On1™ IOS (Intraoral Scannable) Healing Cap

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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™ IOS (Intraoral Scannable) Healing Cap is a prefabricated, implant supported component manufactured from radio opaque PEEK material.

The On1™ IOS Healing Cap is available on Nobel Biocare's On1™ Base, and comes in different platforms sizes and heights depending on the clinical situation.

The On1™ IOS Healing Cap is delivered with a handle (to facilitate the insertion and mounting of the On1™ IOS Healing Cap onto the On1™ Base intraorally) and a Unigrip™ clinical prosthetic screw (to fasten the On1™ IOS Healing Cap onto the On1™ Base).

Intended Use

The On™ IOS Healing Cap is intended to be used in the upper or lower jaw to facilitate in sculpturing of soft tissue, during the healing phase post dental implant surgery.

The On™ IOS Healing Cap is intended to be used in the upper or lower jaw to facilitate digital capturing of the intraoral situation using an approved Nobel Biocare intraoral scanner, so that an individualized CAD/CAM restoration can be designed and ordered electronically, using a Nobel Biocare approved CAD system, and the individualized restoration fabricated in the dental laboratory, clinic or hospital.

The On™ IOS Healing Cap handle is intended to be used to facilitate the insertion and mounting of the On™ IOS Healing Cap onto the On™ Base intraorally.

The clinical prosthetic screw is intended to fasten the On™ IOS Healing Cap onto the On™ Base.

Indications for Use

The On™ IOS Healing Cap is a pre-manufactured adjustable prosthetic component to be directly connected to the On™ Base, which is fixated to an endosseous implant.

The On™ IOS Healing Cap is indicated for temporary use up to 180 days in prosthetic rehabilitation.

The On™ IOS Healing Cap is indicated for single-unit restorations.

Contraindications

It is contraindicated to use On1™ IOS Healing Cap in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients with inadequate bone volume unless an augmentation procedure can be considered.
- 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) and Polyetheretherketone (PEEK).

Materials

On1™ IOS Healing Cap:
Polyetheretherketone (PEEK).

On1™ IOS Healing Cap Handle:
Polyetheretherketone (PEEK).

Clinical prosthetic screw:
Titanium alloy 90% Ti, 6% Al, 4%V.

Warnings

To secure the required functional accuracy for an intraoral CAD/CAM workflow, the On1™ IOS Healing Cap should not be modified. If any modifications are made, the scanning function is impaired or removed.

Cautions

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

On™ IOS Healing Cap must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with On™ IOS Healing Cap 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.

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.

Before Surgery

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.

With respect to pediatric patients, routine treatment is not recommended until the end of the jaw bone growth phase has been properly documented.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

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

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.

At Surgery

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 throat shield).

After the implant installation, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/ or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

After Surgery

To secure the long term treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Handling Procedure

Clinical procedure

- After placement of the On1™ Base (according to the On1™ Base Instructions for Use), for the healing phase and to facilitate the shaping of the soft tissue, insert and mount the On1™ IOS Healing Cap on the On1™ Base, using the provided handle (see Figure A) and carefully hand tighten the clinical prosthetic screw using an Unigrip™ screwdriver.
- The height of the On1™ IOS Healing Cap should be chosen in accordance to the clinical situation (see Table 1 below). Additionally, if a digital impression is going to be taken, see the Instructions for Use of the Intraoral Scanner manufacturer.

Figure A

Note Before inserting the On1™ IOS Healing Cap onto the On1™ Base 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.

– Either a conventional or digital impression can be taken, following the steps defined below:

Conventional impression taking:

– Unfasten the clinical prosthetic screw using an Unigrip™ screwdriver and carefully remove the On1™ IOS Healing Cap.

– Take a conventional impression according to the On1™ Base Instructions for Use.

– After taking a conventional impression, carefully re-insert the On1™ IOS Healing Cap onto the On1™ Base and hand tighten the clinical prosthetic screw using an Unigrip™ screwdriver.

– Send the impression to the laboratory.

Digital impression taking:

– Take a digital impression of the On1™ IOS Healing Cap, following the Intraoral scanner manufacturer's guidelines.

– Send the digital impression to the laboratory.

Caution Never exceed 15 Ncm torque for the On1™ IOS Healing Cap clinical prosthetic screw. Overtightening of the clinical prosthetic screw may lead to a distortion of the On1™ IOS Healing Cap.

The On1™ IOS Healing Cap is available in different heights (see Table 1).

Table 1

Article Name	Height (mm)
On1™ IOS Healing Cap 4.5 mm NP	4.5
On1™ IOS Healing Cap 6 mm NP	6.0
On1™ IOS Healing Cap 4.5 mm RP	4.5
On1™ IOS Healing Cap 6 mm RP	6.0
On1™ IOS Healing Cap 4 mm WP	4.0
On1™ IOS Healing Cap 5 mm WP	5.0

Laboratory procedure

– For conventional laboratory workflow procedures using an On1™ Base, refer to the On1™ Base Instructions for Use.

For procedures based on an intraoral scan, follow the below steps:

– Import the clinical situation into a Nobel Biocare approved CAD software.

– Once imported, open the relevant CAD module and design your restoration, following the instructions in the software tutorial, according to the patient's clinical needs.

– Send designed data file to your in-lab milling machine facility by clicking on the order button in the software, following the instructions in the software tutorial.

– Once the final restoration has been milled, finalize it according to standard laboratory procedures or material manufacturer's instructions.

– Thereafter clean in ultrasonic unit.

– Send restoration to the clinician.

Clinical procedure

– Unfasten the clinical prosthetic screw using an Unigrip™ screwdriver and carefully remove the On1 IOS Healing Cap.

– After removal of the On1™ IOS Healing Cap refer to procedures defined in On1™ Base Instructions for Use, for placement and tightening of the final restoration.

Sterility and Reusability Information

On1™ IOS Healing Caps including handle and 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 as the device sterility and/or integrity may be compromised.

Caution On1™ IOS Healing Caps 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.

Magnetic Resonance (MR) Safety Information

MR Safety Information

MRI Safety Information		
Non-clinical testing has demonstrated the On1™ IOS Healing Caps are 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 Superior to the shoulders: 0.2 W/kg	Inferior to the navel: 2.0 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
Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA

Caution Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

Legal Statements

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	