

Titanium Abutment Blank Nobel Biocare N1™ TCC



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Description

The Titanium Abutment Blank Nobel Biocare N1™ is an individualized dental implant abutment directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitation. It is designed and made individually to fit the requirements for each patient.

It has a pre-fabricated original connection for the Nobel Biocare N1™ TCC TiUltra implants. It is available for NP and RP implant platforms.

The Titanium Abutment Blank Nobel Biocare N1™ is delivered copacked with the clinical screw. For detailed information on the clinical screw refer to Instruction for Use IFU1057.

The Titanium Abutment Blank Nobel Biocare N1™ is milled using DESS® dental holders.

Titanium Abutment Blank	Clinical Screw	Laboratory components	Screwdriver	Tightening Torque
Titanium Abutment Blank Nobel Biocare N1™ TCC NP Ø10 mm	Clinical Screw Nobel Biocare N1™ TCC NP	Lab Screw Nobel Biocare N1™ TCC NP Implant Replica Nobel Biocare N1™ TCC NP IOS Implant Replica Nobel Biocare N1™ TCC NP	Omnigrip Mini	20 Ncm
Titanium Abutment Blank Nobel Biocare N1™ TCC RP Ø10 mm	Clinical Screw Nobel Biocare N1™ TCC RP	Lab Screw Nobel Biocare N1™ TCC RP Implant Replica Nobel Biocare N1™ TCC RP IOS Implant Replica Nobel Biocare N1™ TCC RP	Omnigrip Mini	20 Ncm

Table 1 – Titanium Abutment Blank Nobel Biocare N1™, compatible components and tightening torque

Intended Use

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

Indications

Titanium Abutment Blank Nobel Biocare N1™ TCC is a premanufactured prosthetic component directly connected to an endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation for single and multiple units of up to three units. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

Contraindications

It is contraindicated to use Titanium Abutment Blank Nobel Biocare N1™ TCC in:

- Patients who are medically unfit for an oral surgical procedure
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium), DLC (Diamond Like Carbon) coating
- Patients with parafunctional tendencies such as bruxism and clenching

It is contraindicated to use clinical screws that are not intended to be used in combination with the Titanium Abutment Blank Nobel Biocare N1™ TCC.

The Titanium Abutment Blank Nobel Biocare N1™ TCC is contraindicated for angulations, lengths, margin heights and wall thickness that do not fall within the indicated dimensions limit as stated in the Tables 2 and 3.

For contraindications specific to the Implant and restorative components, refer to the Nobel Biocare Instructions for Use IFU1087 and IFU1057, refer to IFU1085 for more information on the Omnigrip Mini Screwdriver.

Warnings

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

Cautions

General Cautions

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

Titanium Abutment Blank Nobel Biocare N1™ TCC must only be used with compatible Nobel Biocare instruments and screws. Use of instruments and screws that are not intended to be used in combination with Titanium Abutment Blank Nobel Biocare N1™ TCC 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 strongly recommended that clinicians, new as well as experienced users of implants, prosthetics and associated software, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

It is especially important to achieve proper stress distribution through adaptation and fitting of the crown or bridge, by adjusting the occlusion to the opposing jaw. In addition, avoid excessive transverse loading forces, particularly in immediate loading cases.

One hundred percent implant success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) may result in failure.

Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.

Before Surgery

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

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy 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 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 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 laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other component.

At Surgery

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. dental dam, gauze or a throat shield).

After the implant installation, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

Forces that cause bending moments are known to be the most unfavorable, as they can potentially jeopardize the long-term stability of an implant-supported restoration. In order to decrease bending moments, the distribution of forces should be optimized by cross-arch stabilization, minimizing distal cantilevers, having a balanced occlusion as well as decreased cuspal inclination of the prosthetic teeth.

After Surgery

To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform the patient about appropriate oral hygiene.

Handling Procedure

The digital workflow requires the use of the following equipment according to the instructions of the system provider.

Equipment	Requirement
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) 3Shape Dental Designer (the implant libraries are obtained via the 3Shape server in the software) ExoCAD (the implant libraries are downloaded via the exocad DentalCAD server in the software)
Milling unit	CORITEC by imes-icore

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

For setup, validation, use, tools, maintenance, and lifetime information on scanners and milling machines, please refer to manufacturer's instructions.

Warning Do not use any scanner, components, milling units, CAD/CAM software, templates and tools other than those specifically identified for the Titanium Abutment Blanks Nobel Biocare N1™ TCC.

Clinical/Laboratory Procedure - CAD/CAM Scan of Conventional Impression

Take conventional impression (clinical procedure)

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

Fabricate master model (laboratory procedure)

2. Fabricate a working "master" model with base replicas and removable gingival material following conventional laboratory procedures. Ensure that all components are clean and undamaged.

Obtain CAD/CAM scan of master model (laboratory procedure)

3. Before mounting the Position Locator Nobel Biocare N1™ TCC onto the working "master" model, ensure that it is clean and undamaged. Discard the position locator if it is deformed or if there are any scratches on the scan surface, as this can affect the accuracy of the scan.
4. Assemble the required amount of Position Locator Nobel Biocare N1™ TCC onto the working "master" model and visually confirm the fit to the base replicas. Avoid any contact of the position locator(s) to the interproximal teeth. Refer to Nobel Biocare IFU1091 and IFU1087 for information regarding position locators and Nobel Biocare N1™ implants.
5. Perform the scan with the dental scanner by following the scan process provided by the manufacturer.
6. Export/send the scan file to a Nobel Biocare approved dental CAD/CAM software.

Clinical Procedure - CAD/CAM Scan of Patient Mouth

1. Before mounting the Position Locator(s) into the patient mouth ensure that all components are clean and in an undamaged condition, check and discard if any scratches on the scan surface or any other deformation.

2. Assemble the required amount of Position Locator(s) onto the base in the patient mouth and confirm the fit. Avoid any contact of the position locator(s) to the interproximal teeth. Refer to Nobel Biocare IFU1091 for information regarding position locators and IFU1087 for information position locators and Nobel Biocare N1™ implants.
3. Perform the scan procedure with the dental intra oral scanner by following the scan process provided by the manufacturer.
4. Export/send the scan file(s) to the dental CAD/CAM software

Design the prosthetic restoration

1. Import the scan file(s) into the CAD/CAM software.
2. Open the relevant CAD module and design your restoration in accordance with indications for use, following the instructions in the software tutorial and according to the patient's clinical needs.
3. The following design constraints must be followed:

Restoration type	Min screw channel thickness (mm)	Max abutment height from implant level (mm)	Minimum post height (mm)	Maximum post height (mm)	Minimum Diameter (mm)	Maximum Diameter (mm)	Minimum gingival margin height (mm)
Titanium Abutment Blank Nobel Biocare N1™ TCC NP	0.38	16 mm	4.05	15.665	3.21	9.95	0.335
Titanium Abutment Blank Nobel Biocare N1™ TCC RP	0.49	16 mm	4.05	15.665	3.49	9.95	0.335

Table 2 – Design constraints

The maximum margin height at 30 degree angulation is 4.6 mm.

Max abutment angulation	Maximum margin height (mm)
30°	4.6 (at 30 degree angulation)

Table 3 – Design constraints – Angulation

Milling the designed abutment

1. Place the pre-milled abutment blank into the compatible DESS® blank holder
2. Mill the designed abutment with the milling machine and tools taking into account the design constraints in Table 2 and 3.
3. The milling machine and holder manufacturer's specific instruction for use should be considered.
4. Inspect the abutment implant connection and surface of the milled abutment for any damage that may have occurred during the milling process.
5. Clean the milled abutment with steam jet to remove any residuals.
6. Check fit of restoration on model and if adjustment of the milled abutment is needed, connect it to the implant replica using the laboratory screw.

Caution Do not modify or sandblast the seating area

7. If applicable, fabricate a crown or bridge with CAD/CAM technique or with conventional technique.

- Send the milled abutment(s) and if applicable the crown/bridge to the clinician.

Clinical procedure

- Clean and sterilize the milled abutment as per cleaning and sterilization instructions.
- Remove the cover screw or temporary restoration from the implant if applicable. Refer to Nobel Biocare Instructions for Use IFU1016, IFU1028 or IFU1026 for more information on the cover screw or temporary restorations.
- Place the sterilized abutment in the patient's mouth onto the Nobel Biocare N1™ TCC implant.

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

Note If any modification is necessary, use sterilized instruments in a controlled surgical environment using aseptic technique. Don't modify the restoration intraorally.

- Screw the abutment to the implant using the Clinical Screw Nobel Biocare N1™ and the Omnigrip Mini Screwdriver.

Note Tightening torque Clinical Screw Nobel Biocare N1™: 20 Ncm.

Caution When tightening the abutment to the implant make sure to use the Clinical Screw Nobel Biocare N1™ TCC and not the laboratory screw.

Caution Do not exceed 20 Ncm when tightening the abutment to the implant. Overtightening of abutment may lead to a screw fracture and/or damage of the abutment.

- Seat the restoration on the abutment and check the occlusion and the interproximal contacts.
- After sealing of access hole, cement the final crown or framework using conventional procedures (e.g. using Teflon and composite) according to the manufacturer's instructions. Make sure there is no excess cement.

In case the abutment or the screw need to be removed consider the use of the Abutment Retrieval Tool Nobel Biocare N1™ described in Instruction For Use IFU1041 and the abutment screw removal instrumentation described in Instructions For Use IFU1043.

Materials

- Titanium Abutment Blank Nobel Biocare N1™ TCC: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3
- Clinical screw: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.

Sterility and Reusability Information

Caution Titanium Abutment Blank Nobel Biocare N1™ TCC and Clinical Screw 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 Titanium Abutment Blank Nobel Biocare N1™ TCC and Clinical Screw are for single use 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 as the device sterility and/or integrity may be compromised.

Cleaning and Sterilization Instructions

Titanium Abutment Blank Nobel Biocare N1™ TCC and Clinical screw are delivered non-sterile by Nobel Biocare and is intended for single use. Prior to use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable:

- Manual and Automated Cleaning: AAMI TIR 12
- Sterilization: AAMI ST79 and ISO 17665-1

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note The Titanium Abutment Blank Nobel Biocare N1™ TCC and Clinical screw 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

- Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
- Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe. Repeat this step until the lumens are free of any visually datable soil.
- Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED – 100.33) for a minimum of 1 minute until all visible soil is removed.
- 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 1 minute.
- Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

- 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.

- Place the devices in a suitable rack or load carrier (e.g., metal sieve basket).
- Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
- 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 10 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5% alkaline detergent (e.g. Neodisher Mediclean forte)
 - Draining
 - Minimum of 3 minutes neutralization with 0.1% acidic neutralizing agent (e.g. neodisher Z)
 - Draining
 - Minimum of 2 minutes rinsing with cold deionized water
 - Draining
- Run drying cycle at a minimum of 50°C (122°F) for a minimum of 10 minutes
- 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, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying

- Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
- Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 1 minute until all visible soil is removed.
- Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm enzymatic cleaning solution (e.g. Neodisher Medizym) using an irrigation needle connected to a 20 ml syringe.
- 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 1 minute until all visible soil is removed.
- Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solution.

- Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz, effective ultrasonic power 300 W_{eff}) containing an 0.5% enzymatic cleaning agent (e.g. Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).
- Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml of lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
- Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute to remove all cleaning agent.
- Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection

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

Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Selectomat PL/666-1CL (pre-vacuum cycle); Selectomat PL/666-1CL (gravity cycle).

Note It is recommended to perform sterilization with a maximum load of 1 container with 8.6 kg of metal and 2 packages of linen.

- Seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
 - EN ISO 11607 and/or DIN 58953-7.
 - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient steam permeability).
 - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 4 presents examples of suitable sterilization pouches.

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

Table 4 – Recommended Sterilization Pouches

- Label the sterilization pouch with the information necessary to identify the device (e.g., the product name with article number and lot/batch number (if applicable)).
- Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
- 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 30 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 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.

Caution The devices are to be used immediately after sterilization.

Caution Sterilized devices are not to be stored.

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 and Multiple unit Restoration (up to three units)

MRI Safety Information



Non-clinical testing has demonstrated the Titanium Abutment Blank Nobel Biocare N1™ TCC is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient.

Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T)	3-Tesla (3 T).
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 58.9 T/m (5,890 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	Inferior to the neck: 2.0 W/kg Superior to the neck: 0.5 W/kg	Inferior to the xyphoid: 2.0 W/kg Between the xyphoid and neck: 1.0 W/kg Superior to the neck: 0.5 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0°C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 3T MRI system.	

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



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

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Symbols Glossary

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



Authorized Representative in the European Community/ European Union



UK Responsible Person



Authorised Representative in Switzerland



Sterilized using Ethylene Oxide



Sterilized using irradiation



Sterilized using steam or dry heat



Batch code



Catalogue number



Unique Device Identifier



Serial number



Medical device



Magnetic resonance safe



Caution



Magnetic resonance conditional



Non-sterile



Contains hazardous substances



Contains or presence of DEHP phthalate



Contains or presence of natural rubber latex



Contains or presence of phthalate



Contains biological material of animal origin



CE mark



CE mark with Notified Body number



UKCA mark



UKCA mark with Approved Body number



Consult instructions for use



For prescription use only



symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com

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