Universal Bases and Abutments

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Description

Universal Abutments/Base are premanufactured dental implant abutments which can be directly connected to an endosseous dental implant for use as an aid in prosthetic rehabilitation.

Universal Abutments are intended to be used with the following implant systems:

– Universal Abutments which feature a Trioval Conical Connection (TCC) can be used with Nobel Biocare's N1™ TiUltra™ TCC Implant system.

Universal Abutments featuring an internal trioval conical connection are co-packed with a Clinical Screw.

Universal Base is intended to be used with the following implant systems:

– Universal Bases which feature a conical connection (CC) can be used with Nobel Biocare's NobelActive®, NobelParallel™ CC and NobelReplace® CC implant system.

– Universal Bases External Hex are available in NP/RP/WP platforms, feature an external hex connection and can be used with Nobel Biocare's Brånemark System® and/or NobelSpeedy® Groovy implant systems.

Universal Base are co-packed with a Clinical Screw.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1057 for information regarding the Clinical Screw.

Intended Use / Intended Purpose

Universal Base Conical Connection and Brånemark System®

Intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

Universal Base Abutment in combination with endosseous dental implants is indicated for single unit reconstructions, when screw retained prosthetics is preferred.

Universal Abutment Nobel Biocare N1™ TCC

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

Indications

Universal Base Conical Connection and Brånemark System®

The Universal Base and abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The Universal Base and abutment consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Universal Abutment Nobel Biocare N1™ TCC

Universal abutments are indicated to support the placement of single unit, screw retained prosthetic restorations in the maxilla or mandible.

The Universal Abutment consists of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment.

The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Contraindications

It is contraindicated to place Universal 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 (90% titanium, 6% aluminum, 4% vanadium) or DLC (Diamond Like Carbon) coating.

Cautions

General

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

It is strongly recommended that Nobel Biocare surgical instruments and prosthetic components are used only with Nobel Biocare implants, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment for the first time, working with a colleague who is experienced with the new device/treatment 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

Careful psychological and physiological evaluation followed by a 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, orofacial 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.

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 orientations.

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

At Surgery

Care and maintenance of sterile instruments are crucial for successful treatment. Sterilized instruments not only safeguard 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 throat shields).

Before fastening the prosthetic component onto an implant, the implant must be able to withstand the recommended prosthetic tightening torque. For immediate function, the implant should be able to withstand a torque of at least 35 Ncm.

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.

Handling Procedure

The digital workflow requires the use of the following equipment and materials following the standard procedure according to the instructions of the system provider:

Universal Base Conical Connection and Brånemark System®

Equipment/Material	Minimum Requirements
Scanner	TRIOS by 3Shape
Design Software	DTX Studio Lab (the implant Libraries are automatically included in the software installer) or 3Shape Dental Designer (the Implant Libraries are obtained via the 3Shape server in the software)
Restorative Material	Enamic by Vita
Milling Unit	CORiTEC by imes-icore

When using the digital workflow, the standard procedure according to the system provider instructions apply.

The instructions for use of the material manufacturer shall be followed. For setup, validation, use, tools, maintenance, and lifetime information on scanners, ovens, and milling machines, please refer to manufacturer's instructions.

Warning Do not use any dental cements, restorative material, scanners, milling units and CAM software, other than those specifically identified for the Universal Base Conical Connection and Brånemark System®.

The diameter or height of the Universal Base must not be reduced. Restorative design specifications for Universal Base:

Parameter	Specification
Angle from axis of the implant	20° Max
Angle from axis of the implant	0.8 mm min.
Wall thickness circular	0.275 mm min.
Wall thickness margin	5.2 mm min.
Post height	5.2 mm min.
Maximum length, width and height	EM-14 blank 12 x 14 x 18 mm

Cementation requires the use of following materials:

Primer	Monobond Plus by Ivoclar Vivadent
Primer	Monobond Etch & Prime by Ivoclar Vivadent
Adhesive	Multilink Hybrid by Ivoclar Vivadent

Universal Abutment Nobel Biocare N1™ TCC

Equipment/Material	Minimum Requirements
Scanner	Kavo LS3, 3Shape Trios, or other scanners with accuracy equal or higher than 6.9 µm
Design Software	DTX Studio Lab (the Implant Libraries are automatically included in the software installer) or 3Shape Dental Designer (the Implant Libraries are obtained via the 3Shape server in the software)
Restorative Material	Nacera Pearl Doceram Medical Ceramics Minimum wall thickness allowed: ≤0.5 mm
Milling Unit	Roland DWX-52D Indicated for milling zirconia material 5 axis milling technology 30,000 rpm spindle speed

When using the digital workflow, the standard procedure according to the system provided instructions apply.

The instructions for use of the restorative material manufacturer shall be followed. For setup, validation, use, tools, maintenance, and lifetime information on scanners, ovens, and milling units, please refer to the manufacturer's instructions.

Sintering and further processing shall be done according to the restorative material manufacturer's guidelines.

Restorative Design Specifications:

Parameter	Specification
Angle from axis of the implant	20°
Maximum divergence between implants	N/A
Wall thickness circular	0.5 mm
Wall thickness margin	0.35 mm
Post height minimum	5.2 mm
Maximum abutment height (measured from the implant platform)	19.5 mm

Note For restorative design, follow the restorative material manufacturer's guidelines.

The bonding procedure requires the use of following materials:

Primer	i.e., Monobond Plus by Ivoclar Vivadent
Adhesive	i.e., Multilink Hybrid by Ivoclar Vivadent
Glycerin Gel	i.e., Liquid Strip by Ivoclar Vivadent

Warning Do not use any dental cements, restorative material, scanners, components, milling units, CAD/CAM software, templates, and tools other than those specifically identified for the Universal Abutment Nobel Biocare N1™.

Clinical procedure for Universal Base Conical Connection and Brånemark System®

- Remove the cover screw, healing abutment or temporary restoration from the implant.
- Select the appropriate Scan Body and connect it to the implant in the patient's mouth and tighten it using the Scan Body Driver.
- Take a digital impression of the Scan Body and the surrounding teeth, following the Intraoral scanner manufacturer's guidelines. Use Nobel Biocare approved intraoral scanner.
- A list of Nobel Biocare approved systems can be found on www.nobelbiocare.com.
- After scanning, remove the Scan Body using the Scan Body Driver and re-connect the cover screw, healing abutment or temporary restoration to the implant. Send the digital impression to the dental laboratory. Make sure to include the information about the Scan Body used as well as desired restoration material.

Designing and Manufacturing the Restoration using Digital Workflow for Universal Base

Conical Connection, Brånemark System® and Universal Abutment Nobel Biocare N1™ TCC

If using a desktop scanner, go to step 1 below. If receiving IO Scan data from the clinician, go to step 2 below.

Laboratory Procedure

1. Scanning the master cast:
   - Connect a position locator to the implant replica embedded in the master cast.
   - Scan the master cast following the instructions of the scanner manufacturer.
2. Designing the restoration:
   - Import the scan file into the CAD software and choose the desired Universal Abutment based on the restoration type. The latest Durable Medical Equipment (DME) files for the 3Shape Dental Designer are obtained via the 3Shape server in the software.
   - Design the restoration using standard CAD tools. Make sure to respect the restorative material manufacturer's design specifications. Violation of any of the restricted parameters will cause a hard stop in the design process.
3. Production:
   - Send the design file to a milling unit or local production facility.
4. Finalization and bonding:
   - Once the restoration is milled, finalize it following the restorative material manufacturer's instructions.
   - Sandblast the bonding surface of the restoration following the restorative material manufacturer's instructions.
   - Clean the restoration as recommended by the bonding material manufacturer.
   - Connect the Universal Abutment to an implant replica using the Lab Screw. Protect the screw channel of the Universal Abutment before sandblasting.

Caution The use of wax in the screw channel is to be avoided.

- Sandblast the bonding surface of the Universal Abutment with aluminum oxide 50 µm at a maximum of 2 bar. No modifications other than sandblasting are to be performed.
- Clean the bonding surface of the Universal Abutment using steam jet or an ultrasonic bath.

Caution Do not sandblast the seating area. During the blasting procedure, use an implant replica to prevent any modification of the abutment-implant interface.

Bonding Procedure

Note Use an adhesive which is suitable for bonding zirconia structures to titanium abutments and is sterilizable. An additional primer may be used. Follow the adhesive manufacturer's instructions.

- Remove the Universal Abutment/Base from the replica and connect it to the replica embedded in the patient model using the laboratory screw.
- Protect the screw channel of the Universal Abutment before applying the adhesive material.
- Apply a layer of primer onto the contact surface of the Universal Abutment and zirconia restoration.
- Apply a layer of adhesive onto the contact surfaces of the Universal Abutment and zirconia restoration.
- Connect the restoration to the Universal Abutment and press them lightly together making sure that the parts are fully seated and in the correct orientation. Follow the adhesive manufacturer's instructions on curing/polymerization.
- Remove the excess cement after curing/polymerization has started. In order to prevent the formation of an inhibition layer, use a glycerin gel.
- Clear the screw channel.
- Unscrew the restoration from the model, connect it to the replica, polish the cementation joint carefully, and finalize the restoration.
- Send the finalized restoration to the clinician along with the Clinical Screw.

Caution Never exceed the 20 Ncm prosthetic tightening torque for the Universal Abutment Nobel Biocare N1™ TCC. Overtightening of the Abutment Screw may lead to a screw fracture.

Caution Never exceed the 35 Ncm prosthetic tightening torque for the Universal Base Conical Connection and Brånemark System®. Overtightening of the Abutment Screw may lead to a screw fracture.

Caution To tighten the abutment, the implant should be able to withstand the recommended tightening torque of the Abutment Screw.

- It is recommended to verify the final abutment seating using radiographic imaging.
- Block out the screw head before closing the screw access hole with composite.
- If removal of the restoration is needed, open the screw access and untighten the screw using the Omnigrip™ Mini Screwdriver or the Unigrip™.

Clinical Procedure

Caution The final restoration and the Prosthetic Screw must be cleaned and sterilized prior to placement in the patient's mouth, according to the instructions of the material manufacturer.

- Remove the healing abutment or temporary restoration from the implant using the Omnigrip™ Mini Screwdriver or the Unigrip™.
- Connect the Universal Abutment/Base restoration to the implant and hand-tighten the clinical screw.
- Tighten the restoration using the Omnigrip™ Mini Screwdriver or Unigrip™ and Manual Torque Wrench Prosthetic to 20 Ncm for the Universal Abutment Nobel Biocare N1™ TCC and to 35 Ncm for the Universal Base Conical Connection and Brånemark System®.

Caution Never exceed the 20 Ncm prosthetic tightening torque for the Universal Abutment Nobel Biocare N1™ TCC. Overtightening of the Abutment Screw may lead to a screw fracture.

Caution Never exceed the 35 Ncm prosthetic tightening torque for the Universal Base Conical Connection and Brånemark System®. Overtightening of the Abutment Screw may lead to a screw fracture.

Caution To tighten the abutment, the implant should be able to withstand the recommended tightening torque of the Abutment Screw.

- It is recommended to verify the final abutment seating using radiographic imaging.
- Block out the screw head before closing the screw access hole with composite.
- If removal of the restoration is needed, open the screw access and untighten the screw using the Omnigrip™ Mini Screwdriver or the Unigrip™.

Materials

- Universal Abutment/Base: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136.
- Clinical/Abutment screw: Titanium alloy 90% Ti, 6% Al, 4% V and DLC (Diamond Like Carbon) coating according to ASTM F136.

Sterility and Reusability Information

The Universal Abutment/Base, including the co-packed Clinical Screw, is delivered non-sterile and 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 delivered non- sterile and is 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 The Universal Abutment/Base a single use product 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 the device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

Cleaning and Sterilization Instructions

The Universal Abutment/Base, including the screw, is delivered non-sterile by Nobel Biocare and intended for single use. Prior to use, the device 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 Universal Abutment/Base has been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

Automated Cleaning and Drying (Including Pre-cleaning)

Universal Abutment/Base with Restoration

Pre-cleaning

1. Disassemble the Universal Abutment prior to cleaning by removing the screw from the device.
2. Immerse the device in lukewarm water for a minimum of 5 minutes until the next step is initiated.
3. Immerse the device in an 0.5% lukewarm enzymatic cleaning agent (e.g., Neodisher Medizym) for a minimum of 20 minutes.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g., Medsafe MED-100.33) under cold tap water for a minimum of 1 minute until all visible soil and debris is removed.
5. Flush lumina (where applicable) with cold tap water using a 20 ml syringe until all visible soil is removed. Use a single-use wipe to catch dripping fluid from flushing. If the discoloration of the wipe is indicating soil, then repeat steps 2-5.

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 4 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum of 10 minutes cleaning with a minimum temperature of 55°C (131°F) tap water and an 0.5% alkaline detergent (e.g., Neodisher Mediclean).
   - Draining.
   - Minimum of 3 minutes rinsing with cold desalinated water.
   - Draining.
4. Dry with compressed air or clean and lint-free single-use wipes, if any residual moisture remains after the drying cycle.

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.

Manual Cleaning and Drying

Universal Abutment/Base with Restoration

1. Disassemble the Universal Abutment prior to cleaning by removing the screw from the device.

2. Immerse device in lukewarm water until the next step is initiated for a minimum of 5 minutes.

3. Immerse the device in an 0.5% enzymatic cleaning solution (e.g., Neodisher Medizym) prepared with lukewarm tap water for a minimum of 20 minutes.

4. Scrub the outer surfaces of the device with a soft-bristled nylon brush under cold tap water for a minimum of 1 minute until all visible soil and debris is removed.

5. Flush lumina and cavities (where applicable) with cold tap water using a 20 ml syringe. Use a single-use wipe to catch dripping fluid from flushing. If the discoloration of the wipe is indicating soil, then repeat steps 2-5.

6. Prepare an ultrasonic bath (e.g., Bandelin; frequency 35 kHz; effective ultrasonic power 300 W_{eff}) containing the 0.5% enzymatic cleaning agent (e.g., Neodisher Medizym). Degas the solution by running the ultrasonic bath for a minimum of 30 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

7. Immerse the device in the ultrasonic bath (e.g., Bandelin; frequency 35 kHz; effective ultrasonic power 300 W_{eff}) containing the 0.5% enzymatic cleaning agent (e.g., Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).

8. Rinse the device with deionized water for a minimum of 1 minute until all residues of cleaning solution are removed.

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, or if dental debris remains on the device. Properly dispose of any devices that fail the inspection.

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Selectomat PL/669-2CL (pre-vacuum cycle); Selectomat PL/669-2CL (gravity cycle).

Note It is recommended to perform sterilization with devices individually sealed in a sterilization pouch using a sterilizer with a maximum load of 2 containers, with metal instruments, and 2 packages of linen.

1. Reassemble any multi-piece devices (where applicable) 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) and sufficient steam permeability).
   - Sufficient protection of the instruments as well as of the sterilization packaging from mechanical damage.

Table 1 presents examples of suitable sterilization pouches.

Method	Recommended Sterilization Pouch
Gravity Cycle	Steriking pouch (Wipak)
Pre-vacuum Cycle	Steriking pouch (Wipak)

Table 1 – Recommended Sterilization Pouches

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:
   - 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 equipment and 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 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

MR Safety Information for Single Tooth Restoration

MRI Safety Information		
Non-clinical testing has demonstrated that Universal 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 3 T 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 1 411 17 Göteborg 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.

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	