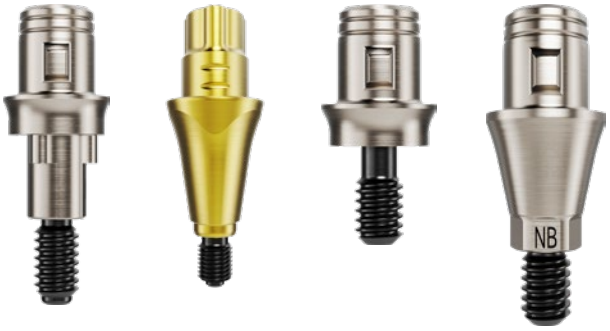
Universal Bases and Abutments



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Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description

Universal bases and abutments are premanufactured dental implant abutments which can be directly connected to an endosseous dental implant to support the placement of a single unit screw-retained dental prosthesis.

An assortment of universal bases and abutments are available for use with the following implant systems:

- Universal Bases Conical Connection (CC) are available in NP/RP/WP platforms, feature a conical connection and can be used with Nobel Biocare's NobelActive®, NobelParallel™ CC and/or NobelReplace® CC implant systems.
- Universal Abutments Nobel Biocare N1™ TCC are available in NP/RP platforms, feature a tri-oval conical connection and can be used with Nobel Biocare's Nobel Biocare N1™ implant system.
- Universal Bases Tri-Channel are available in NP/RP/WP platform, feature an internal tri-channel connection and can be used with Nobel Biocare's NobelReplace®, Replace Select™ and/or NobelSpeedy® Replace™ implant systems.
- Universal Bases Hexternal Hex are available in NP/RP/WP platforms, feature an external hex connection and can be used with Nobel Biocare's Brånemark System® and/or NobelSpeedy® Groovy implant systems.

Table 1 presents a summary of the available universal bases and abutments based on their connection type and identifies the available platforms and margin heights, as well as the compatible screwdriver and the specified tightening torque.

Universal Base/ Abutment for	Available platforms	Available margin heights	Tightening torque	Screwdriver
Conical connection (CC)	NP RP WP	1.5 mm 3.0 mm	35 Ncm	Unigrip™
Tri-oval conical connection (TCC)	NP RP	1.5 mm 3.0 mm	20 Ncm	Omnigrip™ mini
Tri-channel	NP RP WP	1.5 mm 3.0 mm	35 Ncm	Unigrip™
External Hex	NP RP WP	1.5 mm 3.0 mm	35 Ncm	Unigrip™

Table 1: Universal Bases and Abutments – Available Platforms and Margin Heights, Tightening Torques and Compatible Screwdrivers

Universal bases and abutments are co-packed with a clinical screw. Refer to Nobel Biocare Instructions for Use (IFU) IFU1057 for information regarding clinical screws. This IFU is available for download at ifu.nobelbiocare.com.

Universal bases featuring internal conical connection (all platforms), internal tri-channel connection (all platforms) and external hex connection (NP and RP platforms) are also co-packed with a burn-out coping. Universal bases featuring external hex connection (WP platform) do not come co-packed with a burn-out coping. Burn-out copings are intended for laboratory use only and are not intended for intraoral use.

Intended Use / Intended Purpose

Universal Bases and Abutments

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

Indications

Universal bases and abutments are indicated to support the placement of single unit, screw- retained prosthetic restorations in the maxilla or mandible.

Contraindications

It is contraindicated to use universal bases and abutments 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 (90% titanium, 6% aluminum, 4% vanadium) and DLC (Diamond Like Carbon) coating.

In addition, it is contraindicated to place universal bases and abutments which feature a conical connection (CC), internal tri-channel connection or external hex connection in:

- Patients who are allergic or hypersensitive to Polyoxymethylene (POM).

Cautions

General

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

Nobel Biocare surgical instruments and prosthetic components must only be used with Nobel Biocare implants, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory esthetic results.

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

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 for pediatric patients until the end of the jaw bone growth phase has been properly documented.

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

All 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

Because of the small size 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).

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

Universal bases and abutments are intended to be used by dental health care professionals.

Universal bases and abutments are intended to be used in patients subject to dental implant treatment.

Clinical Benefits and Undesirable Side Effects

Clinical Benefits Associated with Universal bases and abutments

Universal bases and abutments are a component 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 Universal bases and abutments

The placement of this device 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 reflex (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, ulcera, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

Notice regarding serious incidents

For a patient / user / third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Handling Procedure

A. Designing and Manufacturing the Restoration using a Conventional Press Workflow (Laboratory Procedure, not applicable for Universal bases external hex WP as those do not have a burn-out coping)

1. Preparation of the Universal Base or Abutment:
   - Hand-tighten the universal base or abutment onto the master cast using a compatible laboratory screw.
2. Preparation of the Burn-out Coping:
   - Seat the burn-out coping onto the universal base or abutment.
   - Adjust the height of the burn-out coping according to the required occlusal plane. Ensure the universal base or abutment remains fully covered.
3. Production:
   - Create a wax-up restoration and use the standard procedure to either press or cast a coping or full-contour crown.
4. Finalization and Bonding:
   - Once the restoration is produced, finalize it following the restorative material manufacturer's instructions.
   - Connect the universal base or abutment to a replica or protection analog using a laboratory screw.
   - Sandblast the contact surface of the universal base or abutment with aluminum oxide 50 µm at a maximum of 2 bar.
   - Clean the bonding surface of the universal base or abutment using a steam jet or an ultrasonic bath.

Caution Do not sandblast the seating area. During the blasting procedure, use a protection analog or implant replica to prevent any modification of the abutment/implant interface. The use of wax in the screw channel is not recommended.

   - Bond the restoration to the universal base or 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 base or abutment needs to 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 replica/protection analog and send it to the clinician along with the clinical screw.

B. Designing and Manufacturing the Restoration using a CAD/CAM Workflow for Desktop Scanners (Laboratory Procedure)

1. Scanning the Master Cast:
   - Connect a position locator to the 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 base or abutment based on the soft tissue anatomy.
   - Design the restoration using standard CAD tools. Make sure to respect the restorative material manufacturer's design specifications.
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 and emergence profile of the abutment before sandblasting by connecting it to a replica or protection analog using the laboratory screw.

Caution The use of wax in the screw channel is not recommended.

   - Sandblast the contact surface of the abutment with aluminum oxide 50 µm at a maximum of 2 bar.
   - Clean the bonding surface using steam jet or an ultrasonic bath.

Caution Do not sandblast the seating area. During the blasting procedure, use a protection analog or implant replica to prevent any modification of the abutment/implant interface. The use of wax in the screw channel is not recommended.

   - Bond the restoration to the universal base or 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 base or abutment needs to 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 replica/protection analog and send it to the clinician along with the clinical screw.

C. Designing and Manufacturing the Restoration using a CAD/CAM Workflow for Intra-oral Scanners (Clinical and Laboratory Procedure)

1. Intra-oral Scanning:
   - Connect a position locator to the implant in the patient's mouth.
   - Take an intra-oral scan of the patient following the instructions of the scanner manufacturer.
2. Designing the Restoration:
   - Import the scan data into the CAD software and choose the desired universal base or abutment based on the soft tissue anatomy.
   - Design the restoration using standard CAD tools.
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 and emergence profile of the abutment before sandblasting by connecting it to a replica or protection analog using the laboratory screw.

Caution The use of wax in the screw channel is not recommended.

- Sandblast the contact surface of the abutment with aluminum oxide 50 µm at a maximum of 2 bar.
- Clean the bonding surface using steam jet or an ultrasonic bath.

Caution Do not sandblast the seating area. During the blasting procedure, use a protection analog or implant replica to prevent any modification of the abutment/implant interface. The use of wax in the screw channel is not recommended.

- Bond the restoration to the universal base or 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 base or abutment needs to 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 replica/protection analog and send it to the clinician along with the clinical screw.

D. Placement of the Final Restoration (Clinical Procedure)

Ensure sufficient implant stability before beginning the prosthetic procedure.

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

- Remove the healing cap or temporary restoration from the patient.
- Connect and hand-tighten the Universal Base/Abutment restoration using the clinical screw. It is recommended to verify the final abutment seating using radiographic imaging.
- Tighten the restoration according to table 1 using dedicated screwdriver and Manual Torque Wrench prosthetic.

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

Caution To tighten the abutment, the implant should be able to withstand the recommended tightening torque of the clinical screw.

- Block out the screw head before closing the screw access hole with composite.
- If removal of the restoration is needed, open the screw access and untighten the screw using the appropriate screwdriver.
- If the abutment cannot be removed, use the Abutment Retrieval Tool. Refer to Nobel Biocare Instructions for Use (IFU) IFU1096 for information regarding Abutment Retrieval Tool.

Materials

- Universal bases and abutments: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- Burn-out Coping: Polyoxymethylene (POM).
- Clinical screws: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 and DLC (Diamond Like Carbon) coating.

Sterility and Reusability Information

Universal bases and abutments are delivered non-sterile and are intended for single use.

The final restoration (comprised of the universal base or abutment with bonded restoration and clinical screw) must be cleaned and sterilized prior to intraoral use following the procedures in the Cleaning and Sterilization Instructions. During processing in the dental laboratory, the supra-construction can be cleaned as necessary without disinfection or sterilization.

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

Caution Universal bases and abutments 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.

The Burn-out Coping is used in the dental laboratory only (no intraoral use) and has no cleaning and/or sterilization requirements.

Cleaning and Sterilization Instructions

Cleaning and sterilization instructions for supra-constructions that include non-metallic materials, which require cleaning and disinfection and/or sterilization prior to patient contact.

Clean, disinfect and/or sterilize the final restoration according to instructions of the restorative material manufacturer.

Magnetic Resonance (MR) Safety Information

Universal bases and abutments CC, Tri-Channel and External Hex

Universal bases and abutments can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that universal bases and abutments are unlikely to impact patient safety under the following MRI conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

Note Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Under the conditions defined above, these devices are expected to produce a maximum temperature rise of 4.1°C (39.4°F) after 15 minutes of continuous scanning.

In the non-clinical testing, the image artifact caused by the devices extends approximately 30 mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Note Although the non-clinical testing demonstrates that universal bases and abutments are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to support a claim of MR Safe or MR Conditional for these products.

Universal Abutment Nobel Biocare N1™ TCC

MR Safety Information for Single Tooth Restoration

MRI Safety Information		
Non-clinical testing has demonstrated that Universal Abutments Nobel Biocare N1™ TCC 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, Universal bases and 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 Universal bases and 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 1 411 17 Göteborg Sweden www.nobelbiocare.com
CE Mark for Class IIb Devices	CE 2797

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

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	