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 External 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.
- 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.

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

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).

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.

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

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 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 Devices in the IFU

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, ulcers, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the universal bases and abutments. The SSCP can be obtained at the following website:
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
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.

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

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

Magnetic Resonance (MR) Safety Information

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

Performance Requirements and Limitations

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

Facilities and Training

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

Storage, Handling and Transportation

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

Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information

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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 IIb Devices	CE 2797
UKCA Mark for Class 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
Universal Bases CC NP/RP/WP	73327470000001697K
Universal Abutments Nobel Biocare N1™ TCC NP/RP	
Universal Bases Tri-Channel NP/RP/WP	
Universal Bases External Hex NP/RP/WP	

Legal Statements

Symbols Glossary

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