NobelProcera® Abutments Titanium and Zirconia

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

The NobelProcera®/Procera® Abutment Titanium is an individualized implant supported dental abutment fabricated from titanium (Ti6Al4V according to ASTM F136).

The NobelProcera®/Procera® Abutment Zirconia is an individualized implant supported dental abutment fabricated from zirconia (Yttria-stabilized tetragonal zirconia according to ISO 13356).

NobelProcera®/Procera® Abutments Titanium and Zirconia are part of an endosseous implant system and are intended for use as an aid in prosthetic rehabilitation to restore chewing function and esthetic appearance.

The NobelProcera®/Procera® Abutments Titanium are available on Nobel Biocare's Internal Conical Connection, External Hex connection, Internal Tri-Channel connections (see Table 1).

The NobelProcera®/Procera® Abutments Zirconia are available on Nobel Biocare's Internal Conical Connection, External Hex connection, Internal Tri-Channel connections (see Table 2).

The design of the abutment is determined in a dental laboratory, hospital or dental practice by scanning, designing and ordering the restoration using an approved Nobel Biocare software and adhering to the pre-defined minimum geometries in the design software.

The restoration once ordered is sent electronically to one of Nobel Biocare's manufacturing sites for fabrication.

After receiving the NobelProcera®/Procera® Abutments Titanium and Zirconia from Nobel Biocare, the dental laboratory finalizes the restoration.

Note For NobelProcera®/Procera® Abutments, laboratory screws are available. The laboratory screws are used only in the dental laboratory for temporary fixation of the abutment to an implant replica and are not intended for intraoral use.

After dental implants have been inserted into the patient's jaw, the individualized NobelProcera®/Procera® Abutment is attached to the implant, by means of a clinical screw which is delivered with the abutment. See Nobel Biocare Instructions for Use (IFU) IFU1057 for additional information regarding the clinical screws. This IFU is available for download at ifu.nobelbiocare.com.

If a cemented crown or bridge is to be placed on top of the abutment, the clinician should follow standard restorative procedures to do so, referring to bonding material manufacturer's Instructions for Use and any excess cement removed, for an optimal clinical outcome.

NobelProcera®/Procera® Abutments Zirconia on Nobel Biocare's Internal Tri-channel connection are pre-assembled with a metal adapter, to act as the engaging/rotational interface between the abutment and implant. Note that the metal adapter is color coded according to the platform size (yellow for RP, magenta for NP, blue for WP and green for the 6.0).

NobelProcera® Abutments Zirconia and Titanium are compatible with the Unigrip™ Screwdriver. NobelProcera® Abutments ASC Titanium are compatible with the Omnigrip™ Screwdriver.

The Ti Abutment ASC system (Angulated screw channel) includes the abutment, the clinical screws and the laboratory (lab) screws. The Ti Abutment ASC is a patient specific abutment which is produced via Nobel Procera centralized milling facilities. The abutment is connected to the implant with a clinical screw and features an angulated screw channel. The clinical screw features the Omnigrip™ interface which allows tightening up to 25° (see Table 3).

After dental implants have been inserted into the patient's jaw, the individualized NobelProcera® Abutment is attached to the implant, by means of a clinical screw which is delivered with the abutment. See Nobel Biocare Instructions for Use (IFU) IFU1057 for additional information regarding the clinical screws. This IFU is available for download at ifu.nobelbiocare.com.

If a cemented crown or bridge is to be placed on top of the abutment, the clinician should follow standard restorative procedures to do so, referring to bonding material manufacturer's Instructions for Use and any excess cement removed, for an optimal clinical outcome.

NobelProcera® Abutments ASC Titanium are compatible with the Omnigrip™ Screwdriver.

Table 1 – Compatibility NobelProcera®/Procera® Abutments Titanium

Titanium Abutment - With Unigrip™					
Connection	**Platform**	**Clinical Screw**	**Lab Screw**	**Screwdriver**	**Torque**
Conical Connection	3.0	Clinical Screw CC 3.0	Lab Screw Implant Level CC 3.0	Unigrip™	15Ncm
	NP	Clinical Screw CC NP	Lab Screw CC NP		35Ncm
	RP	Clinical Screw CC RP/WP	Lab Screw CC RP/WP		
	WP				
Tri-Channel	NP	Abutment Screw NobelReplace® NP	Lab Screw Implant Level NobRpl NP		
	RP	Abutment Screw NobelReplace® RP/WP/6.0	Lab Screw Implant Level NobRpl RP/WP/6.0		
	WP				
	6.0				
External Hex	NP	Abutment Screw Bmk Syst NP	Lab Screw CC NP		
	RP	Abutment Screw Bmk Syst RP	Lab Screw Ext Hex RP		
	WP	Abutment Screw Bmk Syst WP	Lab Screw Implant Level Bmk Syst WP		

Table 2 – Compatibility NobelProcera®/Procera® Abutments Zirconia

Zirconia Abutments - With Unigrip™					
Connection	**Platform**	**Clinical Screw**	**Lab Screw**	**Screwdriver**	**Torque**
Conical Connection	NP	Clinical Screw CC NP	Lab Screw CC NP	Unigrip™	35Ncm
	RP	Clinical Screw CC RP/WP	Lab Screw CC RP/WP		
Tri-Channel	NP	Screw Ceramic Abutment NobRpl NP	Lab Screw Implant Level NobRpl NP		
	RP	Screw Ceramic Abutment NobRpl RP/WP/6.0	Lab Screw Implant Level NobRpl RP/WP/6.0		
	WP				
	6.0				
External Hex	NP	Screw Ceramic Abutment Bmk Syst NP	Lab Screw CC NP		
	RP	Screw Ceramic Abutment Bmk Syst RP	Lab Screw CC RP/WP		
	WP	Screw Ceramic Abutment Bmk Syst WP	Lab Screw Implant Level Bmk Syst WP		

Table 3 – Compatibility NobelProcera® Abutments ASC Titanium

Titanium Abutment ASC - With Omnigrip™					
Connection	**Platform**	**Clinical Screw**	**Lab Screw**	**Screwdriver**	**Torque**
Conical Connection	NP	Omnigrip™ Clinical Screw Titanium CC NP	Omnigrip™ Laboratory Screw Titanium CC NP	Omnigrip™	35Ncm
	RP	Omnigrip™ Clinical Screw Titanium CC RPWP	Omnigrip™ Lab Screw Titanium CC RP/WP		
	WP				
Tri-Channel	NP	Omnigrip™ Clinical Screw Ti Tri-Channel NP	Omnigrip™ Lab Screw Ti Tri-Channel NP		
	RP	Omnigrip™ Clin Screw Ti Tri-Chn RP/WP/6.0	Omnigrip™ Lab Screw Ti Tri-Chn RP/WP/6.0		
	WP				
	6.0				

Intended Use / Intended Purpose

Intended to be finalized into a single-unit dental prosthesis, which is connected to an endosseous dental implant to restore chewing function.

Indications

NobelProcera®/Procera® Abutments Titanium

NobelProcera®/Procera® Abutment Titanium is a patient-matched CAD/CAM prosthetic component directly connected to endosseous dental implants and is indicated for use as an aid in prosthetic rehabilitation.

NobelProcera®/Procera® Abutments Titanium CC 3.0

The NobelProcera® Abutment Titanium is a patient-matched CAD/CAM prosthetic component directly connected to endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation. The NobelProcera® Abutment Titanium on the Internal Conical Connection 3.0 platform is indicated for use on mandibular lateral incisors, mandibular central incisors, and maxillary lateral incisors only.

NobelProcera®/Procera® Abutments Zirconia

The NobelProcera®/Procera® Abutment Zirconia is a patient-matched CAD/CAM prosthetic component directly connected to endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation. The NobelProcera®/Procera® Abutment Zirconia is indicated to be used for an angulation correction up to 20 degrees.

Contraindications

It is contraindicated to use NobelProcera®/Procera® Abutments Titanium and Zirconia (including metal adapter) and clinical screws in:

- Patients who have parafunctional tendencies for example bruxism and/or clenching.
- Patients who are allergic or hypersensitive to Zirconia - Yttria-stabilized tetragonal zirconia polycrystal (Y-TZP), Titanium alloy 90% Ti, 6% Al, 4% V or DLC (diamond like carbon) coating.

The NobelProcera®/Procera® Abutment Zirconia on Internal Tri-channel is contraindicated to use without a mechanically retained adapter.

The NobelProcera®/Procera® Abutment Zirconia (without metal adapter) is contraindicated to use in the posterior region.

The NobelProcera®/Procera® Abutments Titanium and Zirconia are contraindicated to be used with a non-Nobel Biocare manufactured clinical screw.

The NobelProcera®/Procera® Abutments Titanium and Zirconia are contraindicated for length, thickness, margin height and angulation that do not fall within the indicated limits. Refer to the handling procedure for the design constraints.

The NobelProcera® Abutment Titanium Internal Conical Connection 3.0 is contraindicated to use in other positions than for lateral incisors in the maxilla and central and lateral incisors in the mandible.

The NobelProcera® Abutment Titanium Internal Conical Connection 3.0 is contraindicated for use in multiple unit restorations.

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

- NobelProcera® Abutment Zirconia: Yttria-stabilized tetragonal zirconia according to ISO 13356.
- NobelProcera® Abutment Titanium: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136.
- Metal adapters: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136.
- Clinical screws: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and DLC (diamond like carbon) coating.

Cautions

General

The NobelProcera®/Procera® Abutments Titanium and Zirconia NP are not recommended for posterior use.

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

NobelProcera® Abutments Titanium and Zirconia 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® Abutments Titanium and Zirconia 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

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.

Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture 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, a dental dam, or a 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®/Procera® Abutments Titanium and Zirconia are to be used by dental health care professionals.

NobelProcera®/Procera® Abutments Titanium and Zirconia are to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with NobelProcera®/ Procera® Abutments Titanium and Zirconia

NobelProcera® Abutments Titanium and Zirconia 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 NobelProcera®/Procera® Abutments Titanium and Zirconia

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 placement of the NobelProcera® Abutments Titanium and Zirconia, the pharyngeal reflex (gag reflex) may be triggered in patients with a sensitive gag reflex.

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

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the NobelProcera®/Procera® Abutments Titanium and Zirconia The SSCP can be obtained at the following website:

https://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
https://www.nobelbiocare.com/complaint-form

Handling Procedure

Design Guidelines for the NobelProcera®/ Procera® Abutments Titanium and Zirconia

NobelProcera®/Procera® Abutments Titanium and Zirconia are designed and manufactured based on a digital scan performed on a conventional impression, or on a scan performed directly in the patient's mouth (digital impression).

The NobelProcera®/Procera® Abutments are designed to be seated on Nobel Biocare Internal Conical Connection, Internal Tri-Channel Connection and External Hex connection, with a maximum dimension in radius × height in millimeter (r × h) as defined in Table 4.

Table 4 – NobelProcera®/Procera® Abutment Implant Platform Availability Chart with Maximum Dimensions (Radius (r) × Height (h) in millimeters (mm)).

Implant Name / Connection Type	Platform	NobelProcera®/Procera® Abutment	
		Titanium (r × h in mm)	Zirconia (r × h in mm)
Nobel Biocare External Hex Connection	NP	6 ×14	4 ×12
	RP	8 ×15	5 ×15
	WP	8 ×15	5 ×15
Nobel Biocare Internal Conical Connection	3.0	8 ×12	N/A
	NP	8 ×15	4 ×12
	RP	8 ×15	5 ×15
	WP	8 ×15	N/A
Nobel Biocare Internal Tri-channel Connection	NP	8 ×15	4 ×12
	RP	8 ×15	5 ×15
	WP	8 ×15	5 ×15
	6.0	8 ×15	5 ×15

NobelProcera®/Procera® Abutments Titanium and Zirconia must be designed respecting the following design constraints, see Table 5.

Table 5 – Design constraints

Restorationtype	Height Min	Height Max	Diameter Min	Diameter Max	Angulation
NobelProcera®/ Procera® Abutments Titanium	4 mm	15 mm	4.4 mm at implant emergence tapering to 2.8 mm and 1.9 mm above implant platform	16 mm	max. 20°
NobelProcera®/ Procera® Abutments Zirconia	4 mm				
NobelProcera® Titanium Abutment ASC*	4 mm				max 30°

*The minimum wall thickness for the NobelProcera® Titanium ASC is 0.42 mm

Table 6 – Abutment Angulation Ti ASC Abutment

Margin Height (Soft tissue height)	Maximum angulation above Margin Height (Soft tissue height), measured from top of implant
4,4 mm and below	30°
5 mm	27°
6 mm	24°
7 mm	22°
8 mm	19°

Clinical / Laboratory Procedures for CAD/CAM Scan of Conventional Impression

Take Conventional Impression (Clinical Procedure)

1. Take an impression according to standard clinical procedures for restorative operations, and send to the dental laboratory.

Fabricate Master Model (Laboratory Procedure)

1. Fabricate a working "master" model with implant replicas and removable gingival material following standard conventional laboratory procedures.

Verify Master Model (Clinical Procedure)

1. Verify using standard clinical procedures for restorative operations that the master model and patient's scan file are the same.

CAD/CAM Scan of Master Model (Laboratory Procedure)

1. Before mounting the position locator(s) onto the working "master" model, ensure that all components are clean and in an undamaged condition, check and discard if any scratches on the scan surface or any other deformation.
2. Assemble the position locator(s) onto the implant replica(s) in the master model and confirm the fit.
3. Avoid any contact of the position locator(s) to the interproximal teeth.
4. Start the scan procedure with a Nobel Biocare approved scanner.
5. Export/send the scan file to a Nobel Biocare approved CAD software.

Clinical Procedure for CAD/CAM Scan of Patient Mouth (Digital Impression)

1. Before mounting the position locator(s) into the patient mouth ensure that all components are clean and in an undamaged condition, check and discard if any scratches on the scan surface or any other deformation. Refer to the instructions for use provided by the manufacturer for cleaning and sterilization instructions.
2. Assemble the position locator(s) onto the implant(s) in the patient mouth and confirm the fit.
3. Avoid any contact of the position locator(s) to the interproximal teeth.
4. Start the scan procedure with a Nobel Biocare approved scanner.
5. Export/send the scan file to a Nobel Biocare approved CAD software.

Designing the NobelProcera®/Procera® Abutment (Laboratory Procedure)

1. Import the scan file into a Nobel Biocare approved CAD software.
2. Open the relevant CAD module and design the restoration in accordance with indications for use, following the instructions in the software tutorial and according to the patient's clinical needs.
3. Send the scan file to a Nobel Biocare production facility for manufacturing.

Procedure for CAD/CAM Scan of Patient Mouth (Digital Impression): (Laboratory Procedure)

After receiving the NobelProcera® Abutment from the Nobel Biocare production facility, finalize the abutment per one of the following two sets of instructions, depending on the type of restoration:

Finalizing a NobelProcera®/Procera® Abutment Zirconia (With Dental Ceramics Directly Applied)

1. Check fit and design of the abutment. If necessary, make minor adjustments using diamond impregnated finishing tools with fine grit size, under low pressure and using copious water irrigation, adhering to minimum dimensions.
2. Apply dental ceramic material (compatible with Zirconia and within the CTE value of Zr material) directly onto the NobelProcera® Abutment Zirconia to achieve the clinically relevant shade and tooth morphology.
3. Prior to sintering the NobelProcera® Abutment Zirconia on implants with an Internal Tri-channel connection and with ceramic material applied, it is recommended that the metal adapter is removed with a pair of tweezers. Once the ceramic material is fired (according to ceramic material manufacturer's Instructions for Use), carefully re-insert the adapter back into position with a pair of tweezers.
4. Adequate polishing of occlusal surface must be done with any appropriate silicone polishing set intended for polishing ceramic occlusal surface.

Note When adjustments are made near to the connection (to abutment to implant interface) protection analogues must be utilized.

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

Finalizing a NobelProcera®/Procera® Abutment Zirconia and Titanium (With Cemented Crown or Bridge)

1. The user should design and finalize the crown or bridge according to Instructions for Use of the Crown/Bridge manufacturer.

2. Check fit and design of the abutment and crown/bridge. If necessary, make minor adjustments using diamond impregnated finishing tools with fine grit size, under low pressure and using copious water irrigation, adhering to minimum dimensions.

Seating the NobelProcera®/Procera® Abutment (Clinical Procedure)

Caution The NobelProcera® Abutment Titanium and Zirconia and clinical screws 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.

Seating NobelProcera® Abutments Titanium with Internal Conical Connection, External Hex connection, and Internal Tri-Channel Connection, and NobelProcera® Abutments Zirconia with Internal Conical Connection and External Hex Connection

1. Seat the NobelProcera® Abutment Zirconia or NobelProcera® Abutment Titanium onto the implant(s) and carefully insert the clinical screws.

Caution Do not modify or sandblast the seating area of the NobelProcera®/Procera® Abutment as this may negatively affect its strength or fit.

2. Verify the seat of the NobelProcera® Abutment following standard restorative clinical procedures.

3. Once seat is verified, apply the recommended screw tightening torque of the implant manufacturer.

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

4. For NobelProcera® Abutments Titanium and Zirconia intended to be seated on Nobel Biocare implants, once seat is verified, apply recommended screw tightening torque as per Table 7 using a Manual Torque Wrench Prosthetic.

Table 7 – Screw tightening torque

Screw	Tightening Torque
Nobel Biocare Implant Systems (excluded Nobel Active 3.0)	35 Ncm
Nobel Active 3.0	15 Ncm

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® 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.

5. Seal the screw access holes of the restoration using conventional procedures.

6. Verify occlusion and function using conventional procedures.

7. If adjustments are made to the restoration, adequate polishing of occlusal surface must be done with any appropriate silicone polishing set intended for polishing ceramic occlusal surface.

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

8. Seal the screw access holes of the restoration using conventional procedures.

9. Verify occlusion and function using conventional procedures.

10. If adjustments are made to the restoration, adequate polishing of occlusal surface must be done with any appropriate silicone polishing set intended for polishing ceramic occlusal surface.

Note For NobelProcera® Abutments that require the intra-oral cementation of a crown/bridge, it is recommended that the handling instructions of the bonding material manufacturer is followed.

Note During regular checkups it is recommended to check on occlusion and adjust if needed (procedure as described above). In case occlusal surface becomes dull (loses gloss), polish as described above.

Seating NobelProcera® Abutment Zirconia on Implants with an Internal Tri-channel Connection

1. Inspect the metal adapter prior to seating the abutment to ensure there is no damage to the component.

2. Attach the metal adapter to the NobelProcera® Abutment Zirconia. Ensure that the adapter is securely attached to the abutment.

3. Carefully insert the clinical screw into the abutment/adapter assembly and place the assembly onto the implant.

4. Verify the seat of the NobelProcera® Abutment following standard restorative clinical procedures.

5. Once seat is verified, apply the recommended screw tightening torque of the implant manufacturer.

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

6. For NobelProcera® Abutments Zirconia intended to be seated on Nobel Biocare implants, once seat is verified, apply recommended screw tightening torque as per Table 7 using a Manual Torque Wrench Prosthetic.

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® 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.

7. Seal the screw access holes of the restoration using conventional procedures.

8. Verify occlusion and function using conventional procedures.

9. If adjustments are made to the restoration, adequate polishing of occlusal surface must be done with any appropriate silicone polishing set intended for polishing ceramic occlusal surface.

10. Seal the screw access holes of the restoration using conventional procedures.

11. Verify occlusion and function using conventional procedures.

12. If adjustments are made to the restoration, adequate polishing of occlusal surface must be done with any appropriate silicone polishing set intended for polishing ceramic occlusal surface.

Note For NobelProcera® Abutments that require the intra-oral cementation of a crown/bridge, it is recommended that the handling instructions of the bonding material manufacturer is followed.

Note During regular checkups it is recommended to check on occlusion and adjust if needed (procedure as described above). In case occlusal surface becomes dull (loses gloss), polish as described above.

In case the abutment or the screw need to be removed consider the use of the Abutment Retrieval Tool described in IFU1096, Abutment Release Pin described in Instruction For Use IFU1040 and the abutment screw removal instrumentation described in Instructions For Use IFU1043.

Sterility and Reusability Information

The NobelProcera® Abutments Titanium and Zirconia, metal adapters and clinical screws are delivered non-sterile for single use only. Prior to use clean, disinfect and/or sterilize the products using the recommended instructions.

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

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

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 NobelProcera® Abutments Titanium and Zirconia, metal Adapters 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.

The following Cleaning and Sterilization instructions are to be followed for the finalized NobelProcera® Abutment supra-construction (including metal adapters where applicable) prior to seating the abutment intraorally. See Nobel Biocare Instructions for Use IFU1057 for cleaning and sterilization instructions for the clinical screws. The laboratory screws are used in the dental laboratory only (no intraoral use) and have no cleaning and/or sterilization requirements.

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 NobelProcera® Abutment (including metal adapters where applicable) according to the glaze, stain, and/or veneering material manufacturer's instructions prior to use.

Metal adapters 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 Metal Adapters 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.

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 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 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 W_{eff}) 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 8 presents examples of suitable sterilization pouches.

Table 8 – Recommended Sterilization Pouches

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

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 9):

Table 9 – Recommended Sterilization Cycles

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		

[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® Abutment 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® Abutments Titanium and Zirconia 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® Abutments Titanium and Zirconia, 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 IIb Devices	UK CA 0086

Note Regarding Canadian Device Licensure, not all products described in the IFU may have a device licence according to Canadian Law.

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

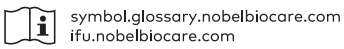
Basic UDI-DI Information

Product	Basic UDI-DI Number
NobelProcera® Abutments Titanium	733274700000021775
NobelProcera® Abutments Zirconia	73327470000002106P

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	