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:

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 3 mm (anatomic shape) 4 mm	Hand-tightening	Omnigrip™ mini
	RP	X	-	●			
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		● (screw)	10 mm	20 Ncm	Omnigrip™ mini
	RP	X		● (screw)			
Universal Abutment Nobel Biocare N1™ Base	NP	X		● (screw)	4 mm	20 Ncm	Omnigrip™ mini
	RP	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 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.

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™, 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

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 (NaH2PO4) or magnesium chloride (MgCl2).

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.

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 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.

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 the Nobel Biocare N1™ Base concept

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 as 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:

https://ec.europa.eu/tools/eudamed[1]

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
https://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 (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 protheses 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.

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 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.

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 (NaH2PO4) and magnesium chloride (MgCl2); 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.

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.

The final restoration including Prosthetic Screw should be cleaned and sterilized per the restorative material manufacturer's instructions for use, prior to use.

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

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. Use a dental probe to remove soil and debris from cavities, where applicable.

Caution All dental debris adhering to impression copings (such as impression material) must be cleaned away after use. It may not be possible to remove the dried debris later in the process. Impression copings shall be discarded if all dental debris 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 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 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.

3. Fill lumina (where applicable) with 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 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 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 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.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and 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 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 lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP / Neodisher Medizym; maximum 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 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_{eff}) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP / Neodisher Medizym) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/maximum 45°C (113°F).
8. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
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.

Visual Inspection

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly discard 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 and Impression Coping Nobel Biocare N1™ Base.

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:
   - EN ISO 11607 and/or DIN 58953-7.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), 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 and Impression Coping Nobel Biocare N1™ Base.

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 3):

Table 3 – Recommended Sterilization Cycles

Cycle	Minimum Temperature	Minimum Sterilization Time	Minimum Drying Time (In Chamber)	Minimum Pressure
Gravity Cycle[1]	132°C (270°F)	15 minutes	20 minutes	≥2868.2 mbar[4]
Pre-Vacuum Cycle[1]	132°C (270°F)	4 minutes		
Pre-Vacuum Cycle[2]	134°C (273°F)	3 minutes		≥3042 mbar[5]
Pre-Vacuum Cycle[3]	134°C (273°F)	18 minutes		

[1] Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance to EN ISO 17665-1.

[2] Recommendation of the Welsh Health Technical Memorandum (WHTM) 01-01 Part C.

[3] Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical / biological indicators) used for this cycle are validated for these conditions.

[4] Saturated steam pressure at 132°C as per required by EN ISO 17665-2.

[5] Saturated steam pressure at 134°C as per required by EN ISO 17665-2.

Note Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, 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 (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, 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 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]	Inferior to the neck: 2.0 W/kg Superior to the neck: 0.5 W/kg	Inferior to the xyphoid: 2.0 W/kg Between the xyphoid and neck: 1.0 W/kg Superior to the neck: 0.5 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0 °C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 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]	Inferior to the shoulders: 2.0 W/kg Superior to the shoulders: 0.2 W/kg	Inferior to the navel: 2.0 W/kg Superior to the navel: 0.1 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0 °C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 2.7 cm from the devices or device assemblies when imaged in a 3T MRI system.	

MR Safety Information for single and multiple tooth restoration for Esthetic Abutments Nobel Biocare N1™ Base

MRI Safety Information		
Non-clinical testing has demonstrated that Esthetic Abutments 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]	Inferior to the neck: 2.0 W/kg Superior to the neck: 0.5 W/kg	Inferior to the xyphoid: 2.0 W/kg Between the xyphoid and neck: 1.0 W/kg Superior to the neck: 0.5 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0 °C after 15 minutes of continuous scanning.	
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 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.

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 UK RP	UK Responsible Person: Nobel Biocare UK Ltd 4 Longwalk Road Stockley Park Uxbridge UB11 1FE United Kingdom
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 Ir/IIa/IIb Devices	CE 2797
UKCA Mark for Class I Devices	UK CA
UKCA Mark for Class IIa/IIb Devices	UK CA 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™ Base TCC	7332747000001687H
Universal Abutments Nobel Biocare N1™ Base Universal Abutments Nobel Biocare N1™ Base Bridge	7332747000001697K
Esthetic Abutment Nobel Biocare N1™ Base	7332747000001687H
Temporary Abutment Nobel Biocare N1™ Base Temporary Abutment Nobel Biocare N1™ Base Bridge	733274700000017278
Clinical Screw Nobel Biocare N1™ Base Prosthetic Screw Nobel Biocare N1™ Base	7332747000001827B
Healing Abutment Nobel Biocare N1™ Base	7332747000001236T
IOS Healing Abutment Nobel Biocare N1™ Base	7332747000001236T
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	7332747000001787L
Screwdriver Machine Nobel Biocare N1™ Base	7332747000001797N

Legal Statements

Symbols Glossary

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

							
Authorized Representative in the European Community / European Union	UK Responsible Person	Authorised Representative in Switzerland	Sterilized using Ethylene Oxide	Sterilized using irradiation	Sterilized using steam or dry heat		
							
Batch code	Catalogue number	Unique Device Identifier	Serial number	Medical device	Magnetic resonance safe		
							
Caution	Magnetic resonance conditional	Non-sterile	Contains hazardous substances	Contains or presence of DEHP phthalate	Contains or presence of natural rubber latex	Contains or presence of phthalate	Contains biological material of animal origin
					Rx only		symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com
CE mark	CE mark with Notified Body number	UKCA mark	UKCA mark with Approved Body number	Consult instructions for use	For prescription use only	Link to Online Symbols Glossary and IFU Portal	
							
Date of manufacture	Manufacturer	Use-by date	Upper limit of temperature	Temperature limit	Do not resterilize	Do not re-use	Non-pyrogenic
							
Date	Tooth number	Patient number	Patient identification	Health care centre or doctor	Patient information website	EU Importer	Swiss Importer
Double sterile barrier system	Single sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside	Do not use if package is damaged and consult instructions for use	Keep away from sunlight	Keep dry	