# On1™ Concept
## Instructions for use

On1™ Base

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 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.

### 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 and 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.

**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).

**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 is indicated to support the placement of single unit, screw-retained prosthetic restorations in the maxilla or mandible.

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 ($MgCl_2$).

## 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.

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

**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:**
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. 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 the On1™ Concept:**
The 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 the 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, and swelling. During abutment placement or removal, the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Implant abutments 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, ulcera, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the On1™ Base, On1™ Base Xeal™, On1™ Clinical Screw, On1™ Prosthetic Screw, On1™ Temporary Abutment, On1™ Universal Abutment, On1™ Esthetic Abutment, On1™ Healing Cap, and On1™ IOS Healing Cap. The SSCP can be obtained at the following website:

https://ec.europa.eu/tools/eudamed[1]

[1] Website available upon launch of the European Database on Medical Devices (EUDAMED)

**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**

https://www.nobelbiocare.com/complaint-form

## Handling Procedure:

**Placement of On1™ Base/On1™ Base Xeal™:**

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:
   - 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.

**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.

**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.

2. Take impression of the On1™ Base/On1™ Base Xeal™ using the On1™ Impression Coping Open Tray or the On1™ Impression Coping Closed Tray.

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

**Caution:** Provisional protheses 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:** 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 protheses 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 C1–6 (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:** 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.
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 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.

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

**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.

## 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 according to ASTM F136 and ISO 5832-3.
- 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 ($MgCl_2$).
- On1™ IOS Healing Cap, Handle for placement of On1™ Base/On1™ Base Xeal™/On1™ IOS Healing Cap/On1™ Temporary Abutment: Polyetheretherketone (PEEK).
- On1™ Screwdriver: Stainless Steel AISI 303/AISI 304/420F Mod according to ASTM F899.
- 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™ IOS Healing Cap, On1™ Prosthetic Screw and On1™ Clinical Screw have been sterilized using irradiation and are intended 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™ IOS Healing Cap, On1™ Prosthetic Screw and On1™ 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 local or systemic infection.

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

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

**Caution:** 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 and On1™ Impression Coping are delivered non-sterile and are intended for reuse. Prior to first use and reuse clean, disinfect and sterilize using the recommended parameters.

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

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

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

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

- If any wear, abrasion of the anodization, deformations or corrosion is visible on the component.
- If the impression coping does not seat accurately or has a loose fit on the On1™ Base, or the On1™ Replica.
- If with light pressure the Unigrip™ Screwdriver does not engage or slips in the receptacle of the screw or guide pin.
- If the guide pin is no longer retained in the On1™ Impression Coping, which indicates that the O-ring for the guide pin has been stripped off or has deteriorated.

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:**

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

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

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

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

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

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

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

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

**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 the device prior to cleaning by removing the screw from the device, where applicable.
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, or if dental debris remains on the device. Properly discard any devices that fail the inspection.

**Manual Cleaning and Drying:**

1. Disassemble the device prior to cleaning by removing the screw from the device, where applicable.
2. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP or Neodisher Medizym; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
5. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
6. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP or Neodisher Medizym) 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. 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, or if dental debris remains on the device. Properly dispose any devices that fail the inspection.

**Sterilization:**
The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 and Selectomat PL/669-2CL (pre-vacuum cycle); Amsco Century Sterilizer and Selectomat PL/669-2CL (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 | | |
| Pre-Vacuum Cycle[2] | 134°C (273°F) | 3 minutes | | ≥3042 mbar[5] |
| Pre-Vacuum Cycle[3] | 134°C (273°F) | 18 minutes | | |

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

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

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

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

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

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

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

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

## Magnetic Resonance (MR) Safety Information:

The On1™ Base/On1™ Base Xeal™, On1™ Universal Abutment, On1™ Esthetic Abutment On1™ Temporary Abutment, On1™ Healing Cap, On1™ IOS Healing Cap, On1™ Prosthetic Screw, and On1™ Clinical Screw contain metallic materials which can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that On1™ Base/On1™ Base Xeal™, On1™ Universal Abutment, On1™ Esthetic Abutment On1™ Temporary Abutment, On1™ Healing Cap, On1™ IOS Healing Cap, On1™ Prosthetic Screw, and On1™ Clinical Screw are unlikely to impact patient safety under the following MRI conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

**Note:** Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Under the conditions defined above, these devices are expected to produce a maximum temperature rise of 4.1°C (39.4°F) after 15 minutes of continuous scanning.

In the non-clinical testing, the image artifact caused by the devices extends approximately 30 mm from the devices when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

**Note:** Although the non-clinical testing demonstrates that the On1™ Base/On1™ Base Xeal™, On1™ Universal Abutment, On1™ Esthetic Abutment On1™ Temporary Abutment, On1™ Healing Cap, On1™ IOS Healing Cap, On1™ Prosthetic Screw, and On1™ Clinical Screw are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to support a claim of MR Safe or MR Conditional for the On1™ Base/On1™ Base Xeal™, On1™ Universal Abutment, On1™ Esthetic Abutment On1™ Temporary Abutment, On1™ Healing Cap, On1™ IOS Healing Cap, On1™ Prosthetic Screw, and On1™ Clinical Screw.

## Performance Requirements and Limitations:

To achieve the desired performance, Nobel Biocare Guided Surgery Tooling 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 Nobel Biocare Guided Surgery Tooling, 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 info please visit www.nobelbiocare.com.

## Storage, Handling and Transportation:

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

## Disposal:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

## Manufacturer and Distributor Information:

**Manufacturer:**
Nobel Biocare AB
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

**Distributed in Australia by:**
Nobel Biocare Australia Pty Ltd
Level 4/7 Eden Park Drive
Macquarie Park, NSW 2114 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 2797 Mark for Class Ir/IIa/IIb Devices

**Note:** Refer to the product label to determine the applicable CE mark for each device.

**Notice Regarding Canadian Device Licensure:** Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

## Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

| Product | Basic UDI-DI Number |
|---|---|
| On1 Bases Conical Connection NP/RP/WP<br>On1 Bases Xeal™ Conical Connection NP/RP/WP<br>On1 Universal Abutments NP/RP/WP<br>On1 Esthetic Abutments Titanium NP/RP/WP<br>On1 Universal Abutments Non-Engaging NP/RP/WP | 73327470000001687H |
| On1 Temporary Abutments Engaging NP/RP/WP<br>On1 Temporary Abutment Non-Engaging NP/RP/WP | 733274700000017278 |
| On1 Clinical Screws NP/RP/WP<br>On1 Prosthetic Screws NP/RP/WP | 73327470000001827B |
| On1 Healing Caps NP/RP/WP<br>On1 IOS Healing Caps NP/RP/WP | 73327470000001236T |
| On1 Impression Copings Closed Tray NP/RP/WP<br>On1 Impression Copings Open Tray NP/RP/WP<br>On1 Impression Copings Open Tray Non-Engaging NP/RP/WP | 733274700000013674 |
| On1 Screwdriver Manual | 73327470000001787L |
| On1 Screwdriver Machine | 73327470000001797N |

## 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

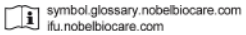

Double sterile barrier system

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