On1 IOS (Intraoral Scannable) Healing Cap
Instructions for use

Important: Please read.

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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 On1 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 On1 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 On1 IOS Healing Cap handle is intended to be used to facilitate the insertion and mounting of the On1 IOS Healing Cap onto the On1 Base intraorally.

The clinical prosthetic screw is intended to fasten the On1 IOS Healing Cap onto the On1 Base.

Indications for use:

The On1 IOS Healing Cap is a pre-manufactured adjustable prosthetic component to be directly connected to the On1 Base, which is fixated to an endosseous implant.

The On1 IOS Healing Cap is indicated for temporary use up to 180 days in prosthetic rehabilitation.

The On1 IOS Healing Cap is indicated for single-unit restorations.

Contraindications:

It is contraindicated to use the 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).

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:

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

It is strongly recommended that the On1 IOS Healing Cap is used only with Nobel Biocare surgical instruments and prosthetic components, 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.

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.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual 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.

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 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.

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient.

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.

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 procedures:

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 Fig. **1**) 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 **A** below). Additionally if a digital impression is going to be taken, see the Instructions for Use of the Intraoral Scanner manufacturer.

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– **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 **A**).

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A

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.

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.

Cleaning and sterilization instructions:

The On1 IOS Healing Cap including handle and screw are delivered sterile and for single use only prior to the labelled expiration date.

Caution: The On1 IOS Healing Cap is a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.

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

Magnetic Resonance (MR) safety information:

The device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

For additional information on Cleaning and Sterilization and Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines for Nobel Biocare Products including MRI Information" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Storage and handling:

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

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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CE 2797

Canada – License Exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription Device – Rx only
Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

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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.

EC REP
Authorized representative in the European Community

LOT
Batch code

REF
Catalogue number

Caution

CE marking

Consult instructions for use

Contains hazardous substances

PHT DEHP
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

Rx Only
For prescription use only

Health care centre or doctor

Keep away from sunlight

Keep dry

symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com
Link to Online Symbols Glossary and IFU Portal

MR
Magnetic resonance conditional

Manufacturer

MD
Medical device

Non-pyrogenic

NON STERILE
Non-sterile

Patient identification

Patient information website

Patient number

SN
Serial number

Single sterile barrier system

Single sterile barrier system with protective packaging inside

Single sterile barrier system with protective packaging outside

STERILE EO
Sterilized using ethylene oxide

STERILE R
Sterilized using irradiation

Temperature limit

Tooth number

Upper limit of temperature

STERILE
Sterilized using steam or dry heat

UDI
Unique Device Identifier

Use-by date

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