

On1™ Concept



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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 can be used with internal conical connections (CC) for the NobelActive® CC, NobelReplace® CC and NobelParallel™ CC implant systems.

The On1™ concept includes components which are intended for use with NP, RP or WP platform sizes; the specific On1™ concept components used must have the same platform size as the implant.

The On1™ concept is comprised of the following components:

On1™ Base and On1™ Base Xeal™

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.

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

On1™ Clinical Screw

The On1™ Clinical Screw is designed to fix the On1™ Base or On1™ Base Xeal™ to an endosseous dental implant.

On1™ Prosthetic Screw

The On1™ Prosthetic Screw is designed to fix the On1™ abutments to an On1™ Base or On1™ Base Xeal™.

On1™ Temporary Abutment

The On1™ Temporary Abutment is placed upon the On1™ Base to support the placement of a provisional dental prosthesis. The On1™ Temporary Abutment includes two options: the On1™ Temporary Abutment Engaging which is supporting provisional crowns, and the On1™ Temporary Abutment Non-Engaging which is supporting provisional bridges.

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

On1™ Universal Abutment

The On1™ Universal Abutment is placed upon the On1™ Base to support the placement of single unit and multiple unit screw-retained dental prostheses.

Note An On1™ Burn-out Coping and On1™ Prosthetic Screw are included with the On1™ Universal Abutment. The On1™ Burn-out Coping is intended for laboratory use only and are not intended for intraoral use.

On1™ Esthetic Abutment

The On1™ Esthetic Abutment is placed upon the On1™ Base to support the placement of single unit and multiple unit screw-retained dental prostheses.

Note An On1™ Prosthetic Screw is included with the On1™ Esthetic Abutment.

On1™ Healing Cap

The On1™ Healing Cap is placed upon the On1™ Base to support healing of the surrounding soft tissue.

On1™ IOS Healing Cap

The On1™ IOS (Intraoral Scannable) Healing Cap is placed upon the On1™ Base to support healing of the surrounding soft tissue.

The On1™ IOS Healing Cap facilitates the digital capturing of an intraoral location of the On1™ Base or On1™ Base Xeal™ from the patient's jaw to a digital model to facilitate the design and fabrication of a dental restoration in the dental laboratory.

Note A pre-mounted handle for placement of the On1™ IOS Healing Cap and a pre-mounted On1™ Prosthetic Screw are included with the On1™ IOS Healing Cap.

On1™ Impression Coping

The On1™ Impression Coping facilitates the transfer of an intraoral location of the On1™ Base or On1™ Base Xeal™ from the patient's jaw to the relative position on a master cast in the dental laboratory.

On1™ Impression Copings are available for both open-tray and closed-tray impression techniques. The open-tray technique is recommended in cases with multiple implants. The closed-tray technique is recommended in patients with less mouth opening, in limited access areas and with patients with a highly-sensitive gagging reflex.

On1™ Impression Copings Open Tray are co-packed with a guide pin. On1™ Impression Copings Closed Tray are co-packed with a screw.

On1™ Screwdriver

The On1™ Screwdriver Manual and On1™ Screwdriver Machine are used to tighten and loosen the clinical or prosthetic screws which fasten the On1™ concept and prosthetic components to the dental implant.

On1™ Laboratory Components (Intended for Laboratory Use 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 working model.

See Table 3 on the last page of this IFU for information regarding the compatibility of the various On1™ Concept components.

Intended Use/Intended Purpose

On1™ Base, On1™ Base Xeal™, On1™ Temporary Abutments, On1™ Universal Abutments, and On1™ Esthetic Abutments

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

On1™ Clinical Screws and On1™ Prosthetic Screws

Intended for use to fasten dental implant system components to a dental implant or to another component.

On1™ Healing Cap

Intended to be temporarily connected to an endosseous dental implant or implant abutment to support healing of the surrounding soft tissue.

On1™ IOS Healing Cap

Intended to be temporarily connected to an endosseous dental implant or implant abutment to support healing of the surrounding soft tissue and transfer of position of a dental implant or implant abutment to a patient model.

On1™ Impression Coping

Intended for use to transfer the direction, position, or orientation of a dental implant to a patient model.

On1™ Screwdrivers (Manual and Machine)

Intended for use to tighten and/or loosen screws used to connect dental implant system components.

Indications

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) with no overhang.

On1™ Base/On1™ Base Xeal™

The On1™ Base and On1™ Base Xeal™ are indicated for use in the maxilla or mandible for supporting tooth replacements to restore chewing function.

On1™ Clinical Screw

The On1™ Clinical Screw is indicated for use to secure an On1™ Base or On1™ Base Xeal™ to a dental implant in the maxilla or mandible for supporting tooth replacements to restore chewing function.

On1™ Prosthetic Screw

The On1™ Prosthetic Screw is indicated for use to secure a On1™ Universal Abutment, On1™ Esthetic Abutment, or On1™ Temporary Abutment to an On1™ Base or On1™ Base Xeal™ in the maxilla or mandible for supporting tooth replacements to restore chewing function.

On1™ Temporary Abutment

The On1™ Temporary Abutment Engaging is indicated for use with single unit, screw-retained temporary dental prosthesis placed on the On1™ Base or On1™ Base Xeal™ in the maxilla or mandible, for up to 180 days.

The On1™ Temporary Abutment Non-Engaging is indicated for use with multiple unit, screw-retained temporary dental prosthesis placed on the On1™ Base or On1™ Base Xeal™ in the maxilla or mandible, for up to 180 days.

On1™ Universal Abutment

The On1™ Universal Abutment Non-Engaging is indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla or mandible for implants with less than 20° overall divergences to allow path of insertion.

On1™ Esthetic Abutment

The On1™ Esthetic Abutment is indicated to support the placement of single unit and multiple unit, cement-retained restorations in the maxilla or mandible.

On1™ Healing Cap

The On1™ Healing Cap is indicated for use with the On1™ Base or On1™ Base Xeal™ and the On1™ Clinical Screw in the maxilla or mandible for supporting single unit and multiple unit procedures.

On1™ IOS Healing Cap

The On1™ IOS Healing Cap is indicated for use with the On1™ Base or On1™ Base Xeal™ and the On1™ Clinical Screw in the maxilla or mandible, for up to 180 days, for supporting single unit and multiple unit procedures.

The On1™ IOS Healing Cap is also indicated for use in combination with an intra-oral scanner to confirm the location, position, and angulation of a On1™ Base or On1™ Base Xeal™, to support creation of the digital model to facilitate the design and fabrication of a dental prosthesis using CAD/CAM technology.

On1™ Impression Coping

The On1™ Impression Copings are indicated to be connected to the On1™ Base or On1™ Base Xeal™ to be used to transfer the location and orientation of the base from the patient's partially edentulous jaw to a master cast in the dental laboratory.

On1™ Screwdriver Manual

Same as Intended Use/Intended Purpose.

On1™ Screwdriver Machine

Same as Intended Use/Intended Purpose.

Contraindications

The contraindicated to use the On1™ concept in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of 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™ is specifically contraindicated for patients who are allergic or hypersensitive to sodium dihydrogen phosphate (NaH_2PO_4) or magnesium chloride (MgCl_2).

Materials

- On1™ Base:
Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3. Handle: Polyetheretherketone (PEEK).
- On1™ Temporary Abutment:
Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3. Handle: Polyetheretherketone (PEEK).
- On1™ Universal Abutment:
Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3. On1™ Universal Abutment Burn-out coping: Polyoxymethylene (POM).

- On1™ Esthetic Abutment Titanium:
Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- On1™ Clinical and Prosthetic Screws:
Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- On1™ Healing Cap:
Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- On1™ Base Replica:
Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- On1™ Impression Coping:
Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3. O-ring: Silicone.
- On1™ Base Xeal™:
Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3, sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride (MgCl_2). Handle: Polyetheretherketone (PEEK).
- On1™ Screwdriver:
Stainless Steel AISI 303/AISI 304/420F
Mod according to ASTM F899.

Warnings

To ensure the accuracy of the scan, the On1™ IOS Healing Cap must not be modified. Any modifications may impact the accuracy of the scan.

Cautions

General

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

On1™ concept must only be used with compatible Nobel Biocare instruments and prosthetic components. Use of instruments and prosthetic components that are not intended to be used in combination with On1™ concept 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 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.

The colored surface of the Nobel Biocare On1™ Base Xeal™ is a result of the Xeal™ surface and does not indicate the platform size.

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 must be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g. cigarette smoking, poor oral hygiene, uncontrolled diabetes, 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.

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 or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery

Particular caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.

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. gauze, dental dam, or a throat shield).

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 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.

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 includes components 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

Placement of On1™ Base/On1™ Base Xeal™

Caution The colored surface of the Nobel Biocare On1™ Base Xeal™ is a result of the Xeal™ surface and does not indicate the platform size.

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. Turn the handle to initially tighten the On1™ Base/On1™ Base Xeal in the implant.

Caution Verify the final seating of the Nobel Biocare On1™ Base and the components attached using radiographic imaging.

2. Tighten the On1™ Clinical Screw:
 - If an On1™ Healing Cap will be placed on the On1™ Base/On1™ Base Xeal™, hand-tighten the On1™ Clinical Screw using the On1™ Screwdriver.
 - If an On1™ Impression Coping, On1™ Temporary Abutment, On1™ Esthetic Abutment, or On1™ Universal Abutment will be placed on the On1™ Base/On1™ Base Xeal™, tighten the On1™ Clinical Screw to 35 Ncm using the On1™ Screwdriver and Manual Torque Wrench Prosthetic. Refer to Nobel Biocare Instructions for Use (IFU) IFU1098 for information regarding the Manual Torque Wrench Prosthetic.

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

Caution Each time a component is connected to the On1™ Base/On1™ Base Xeal™ ensure the On1™ Clinical Screw is not loosened. Re-tighten the screw to 35 Ncm if necessary.

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

Restorative Options for On1™ Concept

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

A. Placement of On1™ Healing Cap for 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. Refer to the Nobel Biocare IFU1085 for information regarding the Unigrip™ Screwdriver.

Caution Verify the final seating of the Nobel Biocare On1™ Base and the components attached using radiographic imaging.

B. Placement of On1™ IOS Healing Cap for Healing Phase

1. Select appropriate On1™ IOS Healing Cap and check occlusal clearance.
2. Connect the On1™ IOS Healing Cap to the On1™ Base/On1™ Base Xeal™ using the handle to facilitate the insertion. Remove the handle and carefully hand-tighten the On1™ IOS Healing Cap using the Unigrip™ Screwdriver. Ensure that the interface of the On1™ Base is clean and free of foreign material that may obstruct the seating of the On1™ IOS Healing Cap.

Caution Verify the final seating of the Nobel Biocare On1™ Base and the components attached using radiographic imaging.

Note Before inserting the On1™ IOS Healing Cap onto the On1™ Base/On1™ Base Xeal™ ensure that the interface of the On1™ Base is clean and free of foreign material that may obstruct the seating of the On1™ IOS Healing Cap.

Caution Never exceed 15 Ncm tightening torque. Overtightening the On1™ Prosthetic Screw may lead to a distortion of the On1™ IOS Healing Cap. Take a digital impression of the On1™ IOS Healing Cap, following the intraoral scanner manufacturer's instructions.

3. Send the digital impression to the dental laboratory.

C. Impression Taking using On1™ Base Impression Copings

1. Remove the On1™ Healing Cap or On1™ IOS Healing Cap from the On1™ Base/On1™ Base Xeal™ and retighten the base if necessary.

Caution Each time a component is connected to the On1™ Base/On1™ Base Xeal™ ensure the On1™ Clinical Screw is not loosened and is re-tightened to 35 Ncm if necessary.

Take impression of the On1™ Base/On1™ Base Xeal™ using the On1™ Impression Coping Open Tray or the On1™ Impression Coping Closed Tray. The open tray technique must be used for implants that diverge more than 25°. The closed tray technique is be used when the implant parallelism is sufficient.

Caution Verify the final seating of the Nobel Biocare On1™ Base and the components attached using radiographic imaging.

D. Placement of Provisional Prosthesis using the On1™ Temporary Abutment (for "Chair-side" Provisional Prostheses)

Caution Provisional prostheses using the On1™ Temporary Abutment must not be placed for more than 180 days, as permanent load may lead to fracture of the provisional prosthesis.

1. Connect and hand tighten the On1™ Temporary Abutment to the On1™ Base using Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic.
2. Check the abutment height. Remove the abutment and modify if necessary, outside of the patient's mouth. Re-connect the abutment to the On1™ Base as described above in Step C1.

Note Temporary abutments should only be exposed to limited occlusal forces by taking the temporary restoration out of the occlusion.

3. Close the screw access hole using conventional techniques.
4. Make a temporary restoration using a pre-fabricated mold with suitable temporary crown material, following the instructions by the material manufacturer.
5. Drill a hole through the mold, loosen the On1™ Prosthetic Screw using a Unigrip™ Screwdriver and remove the restoration.
6. Make final adjustments.
7. Connect and tighten the On1™ Temporary Abutment to 35 Ncm using the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic.

Caution Verify the final seating of the Nobel Biocare On1™ Base and the components attached using radiographic imaging.

Caution Never exceed the recommended maximum tightening torque for the abutment screw. Overtightening of the abutment may lead to a screw fracture.

8. Block the screw access hole using suitable material, before closing it with composite.

E. Placement of Provisional Prosthesis using the On1™ Temporary Abutment (for Laboratory-made Provisional Prostheses)

Caution Provisional prostheses using the On1™ Temporary Abutment must not be placed for more than 180 days, as permanent load may lead to fracture of the provisional prosthesis.

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 D1–6 (Temporization Using the On1™ Temporary Abutment (for "Chair-side" Provisional Prostheses)) to fabricate a single provisional restoration.

F. Placement of 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 Verify the final seating of the Nobel Biocare On1™ Base and the components attached using radiographic imaging.

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 Open Tray or the On1™ Impression Coping Closed Tray.
5. Provisionalize after sealing the access hole.

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.

Clinical Procedure, Post-laboratory:

9. Remove the provisional restoration from the On1™ Base/ On1™ Base Xeal™ and retighten the base if necessary.

Caution Each time a component is connected to the On1™ Base/ On1™ Base Xeal™ ensure the On1™ Clinical Screw is not loosened. Re-tighten the screw to 35 Ncm if necessary.

10. Retighten On1™ Clinical Screw if necessary.
11. Connect and tighten the On1™ Esthetic Abutment to 35 Ncm using the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic.

Caution Verify the final seating of the Nobel Biocare On1™ Base and the components attached using radiographic imaging.

12. 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.

G. Placement of Final Restoration using the On1™ Universal Abutment

Laboratory Procedure, Press Workflow:

1. Preparation of the Universal Abutment:
 - Hand-tighten the On1™ Universal Abutment onto the master cast using the On1™

Prosthetic Lab Screw:

2. Preparation of the On1™ Burn-out Coping:
 - Seat the On1™ Burn-out Coping onto the On1™ Universal Abutment.
 - Adjust the height of the On1™ Burn-out Coping according to the required occlusal plane. Ensure the On1™ Universal Abutment remains fully covered.
3. Production:
 - Create a wax-up restoration and use standard procedures to either press or cast a coping or full-contour crown.
4. Finalization and bonding:
 - Once the restoration is produced, finalize it following the restorative material manufacturer's instruction.
 - Connect the On1™ Universal Abutment to a On1™ Base Replica using the On1™ Prosthetic Lab Screw.
 - Sandblast the contact surface of the On1™ Universal Abutment with aluminum oxide 50 µm at a maximum of 2 bar.
 - Clean the bonding surface of the On1™ Universal Abutment using a steam jet or an ultrasonic bath.

Caution Do not sandblast the seating area. During the blasting procedure, use a On1™ Base Replica to prevent any modification of the abutment/base interface. The use of wax in the screw channel is to be avoided.

- Bond the restoration to the On1™ Universal Abutment according to the cement manufacturer's instructions. Use only self-adhesive dental cement/ bonding material suitable for zirconium dioxide ceramics or PMMA (Polymethylmethacrylate).

Caution The screw channel of the On1™ Universal Abutment needs to be blocked prior to bonding and cleaned thereafter from residues of the bonding material. Follow the bonding material manufacturer's guidelines.

- Disconnect the restoration from the On1™ Base Replica and send it to the clinician along with the On1™ Prosthetic Screw.
- Continue with the Clinical Procedure (Step 5).

Laboratory Procedure, Design and Manufacture of Final Restoration using a CAD/CAM Workflow for Desktop Scanners

1. Scanning the Master Cast:
 - Connect a position locator to the On1™ Base Replica embedded in the master cast.
 - Scan the master cast following the instructions of the scanner manufacturer.
2. Designing the Restoration:
 - Import the scan file into the CAD software and choose the desired On1™ Universal Abutment based on the soft tissue anatomy.
 - Design the restoration using standard CAD tools. Make sure to respect the restorative material manufacturer's design specifications.
3. Production:
 - Send the design file to a milling unit or local production facility.
4. Finalization and Bonding:
 - Once the restoration is milled, finalize it following the restorative material manufacturer's instructions.
 - Sandblast the bonding surface of the restoration following the restorative material manufacturer's instructions.
 - Clean the restoration as recommended by the bonding material manufacturer.
 - Protect the screw channel and emergence profile of the On1™ Abutment before sandblasting by connecting it to a On1™ Base Replica using the On1™ Prosthetic Lab Screw.

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

- Sandblast the contact surface of the On1™ Universal Abutment with aluminum oxide 50 µm at a maximum of 2 bar.
- Clean the bonding surface of the On1™ Universal Abutment using steam jet or an ultrasonic bath.

Caution Do not sandblast the seating area. During the blasting procedure, use a On1™ Base Replica to prevent any modification of the abutment/base interface. The use of wax in the screw channel is to be avoided.

- Bond the restoration to the On1™ Universal Abutment according to the cement manufacturer's instructions. Use only self-adhesive dental cement/ bonding material suitable for zirconium dioxide ceramics or PMMA (Polymethylmethacrylate).

Caution The screw channel of the On1™ Universal Abutment must be blocked prior to bonding and cleaned thereafter from residues of the bonding material. Follow the bonding material manufacturer's guidelines.

- Disconnect the restoration from the On1™ Base Replica and send it to the clinician along with the On1™ Prosthetic Screw.

Clinical Procedure:

Caution The final restoration and the On1™ Prosthetic Screw must be cleaned and sterilized prior to placement in the patient's mouth, following the instructions of the material manufacturer.

5. Remove the On1™ Healing Cap, On1™ IOS Healing Cap, or temporary restoration from the On1™ Base/On1™ Base Xea™, and retighten the base if necessary.

Caution Each time a component is connected to the On1™ Base/On1™ Base Xea™ ensure the On1™ Clinical Screw is not loosened. Re-tighten the screw to 35 Ncm if necessary.

6. Connect and hand-tighten the On1™ Universal Abutment to the On1™ Base/On1™ Base Xea™ using the On1™ Prosthetic Screw.
7. Tighten the restoration using the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic to 35 Ncm.

Caution Verify the final seating of the Nobel Biocare On1™ Base and the components attached using radiographic imaging.

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

Caution To tighten the abutment, the implant should be able to withstand the recommended tightening torque of the On1™ Prosthetic Screw.

8. Block out the screw head before closing the screw access hole with composite.
9. If removal of the restoration is needed, open the screw access and untighten the screw using the Unigrip™ Screwdriver.

Sterility and Reusability Information

The On1™ Base/On1™ Base Xea™, 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 Xea™, 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 Copping, 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-structures 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 Copping 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.
 - Minimum 2 minutes rinsing 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. Cidezime 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 Cycles

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		≥3042 mbar ⁵
Pre-Vacuum Cycle ²	134°C (273°F)	3 minutes		
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	Inferior to the navel: 2.0 W/kg
	Superior to the shoulders: 0.2 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.	

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.

Performance Requirements and Limitations

To achieve the desired performance, the 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 the 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.

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
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
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 Mark for Class Ir/Ila/Ilb Devices	
UKCA Mark for Class I Devices	
UKCA Mark for Class Ila/Ilb Devices	

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 Healing Caps NP/RP/WP	73327470000001236T
On1 IOS Healing Caps NP/RP/WP	
On1 Impression Copings Closed Tray NP/RP/WP	733274700000013674
On1 Impression Copings Open Tray NP/RP/WP	
On1 Impression Copings Open Tray Non-Engaging NP/RP/WP	
On1 Screwdriver Manual	73327470000001787L
On1 Screwdriver Machine	73327470000001797N


















































Legal Statements

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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
					Rx only		
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	
							
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	