Esthetic Abutment Conical Connection/Bmk System/NobelReplace™, Esthetic Abutment Nobel Biocare N1™ TCC

Instructions for use

Important – Disclaimer of Liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof.

Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

Esthetic Abutment is a premanufactured dental implant abutment directly connected to the endosseous dental implant through a clinical screw and is intended for use as an aid in prosthetic rehabilitation. It is delivered with a co-packed clinical/abutment screw. Refer to Nobel Biocare Instructions for Use IFU1057 for information on clinical and abutment screws.

Esthetic Abutment Conical Connection are available in platform 3.0/NP/RP/WP, straight and 15° angulation, feature a conical connection and can be used with Nobel Biocare's NobelActive™, NobelParallel™ CC and NobelReplace ™ Conical Connection implant systems.

Esthetic Abutment Bmk System are available in platform NP/RP/WP, feature an external hex connection, and can be used with Nobel Biocare's Brånemark System and NobelSpeedy Groovy implant system.

Esthetic Abutment NobelReplace™ are available in platform NP/RP/WP/6.0 feature an internal tri-channel connection and can be used with Nobel Biocare's NobelReplace and Replace Select.

Esthetic Abutment Nobel Biocare N1™ TCC are available in platform NP/RP, straight and 15° angulation, feature a tri-oval conical connection and can be used with the Nobel Biocare N1™ implant system.

Table 1 describes the compatibility of the esthetic abutments with clinical screws, screwdrivers and temporary plastic copings in the Nobel Biocare portfolio.

Table 1. Esthetic abutments compatibility

Esthetic Abutment	Connection type	Clinical screw	Color coding	Screwdriver	Plastic/ Temporary coping
Esthetic Abutment Conical Connection 3.0	Conical connection	Clinical Screw Conical Connection 3.0	None	Unigrip	–
Esthetic Abutment Conical Connection NP	Conical connection	Clinical Screw Conical Connection NP	O	Unigrip	–
Esthetic Abutment Conical Connection RP	Conical connection	Clinical Screw Conical Connection RP/WP	O	Unigrip	–
Esthetic Abutment Conical Connection WP	Conical connection	Clinical Screw Conical Connection RP/WP	O	Unigrip	–
Esthetic Abutment Bmk System NP	External hex	Abutment Screw Brånemark System NP	None	Unigrip	Plastic/ Temporary Coping Esthetic Abutment
Esthetic Abutment Bmk System RP	External hex	Abutment Screw Brånemark System RP	None	Unigrip	Plastic/ Temporary Coping Esthetic Abutment
Esthetic Abutment Bmk System WP	External hex	Abutment Screw Brånemark System WP	None	Unigrip	Plastic/ Temporary Coping Esthetic Abutment
Esthetic Abutment NobelReplace™ NP	Tri-channel	Abutment Screw NobelReplace NP	O	Unigrip	Plastic/ Temporary Coping Esthetic Abutment
Esthetic Abutment NobelReplace™ RP	Tri-channel	Abutment Screw NobelReplace RP/WP/6.0	O	Unigrip	Plastic/ Temporary Coping Esthetic Abutment
Esthetic Abutment NobelReplace™ WP	Tri-channel	Abutment Screw NobelReplace RP/WP/6.0	O	Unigrip	Plastic/ Temporary Coping Esthetic Abutment
Esthetic Abutment NobelReplace™ 6.0	Tri-channel	Abutment Screw NobelReplace RP/WP/6.0	O	Unigrip	Plastic/ Temporary Coping Esthetic Abutment
Esthetic Abutment Nobel Biocare N1™ TCC NP	Tri oval conical connection	Clinical Screw Nobel Biocare N1 TCC NP	O (screw)	Omnigrip Mini	–
Esthetic Abutment Nobel Biocare N1™ TCC RP	Tri oval conical connection	Clinical Screw Nobel Biocare N1 TCC NP	O (screw)	Omnigrip Mini	–

Intended Use / Intended Purpose:

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

Indications:

The Esthetic Abutment Nobel Biocare N1™ TCC is a premanufactured prosthetic component connected to an endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation for single units and multiple units of up to three units.

Esthetic Abutment Conical Connection/ Bmk System/ NobelReplace is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation

Esthetic Abutment Conical Connection 3.0 is indicated for use in the treatment of missing maxillary lateral incisors or in the mandibular central and lateral incisors.

Contraindications:

It is contraindicated to use Esthetic Abutments in:

- Patient who are medically unfit for an oral surgical procedure and/or suffer from bruxism.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially pure titanium, titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium), DLC coating, or polycarbonate (material used for the Plastic/Temporary coping).

It is contraindicated to use Esthetic Abutment Conical Connection 3.0 in other positions than for lateral incisors in the maxilla or central and/or lateral incisors in the mandible. Esthetic Abutment Conical Connection 3.0 is not to be used for multiple unit restorations.

For contraindications specific to the screwdrivers and clinical/abutment screw, refer to the Nobel Biocare Instructions for Use IFU1085 and IFU1057.

Cautions:

General:

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

Esthetic Abutments must only be used with compatible Nobel Biocare instruments. Use of instruments that are not intended to be used in combination with Esthetic 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.

Before Surgery:

Special attention must be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

The device has not been evaluated in pediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jaw bone growth phase has been properly documented.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery:
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).

After the implant placement, 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.

Bending moments: 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.

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

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:

Esthetic Abutment Nobel Biocare N1 TCC, Esthetic Abutment NobelReplace, Esthetic Abutment Brånemark System, Esthetic Abutment Conical Connection are to be used by dental health care professionals

Esthetic Abutment Nobel Biocare N1 TCC, Esthetic Abutment NobelReplace, Esthetic Abutment Brånemark System, Esthetic Abutment Conical Connection are to be used in patients subject to dental implant treatment

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Esthetic Abutment:
Esthetic Abutments are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace, Esthetic Abutment Nobel Biocare N1 TCC:
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 abutment placement or removal, the pharyngeal (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, ulcers, 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 [Implantable Device Type(s)]. 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:

Clinical procedure – connecting the abutment:
1. Select appropriate abutment based on the implant system and platform.
2. Connect and tighten the abutment once the implant stability is ensured. It is recommended to verify the final abutment seating using radiographic imaging.

Caution: To tighten the abutment make sure that the implant can withstand the recommended tightening torque of the abutment.

3. Tighten the abutment following the below parameters using the Manual Torque Wrench Prosthetic of the implant system together with the screwdriver.

Refer to Table 2 for the associated tightening torque. Refer to the Nobel Biocare IFU1085 and IFU1098 for information regarding the Omnigrip™ Mini Screwdriver and Manual Torque Wrench Prosthetic.

Table 2. Tightening toque values

Esthetic Abutment	Tightening torque	Screwdriver
Esthetic Abutment Conical Connection/Bmk system/ NobelReplace	35 Ncm	Unigrip Screwdriver
Esthetic Abutment Nobel Biocare N1™ TCC	20 Ncm	Omnigrip Mini Screwdriver
Esthetic Abutment Conical Connection 3.0	15 Ncm	Unigrip Screwdriver

Caution: Do not exceed the tightening torque. Over tightening of abutment screw/clinical screw may lead to a screw fracture.

4. If modification of the abutment is necessary, remove the abutment, place it on a replica and modify it using a carborundum disk and carbide bur.

Caution: Never modify the abutment-implant connection.

Caution: Do not modify the abutment intraorally.

Note: Esthetic Abutment Nobel Biocare N1™ TCC can be modified following the below parameters:

Abutment type	Maximum Modification
Esthetic Abutment Nobel Biocare N1™ TCC 1.75mm	Down to 5.6 mm from implant level
Esthetic Abutment Nobel Biocare N1™ TCC 3mm	Down to 7.1 mm from implant level

5. Take a standard impression after blocking out the screw hole (e.g. with Teflon and composite)
6. Clean and remove any debris from the Esthetic Abutment.
7. Provisionalize after sealing the access hole (e.g. using Teflon and composite). Make sure there is no excess cement. A plastic temporary coping can be used.

Note: A plastic temporary coping is available only for Esthetic Abutment for external hex and internal tri-channel connections.

Caution: Do not use Plastic Temporary coping with polyurethane cements. The cement will not cure.

8. If an implant level impression protocol is followed instead of steps 5-7, transfer the position of the implant from the patient's mouth to the master model using Impression Copings and send it to the laboratory.

   Refer to IFU1086 for detailed information on Impression Copings.

Laboratory procedure
9. Produce a working model with removable gingival material.
10. If applicable, select the Esthetic Abutment and modify it by placing it on a replica and using a carborundum disk and carbide bur.

Note: Esthetic Abutment Nobel Biocare N1™ TCC can be modified following the below parameters:

Abutment type	Maximum Modification
Esthetic Abutment Nobel Biocare N1™ TCC 1.75mm	Down to 5.6 mm from implant level
Esthetic Abutment Nobel Biocare N1™ TCC 3mm	Down to 7.1 mm from implant level

Caution: Never modify the abutment-implant connection.

11. Fabricate a crown or bridge with NobelProcera® technique or with conventional casting technique.

Caution: Esthetic Abutment Nobel Biocare N1 TCC can be used only for short span bridges up to 3 units with no overhang.

12. Veneer the crown or framework if applicable.
13. Send the crown and the Esthetic Abutment to the clinician.

Clinical procedure – cementing the final restoration
14. Remove temporary restoration if applicable.
15. If an implant level impression protocol was followed, tighten the Esthetic Abutment to the implant following the parameters in table 2, otherwise use the compatible Screwdriver and Manual Torque Wrench prosthetic to verify the tightening of the abutment (refer to table 2).

It is recommended to verify the final abutment seating using radiographic imaging.

16. Seat the restoration on the abutment and check the occlusion and the interproximal contacts.
17. Cement the final crown or framework using conventional procedures after sealing of access hole (e.g. using Teflon and composite). Make sure there is no excess cement

Caution: Do not use temporary cement when cementing ceramic crowns and bridges due to increased risk of micro fractures

Removal of the Esthetic Abutment Nobel Biocare N1™TCC:
In case the Esthetic Abutment needs to be removed, and it is stuck in the implant, the Abutment Retrieval Tool Nobel Biocare N1™ TCC can be used.

Note: A new version of the previously existing retrieval tool has to be used, this new version is longer and can be identified by the presence of the laser marking of the platform (e.g. NP or RP) and type of connection (i.e TCC) on the same side of the tool. Below a representation to facilitate the identification of the new version.

Figure A. Old version

Figure B. New version

The Abutment Retrieval Tool Nobel Biocare N1™ is available in two platform sizes, NP and RP and is compatible with Nobel Biocare N1™ TCC titanium abutment. For details information on the Abutment Retrieval Tool refer to IFU1096.

These tools are used to remove the abutments when the clinical screw has been removed but the abutment cannot be removed due to a tight connection seal.

Note: The clinical screw must be unscrewed from both the internal threads of the implant and the abutment. When the screw disengages from implant threads, lift it and keep turning it to disengage it from the abutment threads. In case the loose clinical screw is difficult to remove, use a small amount of sticky wax on the tip of the screwdriver which will aid in retention of the abutment screw head.

Note: If removal of the clinical screw is not possible with the Omnigrip™ Mini Screwdriver, refer to IFU1043 to use the abutment screw retrieval instrumentation

1. Insert the retrieval tool into the abutment and screw it clockwise into place using the Multi-unit Screwdriver until the tip of the tool touches the bottom of the hole inside the implant.
2. Apply torque to the screwdriver to release the abutment from the implant.

Materials:

- Esthetic Abutment Bmk System: Commercially pure titanium grade 1.
- Esthetic Abutment Conical connection, Esthetic Abutment NobelReplace™ and Esthetic Abutment Nobel Biocare N1™ TCC: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- Clinical/abutment screw: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.
- Plastic/Temporary coping: Polycarbonate.

Sterility and Reusability Information:

Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace™, Esthetic Abutment Nobel Biocare N1 TCC are delivered non-sterile and are intended for single use. 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: Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace™, Esthetic Abutment Nobel Biocare N1™ TCC 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.

Cleaning and Sterilization Instructions:

Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace™, Esthetic Abutment Nobel Biocare N1™ TCC are delivered non-sterile by Nobel Biocare and are intended for single use. Prior to each 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 Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace™, Esthetic Abutment Nobel Biocare N1™ TCC been validated to withstand these cleaning and sterilization procedures.

Caution: Do not deviate from the following instructions.

Automated Cleaning and Drying (Including Pre-cleaning):

Pre-cleaning:

1. Disassemble Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace, Esthetic Abutment Nobel Biocare N1 TCC prior to cleaning by removing the screw.
2. Immerse the device in 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
3. Fill lumina (where applicable) with 0.5 % lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
4. 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.
5. 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.
6. 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.
7. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying:

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

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

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

Visual Inspection:

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

Manual Cleaning and Drying:

1. Disassemble Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace™, Esthetic Abutment Nobel Biocare N1™ TCC prior to cleaning by removing the screw.
2. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cydezyme ASP / Neodisher Medizym* ; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
5. 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.
6. Thoroughly rinse the outer surfaces and lumina of the device with lukewarm running tap water at a minimum temperature of 29 °C (84.2 °F) for a minimum of 10 seconds to remove all cleaning solution.
7. Immerse the device in an ultrasonic bath (e.g. Bandelin ; frequency 35 kHz ; effective ultrasonic power 300 W) containing 0.5 % enzymatic cleaning agent (e.g. Cydezyme ASP / Neodisher Medizym*) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/ maximum 45°C(113°F).
8. 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.
9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
10. Dry with compressed air or clean and lint-free single use wipes.

* Neodisher Medizym was used in the validation of Esthetic Abutment Nobel Biocare N1 TCC

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 Selectomat PL/669 – 2CL* (pre-vacuum cycle); Amsco Century Sterilizer and Selectomat PL/669 – 2CL* (gravity cycle).

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

* Selectomat PL/669 – 2CL was used in the validation of Esthetic Abutment Nobel Biocare N1 TCC

1. Reassemble the devices and 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.

Table3. 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)*

* Steriking pouch (Wipak) was used in the validation of Esthetic Abutment Nobel Biocare N1 TCC

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

Table 4: 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 SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance:

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

Containment and Transportation/Shipping to Point of Use:

The container and/or outer packaging used to transport or ship the reprocessed 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:

The Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace, Esthetic Abutment Nobel Biocare N1 TCC contain metallic materials which can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that the Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace, Esthetic Abutment Nobel Biocare N1 TCC unlikely to impact patient safety under the following MRI conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

Note: Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Under the conditions defined above, these devices are expected to produce a maximum temperature rise of 4.1°C (7.4°F) after 15 minutes of continuous scanning.

In the non-clinical testing, the image artifact caused by the devices extends approximately 30 mm from the devices when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Note: Although the non-clinical testing demonstrates that the Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace, Esthetic Abutment Nobel Biocare N1 TCC are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to support a claim of MR Safe or MR Conditional for the Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace, Esthetic Abutment Nobel Biocare N1 TCC.

Performance Requirements and Limitations:

To achieve the desired performance, Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace, Esthetic Abutment Nobel Biocare N1 TCC 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 Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace, Esthetic Abutment Nobel Biocare N1 TCC, 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
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

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 2797
CE Mark for Class Ir/IIa/IIb Devices

Note: Refer to the product label to determine the applicable CE mark for each device.

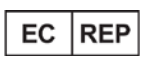
Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Product	Basic UDI-DI Number
Esthetic Abutment Conical Connection, Esthetic Abutment Bmk System, Esthetic Abutment NobelReplace, Esthetic Abutment Nobel Biocare N1 TCC	07332747000001697K

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

Batch code

Catalogue number


Caution


CE mark

CE mark with Notified Body number


Consult instructions for use


Contains hazardous substances

Contains or presence of DEHP phthalate

Contains or presence of natural rubber latex

Contains or presence of phthalate

Date


Date of manufacture

Do not resterilize

Do not re-use


Do not use if package is damaged

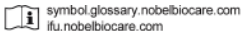

Double sterile barrier system

Rx only
For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional

Magnetic resonance safe


Manufacturer

Medical device


Non-pyrogenic

Non-sterile


Patient identification


Patient information website


Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Sterilized using Ethylene Oxide

Sterilized using irradiation

Sterilized using steam or dry heat


Temperature limit


Tooth number

Unique Device Identifier

Upper limit of temperature

Use-by date