On1™ Concept

Important – Disclaimer of Liability

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Description

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

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

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

The On1™ Concept comprises

On1™ Base/On1™ Base Xeal™

Note Handle and Clinical Screw included.

On1™ Temporary Abutment

Note Handle and Prosthetic Screw included.

On1™ Universal Abutment

Note Prosthetic Screw included.

On1™ Esthetic Abutment unit

Note Prosthetic Screw included.

On1™ Healing Cap

On1™ Impression Coping

On1™ Screwdriver

On1™ Clinical and Prosthetic Screw

On1™ Base Replica

On1™ Prosthetic Lab Screw

Intended Use

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

The On1™ abutments in combination with the On1™ Base/On1™ Base Xeal™ on Nobel Biocare Conical Connection endosseous implants are indicated for single-unit screw and cement retained restorations.

Indications for Use

The On1™ Base/Xeal™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.

The On1™ Universal Abutment consists of three major parts. Specifically, the On1™ Base/On1™ Base Xeal™, the On1™ Universal Abutment, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral

Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Contraindications

It is contraindicated to use 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, PEEK (Polyetheretherketone), sodium dihydrogen phosphate (NaH_2PO_4) or magnesium chloride ($MgCl_2$).

Materials

- On1™ Base:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Base Xeal™:
  Titanium alloy 90% Ti, 6% Al, 4% V, sodium dihydrogen phosphate (NaH_2PO_4) and magnesium chloride ($MgCl_2$).
- On1™ Temporary Abutment:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Universal Abutment:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Esthetic Abutment Titanium:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Clinical and Prosthetic Screws:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- Handle:
  Polyetheretherketone (PEEK).
- On1™ Healing Cap:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Screwdriver:
  Stainless Steel.
- On1™ Base Replica:
  Titanium alloy 90% Ti, 6% Al, 4% V.
- On1™ Impression Coping:
  Titanium alloy 90% Ti, 6% Al, 4% V.

Cautions

General

It is strongly recommended that Nobel Biocare surgical instruments and prosthetic components are used only with Nobel Biocare implants, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory esthetic results.

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

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 strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

It is especially important to achieve proper stress distribution through adaptation and fitting of the crown or bridge by adjusting occlusion to the opposing jaw. In addition, avoid excessive transverse loading forces, particularly in immediate loading cases.

The colored surface of the On1™ Base Xeal™ is the 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 has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism 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 angulation.

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

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.

Milling units and accessory components used for the prosthetic components should be installed, run and maintained as specified by the manufacturer.

At surgery

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

Care and maintenance of instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

Because of the small size of components, 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).

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

Dental cement or any other material used for the attachment of prosthetic components should be processed as specified by the manufacturer.

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

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.

Never exceed 35 Ncm prosthetic tightening torque for the On1™ Clinical Screw and the Prosthetic Screws for the On1™ Abutments. Overtightening of the On1™ Clinical Screw or Prosthetic Screw may lead to a screw fracture.

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

The use of On1™ Temporary Abutment is limited to 180 days.

For additional information on restorative procedures please consult the On1 Concept Restorative Procedures manual available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Handling Procedure

Ensure sufficient implant stability before beginning the prosthetic procedure.

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

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

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

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

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

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

A) Healing phase

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

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

B) Impression taking

1. Remove On1™ Healing Cap.

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

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

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

2. Close the screw access hole using conventional techniques.

3. Make a temporary restoration using a prefabricated mold with suitable temporary crown material.

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

5. Make final adjustments.

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

7. Close the screw access hole using conventional techniques.

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

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

2. Fabricate a working model with removable gingival material.

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

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

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

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

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

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

4. Remove the On1™ Esthetic Abutment and take a base level impression using the On1™ Impression Coping Closed Tray or the On1™ Impression Coping Open Tray.

5. Provisionalize after sealing the access hole.

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

1. Produce a working model with removable gingival material.

2. Fabricate a crown with a conventional casting technique.

3. Veneer the crown if applicable.

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

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

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

F) Final Restoration using the On1™ Universal Abutment (digital workflow)

The digital workflow requires the use of following equipment:

Scanner: TRIOS by 3Shape.

Design Software: 3Shape Dental Designer (the Implant Libraries are obtained via the 3Shape server in the software), DTX Studio Lab (the implant libraries are automatically included in the software installer), or ExoCAD (the implant libraries are obtained via the exocad DentalCAD server in the software).

Restorative Material: Enamic by Vita.

Milling Unit: CORiTEC by imes-icore.

When using the digital workflow, the standard procedure according to the system provider instructions apply.

The instructions for use of the material manufacturer shall be followed. For setup, validation, use, tools, maintenance, and lifetime information on scanners, ovens, and milling machines, please refer to manufacturer's instructions.

Warning Do not use any dental cements, restorative material, scanners, milling units and CAM software, other than those specifically identified for the On1™ Universal Abutment.

The diameter or height of the Universal Base Abutment must not be reduced.

F.1) Final Restoration using the On1™ Universal Abutment (Clinical procedure pre-laboratory, digital workflow)

1. Remove the cover screw, healing abutment or temporary restoration from the On1™ Base/On1™ Base Xeal™.
2. Select the appropriate Scan Body and connect it to the On1™ Base/On1™ Base Xeal™ in the patient's mouth and tighten it using the Scan Body Driver.
3. Take a digital impression of the Scan Body and the surrounding teeth, following the Intraoral scanner manufacturer's guidelines. Use Nobel Biocare approved intraoral scanner.

A list of Nobel Biocare approved systems can be found on nobelbiocare.com.

4. After scanning, remove the Scan Body using the Scan Body Driver and re-connect the cover screw, healing abutment or temporary restoration to the On1™ Base/ On1™ Base Xeal™. Send the digital impression to the dental laboratory. Make sure to include the information about the Scan Body used as well as desired restoration material.

F.2) Final Restoration using the On1™ Universal Abutment (Laboratory procedure, digital workflow): Designing and milling of the crown for the Universal Abutment

1. Import the scan into the CAD software. Ensure that the software library is updated with the latest 3D models by Nobel Biocare. The latest DME files for 3Shape Dental Designer are obtained via the 3Shape server in the software.
2. Design the restoration. Make sure to respect the minimum dimensions of the restorative material. Violation of any of the restricted parameters will cause a hard stop in the design process.

Table 1 – Restorative design specifications for Universal Base

Parameter	Specification
Angle from axis of the implant	20° Max
Wall Thickness Circular	0.8 mm min.
Wall Thickness Margin	0.275 mm min.
Post Height	5.2 mm min.
Maximum Length, Width and Height	EM-14 blank 12x14x18 mm EM-10 blank 8x10x15 mm

3. Send the designed file to the milling machine to manufacture the crown. Ensure that the milling machine is properly set up and validated and that it is maintained in good condition as instructed by the manufacturer. Follow the manufacturers' guidelines on the tooling for the specified restorative material.
4. Once the crown is produced, veneer it, if applicable, following the material manufacturer's instructions.

Note Only suitable self-adhesive cementation systems for the material shall be used. Follow the instructions for use for both the dental material and bonding material manufacturer.

Table 2 – Bonding of the crown to the Universal Abutment (Laboratory procedure, digital workflow)

Cementation requires the use of following materials:
Primer: Monobond Plus by Ivoclar Vivadent
Primer: Monobond Etch & Prime by Ivoclar Vivadent
Adhesive: Multilink Hybrid by Ivoclar Vivadent

Only suitable self-adhesive cementation systems for the material shall be used. Follow the instructions for use for both the dental material and bonding material manufacturer.

Preparation of the Universal Abutment

1. Fix the Universal Abutment to the On1™ Replica and hand tighten with an On1™ Prosthetic Lab Screw.
2. Seal the screw channel with wax.
3. Sandblast the contact surface of the Universal Abutment with aluminium oxide 50 µm at a maximum of 2 bar.

Caution Do not sandblast the seating area. To prevent this, use a On1™ Replica to prevent any modifications of the abutment to base interface.

4. Carefully remove the wax and clean the bonding surface using steam jet or an ultrasonic bath. The cleaned surface must not be contaminated, as this would impair the bond.
5. Condition the bonding surface of the Universal Abutment applying a primer (e.g. Monobond Plus by Ivoclar Vivadent). Let the primer react following the manufacturer's instructions.

Preparation of the crown

1. Clean the crown with steam jet or in an ultrasonic bath. The cleaned surface must not be contaminated, as this would impair the bond.

2. For zirconia: sandblast the bonding surface of the crown with aluminium oxide 100 µm at a maximum of 1 bar and condition the bonding surface (e.g. Monobond Plus by Ivoclar Vivadent). Follow the manufacturer's instructions and allow sufficient reaction time of the primer.

Bonding

1. Seal the screw access hole of the Universal Abutment with a thin layer of wax, making sure not to contaminate the bonding surface.

2. Apply a thin layer of the adhesive (e.g. Multilink Hybrid Abutment by Ivoclar Vivadent) to the bonding surfaces of the crown and the Universal Abutment.

3. Slide the crown onto the Universal Abutment and press them lightly together making sure they are fully seated and in correct orientation. Follow the adhesive manufacturer's instructions on curing/polymerization.

4. Remove the excess adhesive after curing/ polymerization has started.

5. Apply glycerine gel on the cementation joint in order to prevent the formation of an oxygen inhibition layer. Remove it once the polymerization is completed.

6. Polish the bonding joint carefully with a rubber polisher and finalize the restoration.

7. Remove the On1™ Prosthetic Lab Screw.

8. Visually inspect the screw channel for any residuals, and remove any excess material carefully using suitable instruments and clean the restoration thoroughly with steam jet.

F.3) Final Restoration using the On1™ Universal Abutment (Clinical procedure)

1. Clean and sterilize the On1™ Universal Abutment restoration.

2. Remove the On1™ Healing Cap or the temporary restoration from the On1™ Base/On1™ Base Xeal™ and retighten the On1™ Clinical Screw to 35 Ncm if necessary.

3. Connect and tighten the On1™ Universal Abutment restoration to 35 Ncm using the 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.

4. Close the screw access hole using conventional techniques.

Sterility and Reusability Information

The On1™ Base/On1™ Base Xeal™, On1™ Temporary Abutment, On1™ Healing Cap, On1™ Prosthetic and Clinical Screw are delivered sterile for single use only. Do not use after the labeled expiration date.

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

Caution The On1™ Base/On1™ Base Xeal™, On1™ Temporary Abutment, On1™ Healing Cap and On1™ Prosthetic and Clinical Screw are single use products and must not be reprocessed.

Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

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

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

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

Caution The On1™ Universal Abutment and On1™ Esthetic Abutment are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross contamination.

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

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

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

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

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

Cleaning and Sterilization Instructions

Cleaning

1. Remove debris in lukewarm water and immerse device in cleaning solution.

2. Scrub device with soft bristled nylon brush and flush lumen.

3. Manual cleaning: Prepare an ultrasonic bath using an enzymatic cleaning solution and immerse device in ultrasonic bath for at least 5 minutes.

4. Automated cleaning: Load device into washer and run the cleaning and disinfection cycle.

5. Rinse and dry device.

Sterilization

The user should consult the crown/restoration material manufacturer's recommendations regarding sterilization.

For USA: Seal single device in a pouch and steam sterilize at 270°F (132°C) for 4 minutes when using the pre-vacuum method and 15 minutes when using the gravity method.

Table 3 – USA

Method	**Moist heat sterilization**	
Cycle	Pre-vacuum	Gravity
Temperature	270°F (132°C)	

Exposure time	4 minutes	15 minutes
Pre-vacuum	3 times < 60 mbar	N/A
Drying time	20-30 minutes	15-30 minutes
Cooling time	10 minutes at room temperature	

Only use FDA cleared sterilization packaging and sterilizers for the abutments delivered non- sterile and requiring end user sterilization.

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.	

Storage, Handling and Transportation

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

Disposal

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

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

Manufacturer and Distributor Information

Manufacturer 	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
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Caution Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

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	 symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com	
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	Link to Online Symbols Glossary and IFU Portal	
							
Date of manufacture	Manufacturer	Use-by date	Upper limit of temperature	Temperature limit	Do not resterilize	Do not re-use	Non-pyrogenic
							
Date	Tooth number	Patient number	Patient identification	Health care centre or doctor	Patient information website	EU Importer	Swiss Importer
Double sterile barrier system	Single sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside	Do not use if package is damaged and consult instructions for use	Keep away from sunlight	Keep dry	