

# Nobel Biocare N1™ Base Concept



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## 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.

The Nobel Biocare N1™ Base concept is comprised of the following components (Table 1):

Base	Available platforms	Available heights	Tightening torque	Screwdriver
Nobel Biocare N1™ Base Xeal™	NP	1.75 mm/2.5 mm/3.5 mm	20 Ncm	N1™ Base Screwdriver
	RP	1.75 mm/2.5 mm/3.5 mm		

**Table 1 – Nobel Biocare N1™ Base concept - Compatible platforms, Screwdrivers and Torque specifications**

Base level abutments and component	Available platforms	Engaging	Non-engaging	Color coding	Available heights	Tightening torque	Screwdriver
Healing Abutment Nobel Biocare N1™ Base	NP	X	-	●	2 mm	Hand-tightening	Omnigrip™ mini
	RP	X	-	●	3 mm (anatomic shape) 4 mm		
IOS Healing Abutment Nobel Biocare N1™ Base	NP	X	-	● (screw)	4.5 mm	Hand-tightening	Omnigrip™ mini
	RP	X	-	● (screw)			
Temporary Abutment Nobel Biocare N1™ Base	NP	X	X	● (screw)	10 mm	20 Ncm	Omnigrip™ mini
	RP	X	X	● (screw)			
Universal Abutment Nobel Biocare N1™ Base	NP	X	X	● (screw)	4 mm	20 Ncm	Omnigrip™ Mini
	RP	X	X	● (screw)			
Impression Coping Open Tray Nobel Biocare N1™ Base	NP	X	-	●	-	Hand-tightening	Omnigrip™ mini
	RP	X	-	●	-		
Impression Coping Closed Tray Nobel Biocare N1™ Base	NP	X	-	●	-	Hand-tightening	Omnigrip™ mini
	RP	X	-	●	-		
Position Locator Nobel Biocare N1™ Base	NP	X	-	●	-	Hand-tightening	Omnigrip™ mini
	RP	X	-	●	-		
Esthetic Abutment Nobel Biocare N1™ Base	NP	X	-	● (screw)	0.5 mm (buccal margin)	20 Ncm	Omnigrip™ mini
	RP	X	-	● (screw)	0.5 mm (buccal margin)		

### 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.

**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.

## 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

### Nobel Biocare N1™ Base XEAL™, Temporary Abutment Nobel Biocare N1™ Base, and Universal Abutment Nobel Biocare N1™ Base

Intended to be connected to an endosseous dental implant to support the placement of a 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 for use

The Universal Abutment Nobel Biocare N1™ Base consist of three major parts. Specifically, the N1 Base XEAL, the Universal Abutment N1 Base, 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.

### 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.

### Universal Abutment Nobel Biocare N1™ Base Tri

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

### Universal Abutment Nobel Biocare N1™ Base Tri Bridge

The Universal Abutment Nobel Biocare N1™ Base Tri 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 single unit prosthetic rehabilitation.

### 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.

### 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.

## 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 XEAL™, to support creation of the digital model to facilitate the design and fabrication of a dental prosthesis using CAD/CAM.

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

The Clinical Screw and Prosthetic Screw are to be directly connected to the dental implant, abutment or framework, intended for use as an aid in prosthetic rehabilitation.

## 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

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

## 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 static and dynamic 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 the Nobel Biocare N1™ Base XEAL™ in patients who are allergic or hypersensitive to sodium dihydrogen phosphate ( $\text{NaH}_2\text{PO}_4$ ) or magnesium chloride ( $\text{MgCl}_2$ ).

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

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

## Materials

- Nobel Biocare N1™ Base XEAL™: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3, sodium dihydrogen

phosphate ( $\text{NaH}_2\text{PO}_4$ ) and magnesium chloride ( $\text{MgCl}_2$ ); Handle: Polyetheretherketone (PEEK).

- Temporary Abutment Nobel Biocare N1™ Base, Universal Abutment Nobel Biocare N1™ Base, Healing Abutment Nobel Biocare N1™ Base, Base Replica Nobel Biocare N1™ Base, Impression Coping Nobel Biocare N1™ Base and Esthetic Abutment Nobel Biocare N1™ Base: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- Impression Coping Nobel Biocare N1™ Base: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3, O-ring: silicone.
- Clinical Screw Nobel Biocare N1™ Base and Prosthetic Screw Nobel Biocare N1™ Base: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.
- Position Locator Nobel Biocare N1™ Base: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 and zirconium nitride coating 58% Zr, 42% N.
- Prosthetic screw co-packed with Position Locator Nobel Biocare N1™ Base: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- IOS Healing Abutment Nobel Biocare N1™ Base: Polyetheretherketone (PEEK).
- Screwdriver Nobel Biocare N1™ Base: Stainless Steel AISI 303/AISI 304/420F Mod according to ASTM F899.

## Warnings

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

## 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 the case of bruxism, other parafunctional habits, or unfavorable jaw relationships, reappraisal of the treatment option or appropriate pre- and post-treatment measures may be considered.

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

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

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

## At Surgery

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

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. gauze, dental dam or a throat shield).

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.

## 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) IFU1047 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.

**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 (see Table 1).

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 (see Table 1).
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 Abutment Nobel Biocare N1™ Base

1. Connect the Position Locator or IOS Healing Abutment 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.

2. Take an intraoral scan of the patient following the scanner manufacturer's instructions.
3. 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.

4. Send the scan file to the laboratory.

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

The digital workflow requires the use of the following equipment and materials.

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

Equipment / Material	Minimum Requirements
Scanner	Kavo LS3, 3Shape Trios, or other scanners with accuracy equal or higher than 6.9 µm
Design Software	DTX Studio Lab (The Implant Libraries are automatically included in the software installer) or 3Shape Dental Designer (The Implant Libraries are obtained via the 3Shape server in the software) ExoCAD (The implant libraries are obtained via the exocad DentalCAD server in the software)
Restorative Material	Nacera Pearl Doceram Medical Ceramics Minimum wall thickness allowed: ≤0.5 mm
Milling Unit	Roland DWX-52D <ul style="list-style-type: none"> <li>Indicated for milling zirconia material</li> <li>5 axis milling technology</li> <li>30.000 rpm spindle speed</li> </ul>

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

Sintering and further processing shall be done according to the material manufacturer's guidelines

Restorative Design Specifications:

Parameter	Specification	
	Single Unit Restorations	Multiple Unit Restorations
Angle from axis of the implant	20°	N/A
Maximum divergence between implants	N/A	20°
Wall thickness circular	0.5 mm	0.5 mm
Wall thickness margin	0.35 mm	0.35 mm
Post height min.	5.2 mm	5.2 mm
Maximum Abutment height (measured from the N1™ Base platform)	24.95 mm	24.95 mm

**Note** For the restorative design, follow the restorative material manufacturer's guidelines.

Bonding procedure requires the use of following materials:

Primer	i.e., Monobond Plus by Ivoclar Vivadent
Adhesive	i.e., Multilink Hybrid by Ivoclar Vivadent
Glycerin Gel	i.e., Liquid Strip by Ivoclar Vivadent

**Warning** Do not use any dental cements, restorative material, scanners, milling units, components, CAD/CAM software, templates, and tools other than those specifically identified for the Nobel Biocare N1™ Base concept.

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

## Laboratory Procedure

- 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.
- 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. Ensure that the software library is updated with the latest 3D models by Nobel Biocare. The latest Durable Medical Equipment (DME) files for 3Shape Dental Designer are obtained via the 3Shape server in the software.
  - Design the restoration using standard CAD tools. Make sure to respect the restorative material manufacturer's design specifications. Violation of any of the restricted parameters will cause a hard stop in the design process.

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

- Production:
  - Send the design file to a milling unit or local production facility.
- 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.
  - Connect the Universal Abutment to a Base Replica using the Prosthetic Lab Screw. Protect the screw channel of the Universal Abutment before sandblasting.

**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.

### Bonding Instructions for Single Unit Restorations

**Note** Use an adhesive which is suitable for bonding zirconia structures to titanium abutments and is sterilizable. Additional primer may be used. Follow the adhesive manufacturer's instructions.

- Remove the Universal Abutment from the replica and connect it to the replica embedded in the patient model using the laboratory screw.

2. Protect the screw channel of the Universal Abutment before applying the adhesive material.
3. Apply a layer of primer onto the contact surface of the Universal Abutment and zirconia restoration.
4. Apply a layer of adhesive onto the contact surfaces of the Universal Abutment and zirconia restoration.
5. Connect the restoration to the Universal Abutment and press them lightly together making sure that the parts are fully seated and in the correct orientation. Follow the adhesive manufacturer's instructions on curing/polymerization.
6. Remove the excess cement after curing/polymerization has started. In order to prevent the formation of an inhibition layer, use a glycerin gel.
7. Clear the screw channel.
8. Unscrew the restoration from the model, connect it to the replica, polish the cementation joint carefully, and finalize the restoration.
9. Send the finalized restoration to the clinician along with the prosthetic screw.

### Bonding Instructions for Multiple Unit Restorations

**Note** Use an adhesive which is suitable for bonding zirconia structures to titanium abutments and is sterilizable. Additional primer may be used. Follow adhesive manufacturer's instructions.

1. With the Universal Abutments being still connected to the replicas, protect the screw channel of the abutments.
2. Apply a layer of primer onto the contact surface of the Universal Abutments and zirconia restoration.
3. Apply a layer of adhesive onto the contact surfaces of the Universal Abutments and zirconia restoration.
4. Connect the Universal Abutments to the restoration and press them lightly in, making sure that they are fully seated.
5. Before the adhesive has set, unscrew the replicas from the restoration.
6. Connect the restoration to the replicas embedded in the patient model using the laboratory screws. Press the restoration lightly and evenly onto the Universal Abutments, making sure it is fully seated. Follow the adhesive manufacturer's instructions on curing/polymerization.
7. Remove the excess cement after curing/polymerization has started. In order to prevent the formation of an inhibition layer, use a glycerin gel.
8. Clear the screw channels.
9. Unscrew the restoration from the model, connect it to the replicas to polish the cementation joint carefully, and finalize the restoration.
10. Send the finalized restoration to the clinician along with the prosthetic screws.

### 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 Nobel Biocare N1™.

**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 for single unit only.

- Veneer the crown or framework if applicable.
- Send the crown and the Esthetic Abutment Nobel Biocare N1™ Base 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 Xeal™ using the Omnigrip™ Mini Screwdriver.
2. Connect the Universal Abutment or Esthetic Abutment restoration to the Nobel Biocare N1™ Base Xeal™ 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 Xeal™, 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 Xeal™, 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 Xeal™, 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 Coping, which indicates that the O-ring for the guide pin has been stripped off or has deteriorated.

## Cleaning and Sterilization Instructions

The Universal Abutment Nobel Biocare N1™ Base, including the prosthetic screw, are delivered non-sterile by Nobel Biocare and are intended for single-use. Prior to use, the device must be cleaned and sterilized by the user.

The Esthetic Abutment Nobel Biocare N1™ Base including Prosthetic Screw is delivered non-sterile by Nobel Biocare and is intended for single use.

Prior to use, the devices must be cleaned and sterilized by the user. The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The restorative material to be placed intra-orally on the Esthetic Abutment Nobel Biocare N1™ Base should be cleaned and sterilized per the restorative material manufacturer's instructions for use, prior to use.

The Screwdriver Nobel Biocare N1™ Base, Position Locator Nobel Biocare N1™ Base, and Impression Coping Nobel Biocare N1™ Base are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the devices must be cleaned and sterilized by the user.

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

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

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

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

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

**Note** Esthetic Abutment Nobel Biocare N1™ Base, Screwdriver Nobel Biocare N1™ Base, Position Locator Nobel Biocare N1™ Base, and Impression Coping Nobel Biocare N1™ Base have been validated to withstand these cleaning and sterilization procedures.

**Caution** Do not deviate from the following reprocessing instructions. Initial Treatment at Point of Use Prior to Reprocessing:

### Initial Treatment at Point of Use Prior to Reprocessing

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.

**Caution** All dental debris adhering to the impression copings (such as impression material) must be removed immediately after use, as it may not be possible to remove the dried debris later in the process. A dental probe should be used to remove any debris in the cavities of the device. Impression copings shall be discarded if there is any debris which cannot be removed.

3. Rinse the devices with cold running tap water.

### Containment and Transportation/ Shipping to Reprocessing Area

1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as is practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

**Note** Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

### Automated Cleaning and Drying (Including Pre-cleaning)

#### Pre-cleaning

1. Disassemble the devices prior to cleaning by removing the screw from the device with exception of the Position Locator.
2. Immerse the device in an 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
3. Fill lumina (where applicable) with an 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.
5. Brush the inner surfaces, lumina, and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 20 seconds until all visible soil is removed.
6. Thoroughly rinse all outer and inner surfaces, lumina, and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.

7. Rinse lumina (where applicable) with 20 ml of tap water using a 20 ml syringe.

#### Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

**Note** It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
  - Minimum of 2 minutes pre-cleaning with cold tap water
  - Draining
  - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean)
  - Draining
  - Minimum of 3 minutes neutralization with cold desalinated water
  - Draining
  - Minimum of 2 minutes rinsing with cold desalinated water
  - Draining
4. Run drying cycle at a minimum of 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single-use wipes if any residual moisture remains after the drying cycle.

### Universal Abutment with Restoration

#### Pre-cleaning

1. Disassemble the Universal Abutment prior to cleaning by removing the screw from the device.
2. Immerse the device in lukewarm water for a minimum of 5 minutes until the next step is initiated.
3. Immerse the device in an 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 20 minutes.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) under cold tap water for a minimum of 1 minute until all visible soil and debris is removed.
5. Flush lumina (where applicable) with cold tap water using a 20 ml syringe until all visible soil is removed. Use a single-use wipe to catch dripping fluid from flushing. If discoloration of the wipe is indicating soil, then repeat steps 2-5.

#### Automated Cleaning and Drying

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.

**Note** It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).

2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
  - Minimum of 4 minutes pre-cleaning with cold tap water
  - Draining
  - Minimum of 5 minutes cleaning with a minimum of 55°C (131°F) tap water and an 0.5% alkaline detergent (e.g. Neodisher Mediclean forte)
  - Draining
  - Minimum of 6 minutes neutralization with an 0.1% neutralizing agent (e.g. Neodisher Z)
  - Draining
  - Minimum of 3 minutes rinsing with cold desalinated water
  - Draining
4. Dry with compressed air or clean and lint-free single-use wipes, if any residual moisture remains after the drying cycle.

#### Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, or if dental debris remains on the device. Properly discard any devices that fail the inspection.

#### Manual Cleaning and Drying

1. Disassemble the devices prior to cleaning by removing the screw from the device with exception of the Position Locator.
2. Immerse the device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
3. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. Flush the inner surfaces, lumina, and cavities (where applicable) with 20 ml of lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP and Neodisher Medizym; maximum of 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
5. Brush the inner surfaces, lumina, and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm / 2.0 mm / 5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
6. Thoroughly rinse the outer surfaces and lumina of the device with running tap water at a minimum temperature of 29 °C (84.2 °F) for a minimum of 10 seconds to remove all cleaning solution.
7. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W<sub>eff</sub>) containing an 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP t and Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).
8. Flush the inner surfaces, lumina, and cavities (where applicable) with 20 ml of lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
9. Rinse with deionized water to remove all cleaning solutions for a minimum of 10 seconds.
10. Dry with compressed air or clean and lint-free single-use wipes.

\* Neodisher Medizym was used in the validation of Esthetic Abutment Nobel Biocare N1™ Base and Impression Coping Nobel Biocare N1™ Base

#### Universal Abutment with Restoration

1. Disassemble the Universal Abutment prior to cleaning by removing the screw from the device.
2. Immerse the device in lukewarm water until next step is initiated for a minimum of 5 minutes.
3. Immerse device in an 0.5% enzymatic cleaning solution (e.g. Neodisher Medizym) prepared with lukewarm tap water for a minimum of 20 minutes.
4. Scrub the outer surfaces of the device with soft-bristled nylon brush under cold tap water for a minimum of 1 minute until all visible soil and debris is removed.
5. Flush lumina and cavities (where applicable) with cold tap water using a 20 ml syringe. Use a single-use wipe to catch dripping fluid from flushing. If discoloration of the wipe is indicating soil, then repeat steps 2-5.
6. Prepare ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W<sub>eff</sub>) containing an 0.5% enzymatic cleaning agent (e.g. Neodisher Medizym). Degas the solution by running the ultrasonic bath for a minimum of 30 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).
7. Immerse the device in the ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W<sub>eff</sub>) containing an 0.5% enzymatic cleaning agent (e.g. Neodisher Medizym) and treat for a minimum of 5 minutes at a minimum of 40°C (104°F) / maximum 45°C (113°F).
8. Rinse the device with deionized water for a minimum of 1 minute until all residues of cleaning solution are removed.
9. Dry with compressed air or clean and lint-free single-use wipes.

#### Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, or if dental debris remains on the device. Properly dispose of any devices that fail the inspection.

#### Sterilization

The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 and Selectomat PL/669-2CL (pre-vacuum cycle); Amsco Century Sterilizer and Selectomat PL/669-2CL (gravity cycle).

**Note** It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

\* Selectomat PL/669-2CL was used in the validation of Esthetic Abutment Nobel Biocare N1™ Base, Impression Coping Nobel Biocare N1™ Base and Universal Abutment

1. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
  - FDA cleared sterilization accessories are to be used for the recommended sterilization parameters for wrapping the devices supplied non-sterile before user sterilization.
  - EN ISO 11607.
  - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F) and sufficient steam permeability).
  - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 2 presents examples of suitable sterilization pouches.

**Table 2 – Recommended Sterilization Pouches**

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch Steriking pouch (Wipak)
Pre-vacuum Cycle	SteriCLIN® pouch Steriking pouch (Wipak)*

\* Steriking pouch (Wipak) was used in the validation of Esthetic Abutment Nobel Biocare N1™ Base, Impression Coping Nobel Biocare N1™ Base and Universal Abutment

- Label the sterilization pouch with the information necessary to identify the device (e.g. the product name with article number and lot/batch number (if applicable)).
- Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
- Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied using the following recommended parameters:
  - Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure, followed by a minimum drying time of 15 minutes in chamber.
  - Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by a minimum drying time of 20 minutes in chamber.

**Note** FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

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

## Storage and Maintenance

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

## Containment and Transportation/ Shipping to Point of Use

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

# Magnetic Resonance (MR) Safety Information

## For single tooth restoration

MRI Safety Information



Non-clinical testing has demonstrated the Nobel Biocare N1™ Base Xeal™, Universal Abutment Nobel Biocare N1™ Base, Temporary Abutment Nobel Biocare N1™ Base, Healing Abutment Nobel Biocare N1™ Base, IOS Healing Abutment Nobel Biocare N1™ Base, Esthetic Abutments Nobel Biocare N1™, Prosthetic Screw Nobel Biocare N1™ Base, and Clinical Screw Nobel Biocare N1™ Base 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 58.9 T/m (5,890 G/cm).	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Whole body transmit coil	
Maximum Whole-Body SAR [W/kg]	<ul style="list-style-type: none"> <li>Inferior to the neck: 2.0 W/kg</li> <li>Superior to the neck: 0.5 W/kg</li> </ul>	<ul style="list-style-type: none"> <li>Inferior to the xyphoid: 2.0 W/kg</li> <li>Between the xyphoid and neck: 1.0 W/kg</li> <li>Superior to the neck: 0.5 W/kg</li> </ul>
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 3T MRI system.	

## For multiple teeth restorations (without Esthetic Abutments Nobel Biocare N1™ Base)

MRI Safety Information



Non-clinical testing has demonstrated the Nobel Biocare N1™ Base Xeal™, Universal Abutment Nobel Biocare N1™ Base, Temporary Abutment Nobel Biocare N1™ Base, Prosthetic Screw Nobel Biocare N1™ Base, and Clinical Screw Nobel Biocare N1™ Base 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]	<ul style="list-style-type: none"> <li>Inferior to the shoulders: 2.0 W/kg</li> <li>Superior to the shoulders: 0.2 W/kg</li> </ul>	<ul style="list-style-type: none"> <li>Inferior to the navel: 2.0 W/kg</li> <li>Superior to the navel: 0.1 W/kg</li> </ul>
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 2.7 cm from the devices or device assemblies when imaged in a 3T MRI system.	

# Performance Requirements and Limitations

To achieve the desired performance, healing abutments 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 healing abutments, 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](http://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

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### Manufacturer



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PO Box 5190, 402 26  
Västra Hamngatan 1  
Göteborg  
411 17  
Sweden  
[www.nobelbiocare.com](http://www.nobelbiocare.com)

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### Distributed in USA by

Nobel Biocare USA, LLC  
22715 Savi Ranch Parkway  
Yorba Linda, CA, 92887 USA

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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
					<b>Rx only</b>	 <a href="https://symbol.glossary.nobelbiocare.com">symbol.glossary.nobelbiocare.com</a> <a href="https://ifu.nobelbiocare.com">ifu.nobelbiocare.com</a>	
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	