

Nobel Biocare N1™ Base Concept



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 Nobel Biocare N1™ Base concept consists of a pre-manufactured two-piece dental implant base (consisting of the base body and clinical screw) and corresponding abutments and components. The Nobel Biocare N1™ Base concept is to be used in combination with an endosseous dental implant as an aid in

prosthetic rehabilitation. The Nobel Biocare N1™ Base concept can only be used with Nobel Biocare N1™ implant system. The Nobel Biocare N1™ Base concept includes components which are intended for use with NP or RP platform sizes; the specific Nobel Biocare N1™ Base concept components used must have the same platform size as the implant.

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

Nobel Biocare N1™ Base Xeal™

The Nobel Biocare N1™ Base Xeal™ is a component to be connected to the Nobel Biocare N1™ implant at time of surgery and remains in place throughout the restorative procedure. It moves the restorative platform of Nobel Biocare tri-oval conical connection implants from bone level to tissue level.

Note A pre-mounted handle for placement of the Nobel Biocare N1™ Base, and a pre-mounted Clinical Screw Nobel Biocare N1™ Base, are included with the Nobel Biocare N1™ Base.

Clinical Screw Nobel Biocare N1™ Base

The Clinical Screw Nobel Biocare N1™ Base is designed to fix the Nobel Biocare N1™ Base to an endosseous dental implant.

Prosthetic Screw Nobel Biocare N1™ Base

The Prosthetic Screw Nobel Biocare N1™ Base is designed to fix the Nobel Biocare N1™ Base abutments to Nobel Biocare N1™ Base Xeal™.

Temporary Abutment Nobel Biocare N1™ Base

The Temporary Abutment Nobel Biocare N1™ Base is a pre-manufactured dental implant abutment which can be connected to the Nobel Biocare N1™ Base XEAL™ to support the placement of temporary dental prosthesis.

The Temporary Abutment Nobel Biocare N1™ Base is available in two options: Temporary Abutment Nobel Biocare N1™ Base for single unit restorations and Temporary Abutment Nobel Biocare N1™ Base Bridge for multiple unit restorations.

Note Prosthetic Screw Nobel Biocare N1™ Base is included with the Temporary Abutment Nobel Biocare N1™ Base.

Universal Abutment Nobel Biocare N1™ Base

The Universal Abutment Nobel Biocare N1™ Base is a pre-manufactured dental implant abutment which can be connected to Nobel Biocare N1™ Base XEAL™ to support the placement of a screw-retained dental prosthesis.

The Universal Abutment Nobel Biocare N1™ Base is available in two options: Universal Abutment Nobel Biocare N1™ Base for single unit restorations and Universal Abutment Nobel Biocare N1™ Base Bridge for multiple unit restorations.

Note Prosthetic Screw Nobel Biocare N1™ Base is included with the Universal Abutment Nobel Biocare N1™ Base.

Esthetic Abutment Nobel Biocare N1™ Base

The Esthetic Abutment Nobel Biocare N1™ Base is a pre-manufactured dental implant abutment which can be connected to Nobel Biocare N1™ Base XEAL™ to support the placement of a cement-retained dental prosthesis.

The Esthetic Abutment Nobel Biocare N1™ Base is available in two platforms (NP and RP) for single unit restorations and multiple units up to three units.

Note Prosthetic Screw Nobel Biocare N1™ Base is included with the Esthetic Abutment Nobel Biocare N1™ Base.

Healing Abutment Nobel Biocare N1™ Base

The Healing Abutment Nobel Biocare N1™ Base is a pre-manufactured dental implant abutment which can be connected to the Nobel Biocare N1™ Base XEAL™ to support healing of the surrounding soft tissue.

Note The Prosthetic Screw Nobel Biocare N1™ is included with the previous version of the Healing Abutment Nobel Biocare N1™ Base (article numbers 300988 and 300989).

IOS Healing Abutment Nobel Biocare N1™ Base

The IOS Healing Abutment Nobel Biocare N1™ Base is a pre-manufactured adjustable dental implant abutment which can be connected to the Nobel Biocare N1™ Base XEAL™ to support healing of the surrounding soft tissue and to facilitate the transfer of an intraoral location of the Nobel Biocare N1™ Base XEAL™ from the patient's jaw to the relative position on a master cast in the dental laboratory using an intraoral scanning procedure.

Note Prosthetic Screw Nobel Biocare N1™ Base is included with the IOS Healing Abutment Nobel Biocare N1™ Base.

Impression Coping Nobel Biocare N1™ Base

The Impression Coping Nobel Biocare N1™ Base is a pre-manufactured component which facilitates the transfer of an intraoral location of the Nobel Biocare N1™ Base XEAL™ from the patient's jaw to the relative position on a master cast in the dental laboratory, to support creation of a restoration.

The Impression Coping Nobel Biocare N1™ Base is available in two options: Impression Coping Open Tray Nobel Biocare N1™ Base for open-tray technique and Impression Coping Closed Tray Nobel Biocare N1™ Base for closed-tray technique. The open-tray technique is recommended in cases with multiple implants. The open-tray technique must be used for implants that diverge more than 20°. The closed-tray technique is recommended in patients with less mouth opening, in limited access areas and in patients with a highly sensitive gagging reflex.

Impression Copings Open Tray Nobel Biocare N1™ Base are co-packed with a guide pin. Impression Copings Closed Tray Nobel Biocare N1™ Base are co-packed with a screw.

Position Locator Nobel Biocare N1™ Base

The Position Locator Nobel Biocare N1™ Base is a pre-manufactured component which is connected to Nobel Biocare N1™ Base connected to an endosseous dental implant placed in the patient's mouth, or to a base replica embedded in a master cast, to facilitate the design and fabrication of a restoration.

Position Locators are co-packed with a screw which is used to attach the device to the Nobel Biocare N1™ Base or Nobel Biocare N1™ Base replica.

The engraving on the side of the scan body (Figure A) is for identification of the system and the platform size, which can be scanned and recognized on the scan.



Figure A

The table below shows an overview of the Position Locators nomenclature.

Table 1 – Engraving Overview

System	Platform				
	3.0	NP	RP	WP	6.0
External Hex	---	EXN	EXP	EXW	---
CC	CC3	CCN	CCR	CCW	---
Tri-Ch	---	TRN	TRR	TRW	TR6
On1™	---	O1N	O1R	O1W	---
N1™ TCC	---	N1N	N1R	---	---
N1™ Base	---	B1N	B1R	---	---

Screwdriver Nobel Biocare N1™ Base

The Screwdriver Manual Nobel Biocare N1™ Base and Screwdriver Machine Nobel Biocare N1™ Base are used to tighten and loosen the clinical screw which fastens the Nobel Biocare N1™ Base to the dental implant.

Intended Use/Intended Purpose

Nobel Biocare N1™ Base Xeal™, and Universal Abutment Nobel Biocare N1™ Base

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

Temporary Abutment Nobel Biocare N1™ Base

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

Esthetic Abutment Nobel Biocare N1™ Base

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

Clinical Screw Nobel Biocare N1™ Base and Prosthetic Screw Nobel Biocare N1™ Base

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

Healing Abutment Nobel Biocare N1™ Base

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

IOS Healing Abutment Nobel Biocare N1™ Base

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

Impression Coping Nobel Biocare N1™ Base

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

Position Locator Nobel Biocare N1™ Base

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

Screwdriver Nobel Biocare N1™ Base

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

Indications

The Nobel Biocare N1 Base concept is indicated for single-unit restorations and for multiple unit restorations up to 6 units.

Nobel Biocare N1™ Base Xeal™

The Nobel Biocare N1™ Base Xeal™ is indicated for use in the maxilla or mandible for supporting tooth replacements to restore chewing function. It is indicated for single unit restorations and multiple unit restorations up to 6 units with less than 20° divergence to allow path of insertion.

Clinical Screw Nobel Biocare N1™ Base

The Clinical Screw Nobel Biocare N1™ Base is indicated for use to secure a Nobel Biocare N1™ Base Xeal™ to a dental implant in the maxilla or mandible for supporting tooth replacements to restore chewing function.

Prosthetic Screw Nobel Biocare N1™ Base

The Prosthetic Screw Nobel Biocare N1™ Base is indicated for use to secure abutments to the Nobel Biocare N1™ Base Xeal™ in the maxilla or mandible for supporting tooth replacements to restore chewing function.

Temporary Abutment Nobel Biocare N1™ Base

The Temporary Abutment Nobel Biocare N1™ Base is indicated to support the placement of single unit, screw-retained temporary prosthetic restorations in the maxilla or mandible, for up to 180 days.

The Temporary Abutment Nobel Biocare N1™ Base Bridge is indicated to support the placement of multiple unit, screw-retained temporary prosthetic restorations in the maxilla or mandible, for up to 180 days for implants with less than 20° overall divergences to allow path of insertion.

Universal Abutment Nobel Biocare N1™ Base

The Universal Abutment Nobel Biocare N1™ Base is indicated to support the placement of single unit, screw-retained prosthetic restorations in the maxilla or mandible.

The Universal Abutment Nobel Biocare N1™ Base Bridge is indicated to support the placement of multiple unit of up to 6 units, screw-retained prosthetic restorations in the maxilla or mandible for implants with less than 20° overall divergences to allow path of insertion.

Esthetic Abutment Nobel Biocare N1™ Base

The Esthetic Abutment Nobel Biocare N1 Base is a premanufactured prosthetic component connected to an endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation for single units and multiple units of up to three units.

Healing Abutment Nobel Biocare N1™ Base

The Healing Abutment Nobel Biocare N1™ Base is indicated for use with the Nobel Biocare N1™ Base Xeal™ in the maxilla or mandible for supporting single unit and multiple unit procedures, for up to 180 days.

IOS Healing Abutment Nobel Biocare N1™ Base

The IOS Healing Abutment Nobel Biocare N1™ Base is indicated for use with the Nobel Biocare N1™ Base Xeal™ in the maxilla or mandible for supporting single unit and multiple unit procedures, for up to 180 days. In combination with intraoral scanner the IOS Healing Abutment can be used to confirm the location, position, and orientation of the Nobel Biocare N1™ Base, to support creation of the digital model to facilitate the design and fabrication of a dental prosthesis using CAD/CAM.

Impression Coping Nobel Biocare N1™ Base

The Impression Coping Nobel Biocare N1™ Base is indicated to be connected to the Nobel Biocare N1™ Base Xeal™ to be used to transfer the location, position, and orientation of the Nobel Biocare N1™ Base from the patient's partially edentulous jaw to a master cast in the dental laboratory.

Position Locator Nobel Biocare N1™ Base

The Position Locator Nobel Biocare N1™ Base is indicated for use in combination with an intraoral or desktop scanner to confirm the location, position, and orientation of the Nobel Biocare N1™ Base, to support a creation of the digital model to facilitate the design and fabrication of a single or multiple unit dental prosthesis using CAD/CAM technology.

Screwdriver Nobel Biocare N1™ Base

Same as Intended Use/Intended Purpose.

Contraindications

It is contraindicated to use the Nobel Biocare N1™ Base 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, DLC (Diamond Like Carbon) coating or Polyetheretherketone (PEEK).

It is contraindicated to use Nobel Biocare N1™ Base Xeal™ in patients who are allergic or hypersensitive to sodium dihydrogen phosphate (NaH_2PO_4) or magnesium chloride (MgCl_2).

It is contraindicated to use Position Locator Nobel Biocare N1™ in patients who are allergic or hypersensitive to ZrN (zirconium nitride).

It is contraindicated to use Impression Copings Nobel Biocare N1™ Base in patients who are allergic to silicone.

Materials

Nobel Biocare N1™ Base Xeal™

Abutment: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminum, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Abutment is layered with water soluble salt mixture of Sodium dihydrogen phosphate and Magnesium chloride.

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminum, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing carbon coating, containing tungsten carbide and carbon with chromium interlayer between substrate and Diamond like Carbon coating.

Handle (not implantable): Polyetheretherketone (PEEK) polymer.

Temporary Abutment Nobel Biocare N1™ Base, Universal Abutment Nobel Biocare N1™ Base and Esthetic Abutment Nobel Biocare N1™ Base

Abutment: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminum, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminum, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing carbon coating, containing tungsten carbide and carbon with chromium interlayer between substrate and Diamond like Carbon coating.

Healing Abutment Nobel Biocare N1™ Base

Abutment: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminum, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Impression Coping Open Tray Nobel Biocare N1™ Base

Coping: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy.

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy.

O-ring: Silicone rubber.

Impression Coping Closed Tray Nobel Biocare N1™ Base

Coping: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy.

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy.

Clinical Screw Nobel Biocare N1™ Base and Prosthetic Screw Nobel Biocare N1™ Base

Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminum, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing carbon coating, containing tungsten carbide and carbon with chromium interlayer between substrate and Diamond like Carbon coating.

Position Locator Nobel Biocare N1™ Base

Locator: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Locator is partly coated with Zirconia Nitride coating.

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy.

Prosthetic screw Nobel Biocare N1™ Base

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing carbon coating, containing tungsten carbide and carbon with chromium interlayer between substrate and Diamond like Carbon coating.

IOS Healing Abutment Nobel Biocare N1™ Base

Abutment: Polyetheretherketone (PEEK) polymer filled with up to 20 wt.% of Barium Sulfate.

Screw: Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminum, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing carbon coating, containing tungsten carbide and carbon with chromium interlayer between substrate and Diamond like Carbon coating.

Screwdriver Manual Nobel Biocare N1™ Base

Screwdriver: Stainless Steel type UNS S46910.

Pin: Stainless Steel type 303 (UNS S30300).

Washer and handle: Stainless Steel type 304 (UNS S30400).

Screwdriver Machine Nobel Biocare N1™ Base

Screwdriver: Stainless Steel type UNS S46910.

Cautions

General

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

The Nobel Biocare N1™ Base concept must only be used with compatible Nobel Biocare instruments and prosthetic components. Use of instruments and prosthetic components that are not intended to be used in combination with the Nobel Biocare N1™ Base concept can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

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

The colored surface of the Nobel Biocare N1™ Base Xeal™ is a result of the Xeal™ surface and does not indicate the platform size.

Before Surgery

Careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

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

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

The device has not been evaluated in pediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jaw bone growth phase has been properly documented.

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

All components, instruments and tooling used during the clinical and/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. gauze, dental dam or a throat shield).

Small diameter implants and angled abutments are not recommended for the posterior region.

Before fastening the prosthetic component onto an implant, the implant must be able to withstand the recommended prosthetic tightening torque.

After the implant placement, 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.

Bending moments: Forces that cause bending moments are known to be the most unfavorable, as they can potentially jeopardize the long-term stability of an implant-supported restoration. In order to decrease bending moments, the distribution of forces should be optimized by cross-arch stabilization, minimizing distal cantilevers, having a balanced occlusion as well as decreased cuspal inclination of the prosthetic teeth.

Do not deviate from the Handling Procedure described in the sections below.

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 Nobel Biocare N1™ Base concept is intended to be used by dental health care professionals.

The Nobel Biocare N1™ Base concept is to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Devices in the IFU

The Nobel Biocare N1™ Base 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 Nobel Biocare N1™ Base 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, ulcers, 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 Nobel Biocare N1™ Base XEAL™, Clinical Screw Nobel Biocare N1™ Base, Prosthetic Screw Nobel Biocare N1™ Base, Temporary Abutment Nobel Biocare N1™ Base, Universal Abutment Nobel Biocare N1™ Base, and Healing Abutment Nobel Biocare N1™ Base. The SSCP can be obtained at the following website:

ec.europa.eu/tools/eudamed¹

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
www.nobelbiocare.com/complaint-form

Handling Procedure

Placement of Nobel Biocare N1™ Base XEAL™

1. Select an appropriate Nobel Biocare N1™ Base XEAL™ and connect it to the implant using the pre-assembled handle to facilitate the insertion and avoid touching the surface of the device. Remove the handle.

It is recommended to verify the final seating of the Nobel Biocare N1™ Base and the components attached using radiographic imaging.

2. Tighten the Clinical Screw of the Nobel Biocare N1™ Base:

Note If a Healing Abutment Nobel Biocare N1™ Base will be placed on the Nobel Biocare N1™ Base XEAL™, hand-tighten the Clinical Screw Nobel Biocare N1™ Base using the Screwdriver Nobel Biocare N1™ Base.

If an Impression Coping Nobel Biocare N1™ Base, Temporary Abutment Nobel Biocare N1™ Base, Universal Abutment Nobel Biocare N1™ Base or Esthetic Abutment Nobel Biocare N1™ Base will be placed on the Nobel Biocare N1™ Base XEAL™, tighten the Clinical Screw Nobel Biocare N1™ Base to 20 Ncm using the™ Screwdriver Nobel Biocare N1™ Base 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 20 Ncm tightening torque for Nobel Biocare N1™ Base XEAL. Overtightening the Clinical Screw may lead to a screw fracture.

3. If removal of the Nobel Biocare N1™ Base XEAL™ is needed, untighten the screw using the Screwdriver Nobel Biocare N1™ Base.

Note Nobel Biocare N1™ Base XEAL™ should only be replaced in conjunction with the Clinical Screw Nobel Biocare N1™ Base.

Restorative procedures for Nobel Biocare N1™ Base concept

Before beginning the restorative procedure, ensure the sufficient stability of the implant. Before connecting any components to the Nobel Biocare N1™ Base, clear its surface.

A. Placement of Healing Abutment Nobel Biocare N1™ Base for Healing Phase:

1. Select appropriate Healing Abutment Nobel Biocare N1™ Base and check occlusal clearance.
2. Connect the Healing Abutment Nobel Biocare N1™ Base to the Nobel Biocare N1™ Base XEAL™ and hand-tighten using the Omnigrip™ Mini Screwdriver.

Refer to the Nobel Biocare IFU1085 for information regarding the Omnigrip™ Mini Screwdriver.

Caution Never exceed the recommended tightening torque. Overtightening the abutment may lead to a fracture.

It is recommended to verify the final abutment seating using radiographic imaging.

3. If removal of the Healing Abutment Nobel Biocare N1™ Base is needed, untighten it using the Omnigrip™ Mini Screwdriver

B. Impression Taking using Impression Copings Open Tray Nobel Biocare N1™ Base:

1. Select the appropriate impression coping according to the base platform.
2. Connect the impression coping to the Nobel Biocare N1™ Base XEAL™ and hand-tighten it by hand or using the Omnigrip™ Mini Screwdriver.

Check that the impression coping is not in contact with adjacent teeth.

It is recommended to verify the seating of the Impression Coping using radiographic imaging.

3. Relieve and perforate the impression tray to allow full seating of the tray and protrusion of the guide pin. If there is a large opening in the tray, it may be closed off with wax to prevent impression material from escaping.
4. Inject impression material around the impression coping and into the tray.
5. Seat the impression tray fully, so that the tip of the guide pin is identified and record the impression.
6. After the impression material has set, unscrew the guide pin until it has disengaged from the Nobel Biocare N1™ Base using the Omnigrip™ Mini Screwdriver.

Caution Do not remove the guide pin from the embedded impression coping; this might cause loss of the O-ring from the guide pin.

7. Remove the impression tray, keeping the impression coping and the guide pin embedded in the impression material, and check the impression for any irregularities or bubbles.
8. Attach the Nobel Biocare N1™ Base Replica to the impression coping and tighten the guide pin.
9. Send the impression to the dental laboratory.

C. Impression taking using Impression Copings Closed Tray Nobel Biocare N1™ Base:

1. Select the appropriate impression coping according to the base platform.
2. Connect the impression coping to the Nobel Biocare N1™ Base and hand-tighten it by hand or using the Omnigrip™ Mini Screwdriver.

Check that the impression coping is not in contact with adjacent teeth. It is recommended to verify the seating of the impression coping using radiographic imaging.

3. Block out the receptacle for the screwdriver on top of the impression coping (e.g. using wax) to prevent impression material from entering.
4. Inject a medium or heavy body impression material around the impression coping and into the tray.
5. Seat the impression tray and record the impression.
6. After the impression material has set, remove the impression tray, and check the impression for any irregularities or bubbles.
7. Remove the block-out material from the screw, if applicable.
8. Disconnect the impression coping from the Nobel Biocare N1™ Base using the Omnigrip™ Mini Screwdriver.
9. Attach the Nobel Biocare N1™ Base replica to the impression coping and tighten the impression coping screw.
10. Reposition the assembly of the impression coping and replica into its corresponding location in the impression.
11. Send the impression to the dental laboratory.

D. Placement of provisional prosthesis using the Temporary Abutment Nobel Biocare N1™ Base (for chairside provisional prosthesis).

Caution Provisional prostheses using the Temporary Abutment Nobel Biocare N1™ Base must not be placed for more than 180 days, as permanent load may lead to fracture of the provisional prosthesis.

1. Connect the temporary abutment to the Nobel Biocare N1™ Base and check the post height. Modify the abutment, if necessary, outside of the patient's mouth. Do not modify the abutment seating area.

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

2. After modifying the abutment, it must be cleaned and sterilized prior to further intraoral use, following the instructions in the Cleaning and Sterilization Instructions section.
3. Re-connect the abutment to the Nobel Biocare N1™ Base aligning the parts first, then tighten the prosthetic screw using an Omnigrip™ Mini Screwdriver and block the screw access hole.
4. Make a temporary restoration using a pre-fabricated mold with suitable temporary restorative material, following the instructions by the material manufacturer.
5. Drill a hole through the mold, loosen the prosthetic screw using an Omnigrip™ Mini Screwdriver and remove the restoration.
6. Make final adjustments to the restoration. Protect the abutment connection while making adjustments using dedicated instruments.
7. Connect the temporary restoration to the Nobel Biocare N1™ Base and tighten to 20 Ncm using the Omnigrip™ Mini Screwdriver and Manual Torque Wrench Prosthetic.

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

It is recommended to verify the final abutment seating using radiographic imaging.

8. Block the screw access hole using suitable material, before closing it with composite.
9. If removal of the restoration is needed, open the screw access and untighten the screw using the Omnigrip™ Mini Screwdriver.

Note For processing of the temporary restoration in the dental laboratory, a dedicated laboratory screw should be used.

E. Taking an intraoral scan using Position Locator Nobel Biocare N1™ Base or IOS Healing

Assembly of the Position Locator Nobel Biocare N1™ Base

1. Insert the screw from the side slot into the screw hole (Figure B).

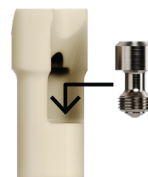


Figure B

2. Insert the Omnigrip™ Mini Screwdriver through the center hole.

3. Insert/connect the Omnigrip™ Mini Screwdriver tip into the screw head and start to turn clockwise the screw into the Position Locator body.
4. Once you see the entire screw thread, the screw is fully inserted.

Placement of the Position Locator Nobel Biocare N1™ Base

1. Insert the Omnigrip™ Mini screwdriver into the Position Locator screw.
2. Place the Position Locator over the Base in the patient mouth (Figure C).
3. Press with the finger of the other hand the Position Locator Body down until is fully seating on the base and then turn the screwdriver clockwise to tightening the screw (Figure D).



Figure C



Figure D

Note It is recommended to use whenever the space allows it, to use the top hole for the screw tightening, as then the screwdriver and the screw are completely aligned. (Figure E)



Figure E – Use of center hole whenever possible

Placement of the IOS Healing Abutment Nobel Biocare N1™ Base

1. Connect the IOS Healing Abutment Nobel Biocare N1™ Base to the Nobel Biocare N1™ Base by hand-tightening the screw using the Omnigrip™ Mini Screwdriver.

It is recommended to verify the seating of the device using radiographic imaging.

Intraoral scanning

1. Take an intraoral scan of the patient following the scanner manufacturer's instructions.
2. For Position Locator Nobel Biocare N1™ Base: Remove the Position Locator by untightening the screw.

For IOS Healing Abutment Nobel Biocare N1™ Base: Leave the component in place for the healing phase up to 180 days and to facilitate the shaping of the soft tissue.

Should adjustments to the IOS Healing Abutment Nobel Biocare N1™ Base be required, they can be performed after the scanning procedure has been completed. Care must be taken that the connection to the Base is not modified. Afterwards make sure to clean any remnants.

3. Send the scan file to the laboratory.

Laboratory procedure

F. Designing and manufacturing the final restoration on Universal Abutment Nobel Biocare N1™ Base using a CAD/CAM workflow.

If using a desktop scanner – go to step 1 below, if receiving IO Scan data from the clinician – go to step 2 below.

1. Scanning the master cast:
 - Connect a position locator to the 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 Universal Abutment Nobel Biocare N1™ Base based on the restoration type.
 - Design the restoration using standard CAD tools. Make sure to respect the restorative material manufacturer's design specifications.

Caution Universal Abutment Nobel Biocare N1™ Base Bridge should be used only for restorations of up to 6 units.

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 of the Universal Abutment before sandblasting by connecting it to a Base Replica using the Prosthetic Lab Screw.

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

- Sandblast the contact surface of the Universal Abutment with aluminum oxide 50 µm at a maximum of 2 bar. No other modifications other than sandblasting are to be performed.
- Clean the bonding surface of the Universal Abutment using steam jet or an ultrasonic bath.

Caution Do not sandblast the seating area. During the blasting procedure, use a 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 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 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 Base Replica and send it to the clinician along with the Prosthetic Screw.

G. Designing and manufacturing the final restoration on Esthetic Abutment Nobel Biocare N1™ Base using conventional workflow

- With the impression received from the clinician produce a working model with removable gingival material.
- Select the appropriate Esthetic Abutment Nobel Biocare N1™ Base.
- If applicable modify the abutment using a carborundum disk and carbide bur by connecting it to the Base Replica with the Lab Screw Nobel Biocare N1™ Base.

Note Esthetic Abutment Nobel Biocare N1™ Base NP and RP can be modified. However, the modification should not reduce the height from the base level below 4.5 mm.

Caution Never modify the abutment-base interface of the Esthetic Abutment.

Caution Do not sandblast the seating area. Sandblast the contact surface with aluminum oxide 50 µm at a maximum of 2 bar. The use of wax in the screw channel is to be avoided.

Caution Do not modify the abutment intraorally

- Fabricate a crown or bridge with NobelProcera® technique or with conventional casting technique.

Caution Esthetic Abutment Nobel Biocare N1™ Base can be used only for short span bridges up to 3 units with no overhang.

- Veneer the crown or framework if applicable.
- Send the crown and the Esthetic Abutment Nobel Biocare N1™ to the clinician.

Clinical Procedure

Before connecting the final restoration, make sure that the clinical screw of the Nobel Biocare N1™ Base is tightened to 20 Ncm.

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

1. Remove the healing abutment or temporary restoration from the Nobel Biocare N1™ Base Heal™ using the Omnigrip™ Mini Screwdriver.
2. Connect the Universal Abutment or Esthetic Abutment restoration to the Nobel Biocare N1™ Base Heal™ aligning the parts first, then hand-tighten the prosthetic screw.
3. Tighten using the Omnigrip™ Mini Screwdriver and Manual Torque Wrench Prosthetic to 20 Ncm.

Caution Never exceed 20 Ncm prosthetic tightening torque. Overtightening of the 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 Prosthetic Screw.

It is recommended to verify the final abutment seating using radiographic imaging.

4. If using Esthetic Abutment, seat the restoration on the abutment and check the occlusion and the interproximal contacts.
5. Block out the screw head before closing the screw access hole with composite.

Caution Do not modify the abutment intraorally

6. Cement the final crown or framework using conventional procedures. Make sure there is no excess cement.
7. If removal of the restoration is needed, open the screw access and untighten the screw using the Omnigrip™ Mini Screwdriver.

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

Note If removal of the prosthetic screw is not possible with the Omnigrip™ Mini Screwdriver, refer to IFU1043 to use the abutment screw retrieval instrumentation.

Sterility and Reusability Information

The Nobel Biocare N1™ Base Heal™, Temporary Abutment Nobel Biocare N1™ Base, Healing Abutment Nobel Biocare N1™ Base, IOS Healing Abutment Nobel Biocare N1™ Base, Prosthetic Screw Nobel Biocare N1™ Base, and Clinical Screw Nobel Biocare N1™ Base 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.

The Universal Abutment Nobel Biocare N1™ Base and Esthetic Abutment Nobel Biocare N1™ Base, including the co-packed Prosthetic Screw Nobel Biocare N1™ Base are delivered non-sterile and is intended for single use only. Prior to use, clean and sterilize the product following the Cleaning and Sterilization Instructions.

Caution The Nobel Biocare N1™ Base Heal™, Temporary Abutment Nobel Biocare N1™ Base, Healing Abutment Nobel Biocare N1™ Base, Universal Abutment Nobel Biocare N1™ Base, Esthetic Abutment Nobel Biocare N1 Base, IOS Healing Abutment Nobel Biocare N1™ Base, Prosthetic Screw Nobel Biocare N1™ Base and Clinical Screw Nobel Biocare N1™ Base 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.

Note In case of modifications of the Temporary Abutment Nobel Biocare N1™ Base during chair-side workflow, it must be cleaned and sterilized prior to further intraoral use, following the instructions in the Cleaning and Sterilization Instructions section.

The Position Locators Nobel Biocare N1™ Base, Screwdriver Nobel Biocare N1™ Base and Impression Coping Nobel Biocare N1™ Base are delivered non-sterile and are intended for reuse. Prior to first use and reuse clean and sterilize using the recommended parameters.

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

Position Locators Nobel Biocare N1™ Base do not require the disassembly of the screw prior to cleaning and sterilization.

The Screwdriver Nobel Biocare N1™ Base 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. Screwdrivers showing those signs shall be discarded.

If the Screwdriver Nobel Biocare N1™ Base does not engage in the Clinical Screw Nobel Biocare N1™ Base, the instrument is worn and shall be discarded.

The Impression Copings Nobel Biocare N1™ Base and Position Locators Nobel Biocare N1™ Base are reusable devices which shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. Impression Copings Nobel Biocare N1™ Base and Position Locators Nobel Biocare N1™ Base shall be discarded if any of the following criteria are met:

- If any wear, abrasion of the anodization and coated surfaces, modifications, deformations or corrosion is visible on the component.
- If the device does not seat accurately or has a loose fit on the Nobel Biocare N1™ Base Xcal™, or the Base Replica Nobel Biocare N1™ Base.
- If with light pressure the Omnigrip™ Mini Screwdriver does not engage or slips in the receptacle of the screw or guide pin.
- If the screw of the Position Locator has disassembled from the body.
- If the guide pin is no longer retained in the Impression Copping, which indicates that the O-ring for the guide pin has been stripped off or has deteriorated.

Cleaning and Sterilization Instructions

These products are intended to be cleaned and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.nobelbiocare.com.

Magnetic Resonance (MR) Safety Information

These products are fabricated from a metal material which can be affected by MR energy. For further information refer to Nobel Biocare publication **Magnetic Resonance (MR) Safety Information** by navigating to ifu.nobelbiocare.com.

Performance Requirements and Limitations

To achieve the desired performance, the devices must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with the devices, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

Storage, Handling and Transportation



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

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
UK Responsible Person <div><div>UK</div><div>RP</div></div>	Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
Distributed in Turkey by	EOT Dental Sağlık Ürünleri ve Dış Ticaret A.Ş. Nispetiye Mah. Aytaç Cad. Metro İş Merkezi No: 10/7 Beşiktaş İSTANBUL Phone: +90 2123614901, Fax: +90 2123614904
Distributed in Australia by	Nobel Biocare Australia Pty Ltd Level 4, 7 Eden Park Drive Macquarie Park, NSW 2113 Australia Phone: +61 1800 804 597
Distributed in New Zealand by	Nobel Biocare New Zealand Ltd 33 Spartan Road Takanini, Auckland, 2105 New Zealand Phone: +64 0800 441 657
CE Mark for Class I/IIa/IIb Devices	 2797
UKCA Mark for Class IIa/IIb Devices	 0086

Note Refer to the product label to determine the applicable conformity marking for each device.

Note Regarding Canadian device licensure, not all products described in the IFU may have a device licence according to Canadian law.

Basic UDI-DI Information

Product	Basic UDI-DI Number
Nobel Biocare N1™ Xeal™ Base TCC	73327470000001687H
Esthetic Abutment Nobel Biocare N1™ Base	
Universal Abutments Nobel Biocare N1™ Base	
Universal Abutments Nobel Biocare N1™ Base Bridge	
Temporary Abutment Nobel Biocare N1™ Base	733274700000017278
Temporary Abutment Nobel Biocare N1™ Base Bridge	
Clinical Screw Nobel Biocare N1™ Base	73327470000001827B
Prosthetic Screw Nobel Biocare N1™ Base	
Healing Abutment Nobel Biocare N1™ Base	73327470000001236T
IOS Healing Abutment Nobel Biocare N1™ Base	73327470000002216U
Impression Coping Closed Tray Nobel Biocare N1™ Base, Impression Coping Open Tray Nobel Biocare N1™ Base, Position Locator Nobel Biocare N1™ Base	733274700000013674
Screwdriver Manual Nobel Biocare N1™ Base	73327470000001787L
Screwdriver Machine Nobel Biocare N1™ Base	73327470000001797N

Legal Statements

EN All rights reserved.

Nobel Biocare, the Nobel Biocare logotype and all other trademarks used in this document are, if nothing else is stated or is evident from the context in a certain case, trademarks of Nobel Biocare. Product images in this folder are not necessarily to scale. All product images are for illustration purposes only and may not be an exact representation of the product.

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.