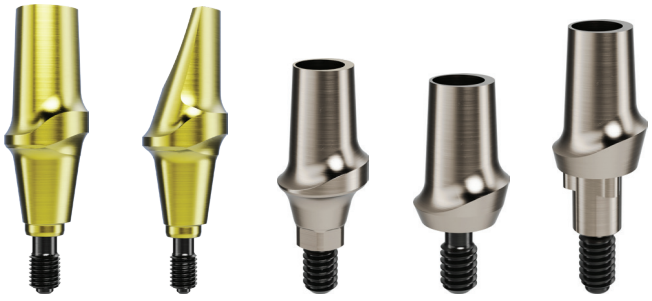
Esthetic Abutment Conical Connection/ Bmk System/ NobelReplace®, Esthetic Abutment Nobel Biocare N1™ TCC



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Description

A premanufactured dental implant abutment directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

Internal conical connection for: NobelActive®, NobelReplace® CC and NobelParallel™ CC.

Internal tri-channel connection for: NobelReplace®, Replace Select™.

External hex connection for: Brånemark System® and NobelSpeedy® Groovy®.

Plastic Temporary Copings are available for Esthetic Abutment for Internal tri-channel connection and External hex connection.

Internal Tri-oval conical connection for: Nobel Biocare N1™.

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	●	Unigrip™	-
Esthetic Abutment Conical Connection RP	Conical connection	Clinical Screw Conical Connection RP/WP	●	Unigrip™	-
Esthetic Abutment Conical Connection WP	Conical connection	Clinical Screw Conical Connection RP/WP	●	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	●	Unigrip™	Plastic/Temporary Coping Esthetic Abutment
Esthetic Abutment NobelReplace® RP	Tri-channel	Abutment Screw NobelReplace® RP/WP/6.0	●	Unigrip™	Plastic/Temporary Coping Esthetic Abutment
Esthetic Abutment NobelReplace® WP	Tri-channel	Abutment Screw NobelReplace® RP/WP/6.0	●	Unigrip™	Plastic/Temporary Coping Esthetic Abutment
Esthetic Abutment NobelReplace® 6.0	Tri-channel	Abutment Screw NobelReplace® RP/WP/6.0	●	Unigrip™	Plastic/Temporary Coping Esthetic Abutment
Esthetic Abutment Nobel Biocare N1™ TCC NP	Tri oval conical connection	Clinical Screw Nobel Biocare N1™ TCC NP	● (screw)	Omnigrip™ Mini	-
Esthetic Abutment Nobel Biocare N1™ TCC RP	Tri oval conical connection	Clinical Screw Nobel Biocare N1™ TCC RP	● (screw)	Omnigrip™ Mini	-

Intended Use / Intended Purpose

Esthetic Abutment Nobel Biocare N1™ TCC

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

Esthetic Abutment Conical Connection/ BmK System/NobelReplace®

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

The abutments in combination with two-stage endosseous implants are used as the foun- dation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructions.

Indications

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

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.

Contraindications

It is contraindicated to use Esthetic Abutments in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of static and dynamic loads.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium).

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.

Warning

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

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 Abutment can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

Before Surgery

Careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

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

In general, implant placement and prosthetic design must accommodate individual patient conditions.

In the case of bruxism, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option or appropriate pre- and post-treatment measures may be considered.

Special caution is advised in patients who receive bisphosphonate therapy.

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 a 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.

Do not deviate from the Handling Procedure described in the sections below.

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.

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 IFU1047 for information regarding the Omnigrip™ Mini Screwdriver and Manual Torque Wrench Prosthetic.

Table 2 – Tightening torque 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.

Caution For Esthetic Abutment Conical Connection 3.0. Never exceed 15 Ncm prosthetic tightening torque for the abutment screw. Over tightening of abutment 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.

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

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.

The Abutment Retrieval Tool Nobel Biocare N1™ is available in two platform sizes, NP and RP and is compatible with the Nobel Biocare N1™ TCC titanium abutments. For details information on the Abutment Retrieval Tool refer to IFU1041.

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.

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 as the device sterility and/or integrity may be compromised.

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 restorative material to be placed intra-orally on the Esthetic Abutment Nobel Biocare N1™ Base should be cleaned and sterilized per the restorative material manufacturer's instructions for use, prior to use.

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 Esthetic Abutments have 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 the Esthetic Abutments 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 / MMM GmbH Type: Uniclean PL-II 15-2 EL.

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 temperature of 55°C (131°F) tap water and 0.5 % mildly alkaline detergent (e.g. Neodisher Mediclean)
   - Draining
   - Minimum of 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 the Esthetic Abutments prior to cleaning by removing the screw.
2. Immerse the 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. Cidezyme 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_{eff}) containing 0.5 % enzymatic cleaning agent (e.g. Cidezyme 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 20ml 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.

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

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, 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 / Selectomat PL/669 – 2CL / Selectomat PL/666-1 CL (pre-vacuum cycle); Amsco Century Sterilizer / Selectomat PL/669 – 2CL / Selectomat PL/666-1 CL (gravity cycle).

Note When using Systec HX-320, Amsco Century Sterilizer, it is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches. When using Selectomat, it is recommended to perform sterilization with a maximum load of 1 container with 8.6 kg of metal and 2 packages of linen.

1. Reassemble the devices and seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - FDA cleared sterilization accessories are to be used for the recommended sterilization parameters for wrapping the devices supplied non-sterile before user sterilization.
   - EN ISO 11607.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 3 presents examples of suitable sterilization pouches.

Table 3 – Recommended Sterilization Pouches

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

1. 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)).

2. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.

3. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters:
   - Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure followed by drying for a minimum of 15 minutes in chamber.
   - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure followed by drying for a minimum of 20 minutes in chamber.

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

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to 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 processed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Magnetic Resonance (MR) Safety Information

MR Safety Information for Single Tooth Restoration

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

Storage, Handling and Transportation

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

Disposal

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

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

Manufacturer and Distributor Information

Manufacturer 	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA 92887 USA

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

Legal Statements

Symbols Glossary

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

							
Authorized Representative in the European Community / European Union	UK Responsible Person	Authorised Representative in Switzerland	Sterilized using Ethylene Oxide	Sterilized using irradiation	Sterilized using steam or dry heat		
							
Batch code	Catalogue number	Unique Device Identifier	Serial number	Medical device	Magnetic resonance safe		
							
Caution	Magnetic resonance conditional	Non-sterile	Contains hazardous substances	Contains or presence of DEHP phthalate	Contains or presence of natural rubber latex	Contains or presence of phthalate	Contains biological material of animal origin
					Rx only		symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	Link to Online Symbols Glossary and IFU Portal	
							
Date of manufacture	Manufacturer	Use-by date	Upper limit of temperature	Temperature limit	Do not resterilize	Do not re-use	Non-pyrogenic
							
Date	Tooth number	Patient number	Patient identification	Health care centre or doctor	Patient information website	EU Importer	Swiss Importer
Double sterile barrier system	Single sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside	Do not use if package is damaged and consult instructions for use	Keep away from sunlight	Keep dry	