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

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.

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

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.

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 for N1™TCC, Brånemark System®, Conical Connection 3.0, RP, WP:
  Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.
- Abutment Screw for NobelReplace®, Conical Connection NP:
  Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- Plastic/Temporary coping:
  Polycarbonate.

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 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

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 Devices in the IFU

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 Esthetic Abutments. The SSCP can be obtained at the following website: ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED)

Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Handling Procedure

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 1 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 1 – 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 1, otherwise use the compatible Screwdriver and Manual Torque Wrench prosthetic to verify the tightening of the abutment (refer to table 1).

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.

In case the Esthetic Abutment needs to be removed, and it is stuck in the implant, the Abutment Retrieval Tool can be used, refer to Instructions for Use IFU1096/IFU1041.

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 only. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Caution 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.

Cleaning and Sterilization Instructions

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

Magnetic Resonance (MR) Safety Information

These products are fabricated from a metal material which can be affected by MR energy. For further information refer to Nobel Biocare publication **MRI Safety Information** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with the devices, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

Storage, Handling and Transportation

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information

Manufacturer	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 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
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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 Refer to the product label to determine the applicable conformity marking for each device.

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

Basic UDI-DI Information

Product	Basic UDI-DI Number
Esthetic Abutment Conical Connection	73327470000001697K
Esthetic Abutment Bmk System	
Esthetic Abutment NobelReplace®	
Esthetic Abutment Nobel Biocare N1 TCC	

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.