On1™ Concept
Instructions for Use

On1™ Base including On1™ Clinical Screw

On1™ Base Xeal™

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:

The On1™ Concept consists of a pre-manufactured, two-piece dental implant base and abutment and restorative components which can be directly connected to an endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

The On1™ Concept includes two options for the On1™ Base: the On1™ Base Xeal™ which has the Xeal™ surface, and the On1™ Base with the standard surface.

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

The On1™ Concept can be used with internal conical connections (CC) NP/RP/WP for the following implant systems: NobelActive® CC, NobelReplace® CC and NobelParallel™ CC.

The On1™ Concept is comprised of the following components:

- On1™ Base or On1™ Base Xeal™ *

Note: A pre-mounted handle for placement of the On1™ Base, as well as the On1™ Clinical Screw*, are included with the On1™ Base and On1™ Base Xeal™.

- On1™ Temporary Abutment*

Note: A pre-mounted handle for placement and the On1™ Prosthetic Screw* are included with the On1™ Temporary Abutment.

- On1™ Universal Abutment*

Note: The On1™ Burn-out Coping and On1™ Prosthetic Screw* are included with the On1™ Universal Abutment.

- On1™ Esthetic Abutment*

Note: The On1™ Prosthetic Screw* is included with the On1™ Esthetic Abutment.

- On1™ Healing Cap*
- On1™ Impression Coping
- On1™ Screwdriver (manual and machine* version)
- On1™ Clinical Screw*
- On1™ Prosthetic Screw*
- On1™ Base Replica
- On1™ Prosthetic Lab Screw

* Class II device; see applicable CE Mark (CE 0086)

Intended Use:

On1™ Base / On1™ Base Xeal™, On1™ Healing Cap, On1™ Abutments:

The On1™ Bases, On1™ Healing Cap, and On1™ Abutments 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 On1™ 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™ Concept is comprised of premanufactured prosthetic components which are directly connected to an endosseous implant and are intended for use in prosthetic rehabilitation. The On1™ Concept is indicated for single-unit cement and screw retained restorations and for multiple-unit cement and screw retained short spanned bridges (2-3 units). 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 in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), stainless steel, polyoxymethylene (POM) or Polyetheretherketone (PEEK).

The On1™ Base Xeal™ specifically is contraindicated for patients who are allergic or hypersensitive to sodium dihydrogen phosphate (NaH_2PO_4) or magnesium chloride ($MgCl_2$).

Cautions:

General:

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a 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 aesthetic results.

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.

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 especially important to achieve proper stress distribution through adaptation and fitting of the crown or bridge by adjusting 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 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, 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 may be considered.

With respect to pediatric patients, routine treatment is not recommended until the end of the 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 procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery:

Care and maintenance of 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.

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.

After Surgery:

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. .

Handling Procedure:

1. Place an appropriate On1™ Base/ On1™ Base Xeal™ 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™ 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™ Clinical Screw may lead to a screw fracture.

Caution: Each time a component is connected to the On1™ Base / On1™ Base Xeal™ make sure the On1™ Clinical Screw is not loosened an is re-tightened if necessary.

Caution: The On1™ 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 / On1™ Base Xeal™ and hand tighten using the Unigrip™ Screwdriver.

B) Impression taking:

1. Remove On1™ Healing Cap.
2. Take impression of the On1™ Base / On1™ Base Xeal™ 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 steps C1–5 (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™ 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.

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

Caution: Remove any excess cement in order to avoid contact with sub-mucosal tissue.

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 / On1™ Base Xeal™, and retighten the Base if necessary.
4. Connect and tighten the On1™ Universal Abutment to the On1™ Base / On1™ Base Xeal™ 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, On1™ Temporary Abutment, On1™ Universal Abutment, On1™ Esthetic Abutment Titanium, On1™ Clinical and Prosthetic Screws, On1™ Healing Cap, On1™ Base Replica, and On1™ Impression Coping: Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Base Xeal™: Titanium alloy 90% Ti, 6% Al, 4% V, sodium dihydrogen phosphate (NaH2PO4) and magnesium chloride (MgCl2).
- Handle for placement of On1™ Base / On1™ Base Xeal™: Polyetheretherketone (PEEK).
- On1™ Screwdriver: Stainless Steel.
- On1™ Universal Abutment Burn-out coping: Polyoxymethylene (POM).

Sterility and Reusability Information:

The On1™ Base / On1™ Base Xeal™, 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™ Base Xeal™, On1™ Temporary Abutment, On1™ Healing Cap, 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 infection.

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

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

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 infection.

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

The On1™ Screwdriver is a reusable instrument which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. Please check if any wear, deformations or corrosion is visible on the instrument. The screwdriver showing those signs shall be disposed.

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

The On1™ Impression Coping is a reusable component which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. Please check if any wear, abrasion of the anodization, deformations or corrosion is visible on the component. The impression coping showing those signs shall be disposed.

If the On1™ Impression Coping does not seat accurately or has a loose fit in the On1™ Base / On1™ Base Xeal™ or the On1™ Replica, the impression coping is worn and shall be disposed.

Warning: Use of non-sterile device may lead to infection of tissues 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 used in the dental laboratory only (no intraoral use) and have no cleaning and/or sterilization requirements.

Cleaning and Sterilization Instructions:

Cleaning and sterilization instructions for devices which are delivered non-sterile by Nobel Biocare, are intended for single use or reuse, and must be sterilized by the user prior to each use, where the devices are individually sealed in pouches during sterilization.

With these cleaning and sterilization instructions, Nobel Biocare provides a validated procedure to ensure clean and sterile products. According to EN ISO 17664, it remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieves the desired result. Likewise, any deviation by the processor from the provided instructions should be properly evaluated for effectiveness and potential adverse consequences.

Cleaning Guidelines:

Clean the device using automated or manual cleaning, disinfect and dry the device.

Automated Cleaning, Disinfection and Drying (Including Pre-cleaning):

The following washer/disinfector was used in the Nobel Biocare validation: Miele G7836 CD.

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

1. Disassemble the devices, where applicable.

2. Immerse in cold enzymatic cleaning agent 0.5% (e.g. Neodisher Medizym) for 5 minutes.
3. Fill lumina (where applicable) with cleaning solution 0.5% (e.g. Neodisher Medizym) with a syringe.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) until all visible residues are removed.
5. Brush the inner surfaces, lumina and cavities (where applicable) with bottle brushes (e.g. OD = 1.2mm / 2.0mm / 5.0mm) until all visible residues are removed.
6. Rinse with cold running tap water.
7. Rinse lumina (where applicable) with a syringe with 20ml tap water.
8. Load devices into washer / disinfector.
9. Perform automatic cleaning and disinfection under consideration of national requirements with regard to the A0-Value (EN ISO 15883). The following parameters are based on the Vario TD program on the Miele G7836 CD Washer-disinfector:
   - 2 min pre-cleaning with cold water
   - Draining
   - 5 minutes cleaning with 55°C tap water and 0.5% alkaline cleaning agent (e.g. Neodisher Mediclean)
   - Draining
   - 3 minutes neutralization with cold desalinated water
   - Draining
   - 2 minutes rinsing with cold desalinated water
   - Draining
10. Run drying cycle.
11. Dry with compressed air or wipes if needed.

Manual Cleaning, Disinfection and Drying:

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

1. Disassemble the device(s), where applicable.
2. Immerse devices for a minimum of 5 minutes in sterile NaCl solution.
3. Scrub the outer side of the devices with soft bristled nylon brush until all visible soil is removed.
4. Flush channels / lumina (where applicable) with 20ml cleaning solution (e.g. Cidezyme ASP) with an irrigation needle connected to a 20ml syringe.
5. Brush lumina (where applicable) with a bottle brush (e.g. OD = 1.2mm / 2.0mm / 5.0mm).
6. Rinse the outer side and lumina of the devices with cold running tap water to remove all cleaning solutions.
7. Immerse in ultrasonic bath with 0.5% enzymatic Detergent Solution (e.g. Cidezyme ASP) and treat for 5 min at 40°C (104°F).
8. Flush inner lumina (where applicable) with 20ml cold running tap water with an irrigation needle connected to a 20ml syringe.
9. Rinse the outer side of the devices with purified or sterile water to remove all cleaning solutions.
10. Repeat cleaning steps if needed.
11. Immerse in 100% disinfection solution (e.g. Cidex OPA) for 5 minutes.
12. Flush internal channels / lumina (where applicable) with disinfection solution.
13. Rinse and flush lumina and outer side of devices with cold running tap water.
14. Flush internal channels / lumina (where applicable) with purified or sterile water.
15. Dry with compressed air or wipes.
16. Repeat complete cleaning and disinfection if needed.

Visual Inspection:

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

Sterilization:

Assemble (where applicable), inspect and seal the single device in a suitable sterilization pouch and steam sterilize. Both the gravity cycle (saturated steam) and pre-vacuum (forced air removal) cycle can be applied, using the following parameters:

- Gravity Cycle Method: Steam sterilization at 132°C (270°F) for 10 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method: Steam sterilization at 132°C (270°F) for 3 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method (for UK): Steam sterilization at 134°C (273°F) for 3 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method (recommended to ensure inactivation of prions): Steam sterilization at 134°C (273°F) for 18 minutes, followed by drying for a minimum of 20 minutes in chamber.

Magnetic Resonance (MR) Safety Information:

The On1™ Concept devices 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 these devices in the MR environment is unknown. Scanning a patient who has these devices 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:

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:

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CE Mark for Class I Devices

CE 0086 Mark for Class II Devices

Canada – License Exemption: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

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Symbols Glossary:

The following table describes symbols which may be present on the device labeling. Refer to the device labeling for the symbols which are applicable to the device.

Batch code

Catalogue number


Caution


Consult instructions for use

Contains or presence of phthalate


Date of manufacture

Do not re-sterilize

Do not re-use

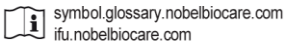

Do not use if package is damaged

For prescription use only

Patient Identifier


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal


Manufacturer

Medical device

Magnetic resonance conditional

Non-sterile

Patient number

Serial number

Sterilized using irradiation


Use-by date