

Cautions

General

One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) may result in failure.

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

NobelProcera® Abutment Zirconia NP is not recommended for posterior use.

NobelProcera® Angulated Screw Channel Abutments must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with NobelProcera® Angulated Screw Channel Abutments 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.

It is especially important to achieve proper stress distribution through adaptation and fitting of the crown or bridge, by adjusting the occlusion to the opposing jaw. In addition, avoid excessive transverse loading forces, particularly in immediate loading cases.

Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue of implants.

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 has to 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

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 installation, 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.

Forces that cause bending moments are known to be the most unfavorable, as they can potentially jeopardize the long-term stability of an implant-supported restoration. In order to decrease bending moments, the distribution of forces should be optimized by cross-arch stabilization, minimizing distal cantilevers, having a balanced occlusion as well as decreased cuspal inclination of the prosthetic teeth.

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

NobelProcera® ASC Abutment Zirconia are to be used by dental health care professionals.

NobelProcera® ASC Abutment Zirconia are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with NobelProcera® ASC Abutment Zirconia

NobelProcera® ASC Abutment Zirconia 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 NobelProcera® ASC Abutment Zirconia

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 connection or removal of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Implant prosthetics are components of a system that replaces teeth and as a result, the recipient may experience side effects similar to those associated with teeth, such as retained cement, calculus, mucositis, ulcers, soft tissue hyperplasia, soft and/or hard tissue recessions. When restoring or adapting a patient's dentition, lip biting, bruxism, and phonetic alterations may occur, and the neighboring/opposing prostheses may need adjustment or relining. Some patients may experience discoloration in the mucosal area such as wear of neighboring/opposing dentition/ prostheses.

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

Instructions for dental laboratory

NobelProcera® CAD abutment design

Scan and import clinical situation into software:

- Select and carefully mount appropriate NobelProcera® abutment position locator to facilitate the correct depth and orientation of the implant into the front-end software, prior to designing the abutment.
- Scan the clinical situation and the abutment position locators using a NobelProcera® scanner (or an approved NobelProcera® System), according to the tutorial found within the software.
- Once scanned, open the abutment CAD module and design your abutment, follow the instructions in the software tutorial, according to the patient's clinical needs whilst ensuring to provide adequate support for veneering material or crown retention.
- When designing the abutment, it is recommended to avoid designs where the margin height is higher than 4 mm in combination with abutment body angulations above 30 degrees.

NobelProcera® Wax-up abutment design

Scan and import clinical situation into the software:

- If optical wax is not used, the surface needs to be coated with a conventional optical scanning spray.
- Design abutment to provide adequate crown retention or support for veneering material.

Design recommendations

Although the minimum design shape is controlled by the software the following is a list of basic design recommendations:

- Height min. = 4 mm above implant platform to allow sufficient prosthetic retention.
- Height max. = 20 mm and diameter max 20 mm.
- Max. outer constraints are diameter 16 mm and a height of 15 mm.
- Min and Max constraints are enforced by the software.
- Once abutment is designed, dispatch order to NobelProcera® production plant.

Please refer to Table 4 for further design recommendations.

Recommended max angulation degree	
Margin height	**Recommendation for max upper body angulation**
0 mm	59°
1 mm	51°
2 mm	44°
3 mm	37°
4 mm	31°
5 mm	27°
6 mm	24°
7 mm	22°
8 mm	19°

Table 4 – Design recommendations for the angulation of Zirconia abutment

Note Omnigrip™ laboratory screws (identified by blue color-coding on entire screw) are available for temporary fixation of the abutments – used during the finalization of the restoration within the dental laboratory.

Finalizing procedures NobelProcera® ASC Abutments Zirconia

Caution Do not make any modifications to the seating area of the NobelProcera® Angulated Screw Channel Abutments as this may negatively affect its strength or fit.

- If necessary, make minor adjustments with diamond bur or flex disc with fine grit size under low pressure and with copious water irrigation.
- Proper surface finishing is mandatory if minor adjustments on the sintered frameworks were made.
- Sandblast using max. one bar of pressure utilizing 110 µm aluminum oxide, at an approximate distance of 10 mm.
- Clean in an ultrasonic unit.
- For single tooth screw-retained restorations it is possible to apply dental ceramics (veneering material) directly onto the abutment.

For long-term clinical success please follow the recommendations and handling instructions of the veneering material manufacturer.

- If a cement retained crown or bridge is required, follow the current workflow for the separate fabrication of this restoration. Please refer to NobelProcera® Crown and Bridge Instructions For Use, and software tutorials, for the fabrication of this restoration.

Clinical procedure

Caution The NobelProcera® Angulated Screw Channel Abutments are delivered non-sterile and must be cleaned, disinfected, and sterilized prior to placement in the patient's mouth. Refer to the Cleaning and Sterilization Instructions for greater detail.

1. Ensure that adapter is securely attached to the abutment, then insert the screw into the abutment, and place the assembly onto the implant. It is recommended to verify the final abutment seating using appropriate means.

Caution If modifying the restoration, use copious irrigation and appropriate protection equipment. Avoid inhalation of dust.

Note Post placement of the abutment, if it is necessary to remove the abutment for whatever reason from its seating in the oral environment, it may occur that the abutment's metal adapter remains in the implant. If this is the case, the metal adapter can easily be removed with minimal force utilizing Nobel Biocare Abutment Retrieval Instrument Zirconia Conical Connection.

2. Tighten the clinical screw in the abutment to 35 Ncm, using the corresponding Nobel Biocare torque wrench and Omnigrip™ Screwdriver.

Caution Only use clinical screws manufactured by Nobel Biocare when seating the NobelProcera® Angulated Screw Channel Abutments. Do not use laboratory screws to seat the NobelProcera® Angulated Screw Channel Abutments. The laboratory screws must be utilized in the dental laboratory only and not in patient.

3. Once the abutment is inserted into the implant, its seating verified and the defined torque applied, using conventional procedures the screw access hole of the screw retained crown can be sealed. Alternatively, if a final crown or bridge is to be cemented conventional procedures are to be followed and any excess cement removed.

Caution Never exceed the recommended prosthetic tightening torque given by the original manufacturer's Instruction for Use for the clinical screw. Over tightening may lead to screw fracture and/or damage of the restoration.

Caution For NobelProcera® Angulated Screw Channel Abutments on Nobel Biocare implants, never exceed the recommended prosthetic tightening torque for the clinical screw. Over tightening may lead to screw fracture and/or damage of the restoration.

The ASC Abutments are delivered with Omnigrip™ screws (identified by blue color- coding on screw head) require the use of the Omnigrip™ screwdriver (identified by blue color-coding – blue ring on driver shaft). The Omnigrip™ screws and screwdriver are not compatible with the Unigrip™ system.

Sterility and Reusability Information

The Nobel Biocare's NobelProcera® ASC Abutment Zirconia is delivered non-sterile and must be cleaned and then disinfected and/or sterilized prior to intraoral use following the procedures in the Cleaning and Sterilization Instructions.

During processing in the dental laboratory, the supra-construction can be cleaned as necessary without disinfection or sterilization.

The Clinical screw and the Adapter for ASC abutment NP/RP/WP 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.

Refer to the following Nobel Biocare IFU for information regarding the cleaning and sterilization procedures for the Clinical Screw (Table 5):

Component	IFU Number
Clinical Screw	IFU1057

Table 5 – Instruments with Cleaning/Sterilization Information in Other IFU

Caution The NobelProcera® Angulated Screw Channel Abutments, Adapter for ASC abutment NP/RP/WP and clinical screws 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

Cleaning and sterilization instructions for NobelProcera® supra-constructions that include non-metallic materials, which require cleaning and disinfection and/or sterilization prior to patient contact.

Clean, disinfect, and sterilize the Nobel Biocare's NobelProcera® ASC Abutment Zirconia according to the glaze, stain, and/or veneering material manufacturer's instructions prior to use.

The Adapter for ASC abutment NP/RP/WP 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.

Warning Do not use device if the packaging has been damaged or previously opened.

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 Adapter for ASC abutment NP/RP/WP have been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following processing 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. Repeat this step until the lumens are free of any visually datable soil.
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., 1.2mm / 2.0mm / 5.0mm diameter) for a minimum of 20 seconds.
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 of 2 minutes pre-cleaning with cold tap water
   - Draining
   - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5 % mildly alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 3 minutes neutralization with cold desalinated water
   - Draining
   - Minimum of 2 minutes rinsing with cold desalinated water
   - Draining
4. Run drying cycle at a minimum of 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 the 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 of lukewarm enzymatic cleaning solution (e.g. Cydezyme ASP; maximum of 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 an 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 Weff) containing an 0.5% enzymatic cleaning agent (e.g. Cydezyme ASP) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water 20 ml 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 (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 6 presents examples of suitable sterilization pouches.

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

Table 6 – Recommended Sterilization Pouches

2. Label the sterilization pouch with the information necessary to identify the device (e.g., 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 7):

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		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

Table 7 – 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 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

MRI Safety Information		
Non-clinical testing has demonstrated the NobelProcera® ASC Abutment Zirconia and Adapter is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient.		
Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T)
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 58.9 T/m (5,890 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	Inferior to the neck: 2.0 W/kg Superior to the neck: 0.5 W/kg	Inferior to the xyphoid: 2.0 W/kg Between the xyphoid and neck: 1.0 W/kg Superior to the neck: 0.5 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0 °C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 3T MRI system.	

Performance Requirements and Limitations

To achieve the desired performance, NobelProcera® Angulated Screw Channel 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 NobelProcera® Angulated Screw Channel, 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
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 Im/IIa/IIb Devices	UK CA 0086

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

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

Basic UDI-DI Information

Product	Basic UDI-DI Number
NobelProcera® Angulated Screw Channel Abutment Zirconia	7332747000001677F
Adapter for Zirconia Abutments	

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

CE mark

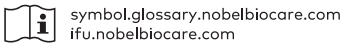
CE mark with Notified Body number

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