On1™ Concept
Instructions for use

Important: Please read.

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, it is his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instructions 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.

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

Intended use:

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:

The On1™ Concept is contraindicated for:

– 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).

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

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.

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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):

6. Produce a working model with removable gingival material.
7. Fabricate a crown with a conventional casting technique.
8. Veneer the crown if applicable.

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

9. Remove temporary restoration.
10. Retighten On1™ Base Clinical Screw if necessary.
11. Connect and tighten the On1™ Esthetic Abutment to **35 Ncm** using the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic.
12. 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.

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.

Cleaning and sterilization instructions:

The On1™ Base, On1™ Temporary Abutment, On1™ Healing Cap, On1™ Prosthetic and Clinical Screw are delivered sterile for single use only. 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™ Temporary Abutment, On1™ Healing Cap and On1™ Prosthetic and Clinical Screw are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause cross contamination.

The On1™ Universal Abutment and On1™ Esthetic Abutment are delivered non-sterile for single use only. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

Warning: Use of non-sterile components may lead to infection of tissue or infectious diseases.

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

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. Re-use could cause cross contamination.

The On1™ Screwdriver and On1™ Impression Coping are delivered non-sterile and intended for re-use. Prior to use and re-use clean, disinfect and sterilize using the recommended parameters.

Warning: Use of non-sterile components may lead to infection of tissue or infectious diseases.

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

The On1™ Base Replica and On1™ Prosthetic Lab Screw are delivered non-sterile and for laboratory use only.

The On1 Base Replica and On1 Prosthetic Lab Screw are only used in the dental laboratory only (no intraoral use) and have no cleaning and sterilization requirements.

Clean the device using manual or automated cleaning, disinfect and dry the device following instructions in Cleaning and Sterilization Guidelines available at www.nobelbiocare.com/sterilization.

Inspect and seal the single device in a pouch and steam sterilize, both the gravity cycle (saturated steam) and pre-vacuum (forced air removal) cycle can be applied, using the following parameters:

For USA: FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters. For outside USA: Temperature 132°C (270°F), max 137°C (279°F) for 3 minutes (up to 20 minutes). Dry for 10 minutes in chamber.

Alternative UK: Temperature 134°C (273°F), max 137°C (279°F) for 3 minutes (up to 20 minutes). Dry for 10 minutes in chamber.

Full set of recommended parameters are provided in "Cleaning & Sterilization Guidelines including Magnetic Resonance Imaging information of Nobel Biocare Products" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Magnetic Resonance (MR) safety information:

This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration and image artifact in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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CE 2797

Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

For Prescription Use Only.
Caution: Federal (United States) law restricts this device to sale by or on the order of a clinician, medical professional or physician.

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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

Batch code

Catalogue number

Caution

CE marking

Consult instructions for use

Contains hazardous substances

Contains or presence of phthalate

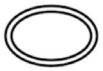
Date

Date of manufacture

Do not resterilize

Do not re-use

Do not use if package is damaged



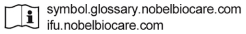
Double sterile barrier system

For prescription use only

Health care centre or doctor

Keep away from sunlight

Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional

Manufacturer

Medical device

Non-pyrogenic

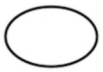
Non-sterile

Patient identification

Patient information website

Patient number

Serial number



Single sterile barrier system

Single sterile barrier system with protective packaging inside

Single sterile barrier system with protective packaging outside

Sterilized using ethylene oxide

Sterilized using irradiation

Temperature limit

Tooth number

Upper limit of temperature

Sterilized using steam or dry heat

Unique Device Identifier

Use-by date

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