On1™ Concept

Internal conical connection (CC) NP/RP/WP for the following implant systems: NobelActive® CC, NobelReplace® CC and NobelParallel™ CC.

The On1™ Concept comprises

On1™ Base

Note Handle and Clinical Screw included.

On1™ Temporary Abutment

Note Handle and Prosthetic Screw included.

On1™ Universal Abutment

Note Burn-out Coping and Prosthetic Screw included.

On1™ Esthetic Abutment

Note Prosthetic Screw included.

On1™ Healing Cap

On1™ Impression Coping

On1™ Screwdriver

On1™ Clinical and Prosthetic Screw

On1™ Base Replica

On1™ Prosthetic Lab Screw

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

A premanufactured dental implant 2-piece abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

The On1™ Base is intended to be connected at time of surgery and to stay on the implant. The On1™ Abutment and On1™ Healing Cap are then placed upon the On1™ Base according to the planned treatment plan.

Intended Use/Intended Purpose

On1™ Base, On1™ Healing Cap, On1™ Abutments

The On1™ devices are intended for use in the field of dentistry. They are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function and esthetics.

The On1™ Healing Cap protects the internal connection and the Clinical Screw of the Base.

On1™ Impression Coping

The On1™ Impression Copings are premanufactured devices directly connected to the On1™ Base used to transfer the location and orientation of dental implants, via a closed or open tray impression technique, from the patients partially edentulous jaw to a working dental laboratory model.

On1™ Lab Components (On1™ Base Replica, On1™ Prosthetic Lab Screw)

The On1™ Lab Components are intended to be used in the dental laboratory only. The On1™ Base Replica acts as a substitute of the assembly constituted by dental implant and On1™ Base. The On1™ Prosthetic Lab Screw is used for temporary fixation of the restorations, to a replica in a plaster model.

On1™ Screwdriver

The On1™ Screwdriver is intended to screw and unscrew screws which are used for the On1™ implant based dental restorations.

On1™ Clinical and Prosthetic Screw

The On1™ Clinical/Prosthetic Screw is intended to be used as screw for tightening the supporting substructure/framework onto the Nobel Biocare conical connection dental implants and On1™ abutments.

Indications

The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation, indicated for single-unit cement and screw retained restorations and for multiple-unit cement and screw retained short spanned bridges. The On1 Universal Abutment Non-Engaging is indicated for implants with less than 20° overall divergences to allow path of insertion.

Contraindications

It is contraindicated to use On1™ Concept in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), Stainless Steel, Polyoxymethylene (POM) or PEEK (Polyetheretherketone).

Materials

- On1™ Base:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Temporary Abutment:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Universal Abutment:
  Titanium alloy 90% Ti, 6%Al, 4% V.
- On1™ Esthetic Abutment Titanium:
  Titanium alloy 90% Ti, 6%Al, 4% V.
- On1™ Clinical and Prosthetic Screws:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- Handle:
  Polyetheretherketone (PEEK).
- On1™ Healing Cap:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Screwdriver: Stainless Steel.
- On1™ Universal Abutment Burn-out coping:
  Polyoxymethylene (POM).
- On1™ Base Replica:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Impression Coping:
  Titanium alloy 90% Ti, 6% Al, 4% V.

Cautions

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

It is strongly recommended that clinicians, new as well as experienced implant users, 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 info please visit www.nobelbiocare.com.

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. 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, infections in the neighbouring 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 or unfavourable jaw relationships reappraisal of the treatment option may be considered.

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

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

Because of the small size of components, care must be taken that they are not swallowed or aspirated by the patient.

To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Caution Whenever using cement to retain the restoration, it is recommended to remove any excess in order to avoid sub-mucosal cement remains.

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

Intended Users and Patient Groups

The On1™ concept is intended to be used in a dental practice, hospital or dental laboratory environment by dental health care professionals.

The On1™ concept is intended to be used in patients who require dental restoration in the upper or lower jaw to support the replacement of chewing function and esthetics.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with On1™ Concept

On1™ concept 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 On1™ concept

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, swelling. During placement or removal of the device, the pharyngeal reflect (gag reflex) may be triggered in patients with a sensitive gag reflex.

Implant abutments and implant prosthetics 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. When restoring or adapting a patient's dentition, lip biting, bruxism, and phonetic alterations may occur, and the neighboring/opposing prostheses may need adjustment or relining. Some patients may experience discoloration in the mucosal area such as graying, or wear of neighboring/opposing dentition/prostheses.

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

1. Place an appropriate On1™ Base onto a Nobel Biocare implant with a CC connection and NP/RP/WP platform using the Handle to facilitate the insertion. It is recommended to verify the final On1™ Base seating and components attached using radiographic imaging.

2. Tighten the On1™ Base Clinical Screw to 35 Ncm, using the On1™ Screwdriver and Manual Torque Wrench Prosthetic.

Caution Never exceed 35 Ncm prosthetic tightening torque. Over tightening of the On1™ Base Clinical Screw may lead to a screw fracture.

Caution Each time a component is connected to the On1™ Base make sure the On1™ Base Clinical Screw is not untightened.

Caution The On1™ Base Clinical Screw can only be used with the On1™ Screwdriver which is laser marked with a ring.

Based upon the preferred clinical and laboratory workflow, the following restorative options and workflows are available for the On1™ Concept.

A) Healing phase

1. Select appropriate On1™ Healing Cap and check occlusal clearance.

2. Connect the On1™ Healing Cap to the On1™ Base and hand tighten using the Unigrip™ Screwdriver.

B) Impression taking

1. Remove On1™ Healing Cap.

2. Take impression of the On1™ Base using the On1™ Impression Coping closed tray or open tray.

C) Temporization using the On1™ Temporary Abutment (Chair-side made provisional)

1. Connect and hand tighten the On1™ Temporary Abutment to the On1™ Base using Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic and modify the abutment height if necessary using copious irrigation.

2. Close the screw access hole using conventional techniques.

3. Make a temporary restoration using a pre-fabricated mold with suitable temporary crown material.

4. Drill a hole through the mold, loosen the On1™ Prosthetic Screw using a Unigrip™ Screwdriver and remove the restoration.

5. Make final adjustments.

6. Connect and tighten the On1™ Temporary Abutment to 35 Ncm using the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic.

7. Close the screw access hole using conventional techniques.

D) Temporization using the On1™ Temporary Abutment (Laboratory made provisional)

1. Assemble the On1™ Impression Coping and On1™ Base Replica and carefully reposition into the impression.

2. Fabricate a working model with removable gingival material.

3. Follow step C 1–5 from the "Temporization using the On1™ Temporary Abutment (Chair-side made provisional)" to fabricate a single provisional restoration.

E.1) Final Restoration using the On1™ Esthetic Abutment (Clinical procedure pre-laboratory)

1. Select the appropriate On1™ Esthetic Abutment, connect to the On1™ Base and check occlusal clearance.

2. Connect and tighten the On1™ Esthetic Abutment to 35 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic.

Caution Never exceed 35 Ncm prosthetic tightening torque. Overtightening of the On1™ Prosthetic Screw may lead to a screw fracture.

3. Modify the On1™ Esthetic Abutment if necessary using copious irrigation.

4. Remove the On1™ Esthetic Abutment and take a base level impression using the On1™ Impression Coping closed or open tray.

5. Provisionalize after sealing the access hole.

E.2) Final Restoration using the On1™ Esthetic Abutment (Laboratory procedure)

1. Produce a working model with removable gingival material.

2. Fabricate a crown with a conventional casting technique.

3. Veneer the crown if applicable.

E.3) Final Restoration using the On1™ Esthetic Abutment (Clinical procedure post-laboratory)

1. Remove temporary restoration.
2. Retighten On1™ Base Clinical Screw if necessary.
3. Connect and tighten the On1™ Esthetic Abutment to 35 Ncm using the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic.
4. Cement the final crown using conventional procedures after sealing of access hole.

F.1) Final Restoration using the On1™ Universal Abutment (Laboratory procedure, press workflow)

1. Hand tighten the On1™ Universal Abutment onto the working model. Make sure to use an On1™ Prosthetic Lab Screw.
2. Seat the Burn-out coping onto the On1™ Universal Abutment.
3. Adjust the height of the Burn-out coping according to the required occlusal plane. Make sure the On1™ Universal Abutment remains fully covered.
4. Create a wax-up restoration and use standard procedures to either press the coping or full-contour crown.
5. Once the restoration is produced, finalize it following the restorative material manufacturer's instruction.

F.2) Final Restoration using the On1™ Universal Abutment (Clinical procedure)

1. Remove the laboratory produced restoration from the working model.
2. Clean and disinfect the final restoration as applicable per restorative material manufacturer's instruction.
3. Remove the On1™ Healing Cap or temporary restoration from the On1™ Base and retighten the On1™ Base if necessary.
4. Connect and tighten the On1™ Universal Abutment to the On1™ Base using the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic to tighten to 35 Ncm.

Caution Never exceed 35 Ncm prosthetic tightening torque. Overtightening of the On1™ Prosthetic Screw may lead to a screw fracture.

Sterility and Reusability Information

The On1™ Base/On1™ Base Xeal™, On1™ Temporary Abutment, On1™ Healing Cap, On1™ IOS Healing Cap, On1™ Clinical Screw and On1™ Prosthetic Screw been sterilized using irradiation and are intended for single use. Do not use after the labeled expiration date.

Warning Do not use device if the packaging has been damaged or previously opened.

Caution The On1™ Base/On1™ Base Xeal™, On1™ Temporary Abutment, On1™ Healing Cap, On1™ IOS Healing Cap, On1™ Clinical Screw and On1™ Prosthetic Screw 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.

On1™ Universal Abutment and On1™ Esthetic Abutment are delivered non-sterile and are intended for single use. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Caution The On1™ Universal Abutment and On1™ Esthetic Abutment 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.

The On1™ Screwdriver is a reusable instrument which shall be inspected before each re-use to ensure that the integrity and performance continues to be maintained. Check if any wear, deformations or corrosion is visible on the instrument. On1™ Screwdrivers showing those signs shall be discarded.

If the On1™ Screwdriver does not engage in the On1™ Clinical Screw, the instrument is worn and shall be discarded.

The On1™ Impression Copings are reusable devices which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. On1™ Impression Copings shall be discarded if any of the following criteria are met:

- If any wear, abrasion of the anodization, deformations or corrosion is visible on the component.
- If the impression coping does not seat accurately or has a loose fit on the On1™ Base, or the On1™ Replica.
- If with light pressure the Unigrip™ Screwdriver does not engage or slips in the receptacle of the screw or guide pin.

If the guide pin is no longer retained in the On1™ Impression Coping, which indicates that the O-ring for the guide pin has been stripped off or has deteriorated.

Warning Do not use device if the packaging has been damaged or previously opened.

Cleaning and Sterilization Instructions

Cleaning and sterilization instructions for supra-constructions that include non-metallic materials, which require cleaning and disinfection and/or sterilization prior to patient contact.

The final On1™ Universal Abutment should be cleaned and sterilized, as applicable per the glaze, stain, and/or veneering material manufacturer's instructions for use, prior to use.

Instructions for Devices Which Are Individually Sterilized in a Single Pouch:

The On1™ Esthetic Abutment are delivered non-sterile by Nobel Biocare and are intended for single. Prior to use, the devices must be cleaned and sterilized by the user.

The On1™ Screwdriver and On1™ Impression Coping are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the devices must be cleaned and sterilized by the user.

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

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

- Manual and Automated Cleaning: AAMI TIR 12.

– Sterilization: AAMI ST79 and ISO 17665-1.

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

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

Note The On1™ Esthetic Abutment, On1™ Screwdriver and On1™ Impression Coping been validated to withstand these cleaning and sterilization procedures.

Caution Do not deviate from the following reprocessing instructions.

Initial Treatment at Point of Use Prior to Reprocessing

1. Discard single-use instruments and worn reusable instruments immediately after use.

2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe for soil and debris in cavities.

Caution All dental debris adhering to the impression copings (such as impression material) must be cleaned away after use. It may not be possible to remove the dried debris later in the process. Impression copings shall be discarded if dental debris cannot be removed.

3. Rinse the devices with cold running tap water.

Containment and Transportation/ Shipping to Reprocessing Area

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.

2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

Note Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning)

Pre-cleaning

1. Disassemble On1™ Impression Coping prior to cleaning by removing the screw from the coping. Disassemble On1™ Esthetic Abutment prior to cleaning by removing the screw from the Abutment.

2. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.

3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.

4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.

5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 20 seconds until all visible soil is removed.

6. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.

7. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying

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

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

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).

2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.

3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.

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 On1™ Impression Coping prior to cleaning by removing the screw from the coping. Disassemble On1™ Esthetic Abutment prior to cleaning by removing the screw from the abutment.

2. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.

3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.

4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic

cleaning solution (e.g. Cidezyme ASP or 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 cold running tap water 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. Cydezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C(104°F)/maximum 45°C (113°F).

8. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.

9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.

10. Dry with compressed air or clean and lint-free single use wipes.

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 (pre-vacuum cycle); Amsco Century Sterilizer (gravity cycle).

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

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:
   - 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 1 presents examples of suitable sterilization containers, pouches, and wraps.

Table 1 – Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch
Pre-vacuum Cycle	SteriCLIN® pouch

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).

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

4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 2):

Table 2 – Recommended Sterilization

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar[4]
Pre-Vacuum Cycle[1]	132°C (270°F)	4 minutes		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

[1] Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

[2] Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

[3] Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.

[4] Saturated steam pressure at 132°C as per required by EN ISO 17665-2.

[5] Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance

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

Containment and Transportation/ Shipping to Point of Use

The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the sterility of the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Magnetic Resonance (MR) Safety Information

MRI Safety Information		
Non-clinical testing has demonstrated the device 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 44.4 T/m (4,440 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	Inferior to the shoulders: 2.0 W/kg Superior to the shoulders: 0.2 W/kg	Inferior to the navel: 2.0 W/kg Superior to the navel: 0.1 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.	
Caution	Configurations with more than 2 Zygoma implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of configurations with more than 2 Zygoma implants in the MR environment is unknown. Scanning a patient who has this configuration may result in patient injury.	

Performance Requirements and Limitations

To achieve the desired performance, On1™ concept 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 On1™ concept, 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
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş Nispetiye Mah. Aytar Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
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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 I Devices	CE
CE Mark for Class Ir/IIa/IIb Devices	CE 2797
UKCA Mark for Class I Devices	UK CA
UKCA Mark for Class IIa/IIb Devices	UK CA 0086

Note Regarding Canadian Device Licensure, not all products described in the IFU may have a device licence according to Canadian Law.

Note Refer to the product label to determine the applicable conformity marking for each device.

Basic UDI-DI Information

Product	Basic UDI-DI Number
On1 Bases Conical Connection NP/RP/WP On1 Bases Xeal™ Conical Connection NP/RP/WP On1 Universal Abutments NP/RP/WP On1 Esthetic Abutments Titanium NP/RP/WP On1 Universal Abutments Non-Engaging NP/RP/WP	733274700000001687H
On1 Temporary Abutments Engaging NP/RP/WP On1 Temporary Abutment Non-Engaging NP/RP/WP	733274700000017278
On1 Clinical Screws NP/RP/WP On1 Prosthetic Screws NP/RP/WP	733274700000001827B
On1 Healing Caps NP/RP/WP On1 IOS Healing Caps NP/RP/WP	733274700000001236T
On1 Impression Copings Closed Tray NP/RP/WP On1 Impression Copings Open Tray NP/RP/WP On1 Impression Copings Open Tray Non-Engaging NP/RP/WP	733274700000013674
On1 Screwdriver Manual	733274700000001787L
On1 Screwdriver Machine	733274700000001797N

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.

EC REP Authorized Representative in the European Community/ European Union	UK RP UK Responsible Person	CH REP Authorised Representative in Switzerland	STERILE EO Sterilized using Ethylene Oxide	STERILE R Sterilized using irradiation	STERILE Sterilized using steam or dry heat	
LOT Batch code	REF Catalogue number	UDI Unique Device Identifier	SN Serial number	MD Medical device	MR Magnetic resonance safe	
Caution	MR Magnetic resonance conditional	NON STERILE Non-sterile	Contains hazardous substances	PHT DEHP Contains or presence of DEHP phthalate	LATEX Contains or presence of natural rubber latex	PHT Contains or presence of phthalate	BIO Contains biological material of animal origin
CE CE mark	CE 2797 CE mark with Notified Body number	UKCA UKCA mark	UKCA 0086 UKCA mark with Approved Body number	Consult instructions for use	Rx only 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	