Universal Base Abutment
Instructions for use

Important: Please read.

Disclaimer of liability:
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Description:

A premanufactured dental implant abutment to be directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

Internal conical connection for the following implant systems: NobelActive®, NobelReplace® CC and NobelParallel™ CC.

Internal tri-channel connection for the following implant systems: NobelReplace®, Replace Select™ and NobelSpeedy® Replace.

External hex connection for the following implant systems: Brånemark System® and NobelSpeedy® Groovy.

Note: Burn-out Coping (not for clinical use) and Clinical Screw included.

Intended use:

Dental implant abutments are to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

Indications:

The Universal Base Abutment in combination with Nobel Biocare endosseous implants are indicated for single-unit if screw retained and for multiple-unit if cement retained crowns are used.

Contraindications:

It is contraindicated to use Universal Base Abutment 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-6A-4V (titanium, aluminum, vanadium) or Polyoxymethylene (POM).

Cautions:

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

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Special attention has to 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 or unfavorable jaw relationships reappraisal of the treatment option may be considered.

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

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

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient.

To secure the long term treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

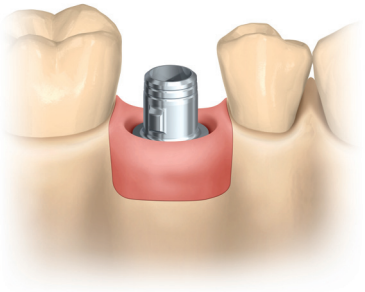
Never exceed **35 Ncm** prosthetic tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Handling procedure:

Conventional press workflow:

1. Universal Base preparation

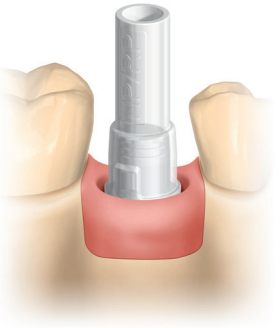
– Hand-tighten the Universal Base onto the model. Make sure to use the laboratory screw.



2. Burn-out coping preparation

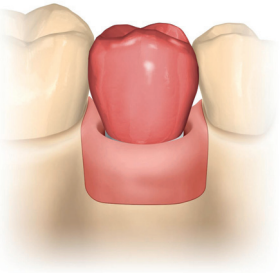
– Seat the burn-out coping onto the Universal Base.

– Adjust the height of the burn-out coping according to the required occlusal plane. Make sure the Universal Base remains fully covered.



3. Production

– Create a wax-up restoration and use the standard procedure to either press or cast the coping or full-contour crown. Finalize the restoration.



4. Finalization

– Once the restoration is produced, finalize it following the restorative material manufacturer's instruction

– Seal the screw channel with wax.

– Sandblast the contact surface of the Universal Base with aluminum oxide 50 µm at a maximum of 2 bar.

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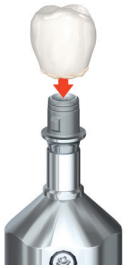
Caution: Do not sandblast the seating area. During the blasting procedure, use a protection analog to prevent any modification of the abutment/implant interface.

– Clean the surface as recommended by the bonding material manufacturer.

– Bond the restoration to the Universal Base according to the cement manufacturer's instructions. Use only self-adhesive dental cement/bonding material suitable for zirconium dioxide ceramics or PMMA (Polymethylmethacrylat)

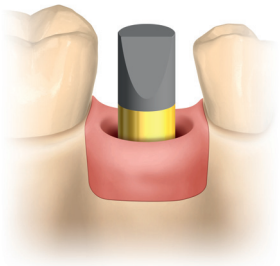


CAD/CAM workflow with exocad® software:

1. Scanning

– Insert the NobelProcera Abutment Position Locator onto the model.

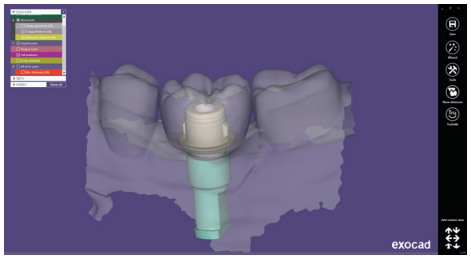
– Scan by following the usual scan routines.



2. Designing

– In the implant library select the height and implant diameter for the Universal Base.

– Design the implant crown using standard CAD tools.



3. Milling

– Send the design file to a milling unit or production facility that accepts exocad design files.

4. Finalization

– Once the restoration is produced, finalize it following the restorative material manufacturer's instruction

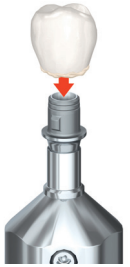
– Seal the screw channel with wax.

– Sandblast the contact surface of the Universal Base with aluminum oxide 50 µm at a maximum of 2 bar.

Caution: Do not sandblast the seating area. During the blasting procedure, use a protection analog to prevent any modification of the abutment/implant interface.

– Clean the surface as recommended by the bonding material manufacturer.

– Bond the restoration to the Universal Base according to the cement manufacturer's instructions. Use only self-adhesive dental cement/bonding material suitable for zirconium dioxide ceramics or PMMA (Polymethylmethacrylat).

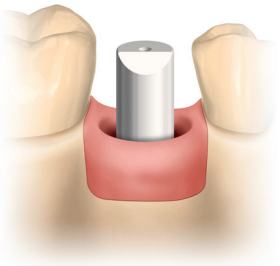


CAD/CAM workflow with 3Shape® Dental System™:

1. Scanning

– Use the ELOS™ Pinol Screwdriver to screw the ELOS™ Desktop Scan Body on the model.

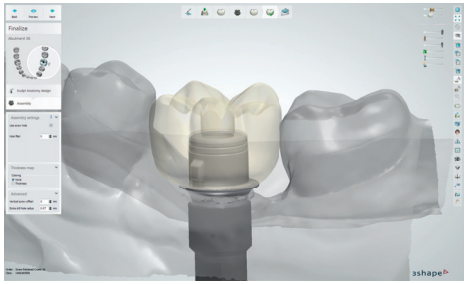
– Scan following the usual scan routines.



2. Designing

– In the implant library select the height and implant diameter for the Universal Base.

– Design the implant crown using standard CAD tools.



3. Milling

– Send the design file to a milling unit or production facility accepting 3Shape® design files.

4. Finalization

– Once the restoration is produced, finalize it following the restorative material manufacturer's instruction.

– Seal the screw channel with wax.

– Sandblast the contact surface of the Universal Base with aluminum oxide 50 µm at a maximum of 2 bar.

Caution: Do not sandblast the seating area. During the blasting procedure, use a protection analog to prevent any modification of the abutment/implant interface.

– Clean the surface as recommended by the bonding material manufacturer.

– Bond the restoration to the Universal Base according to the cement manufacturer's instructions. Use only self-adhesive dental cement/bonding material suitable for zirconium dioxide ceramics or PMMA (Polymethylmethacrylat).

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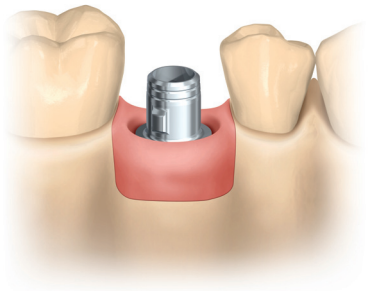
CAD/CAM workflow without component integration:

1. Scanning

– Hand-tighten the Universal Base onto the model. Make sure to use the laboratory screw.

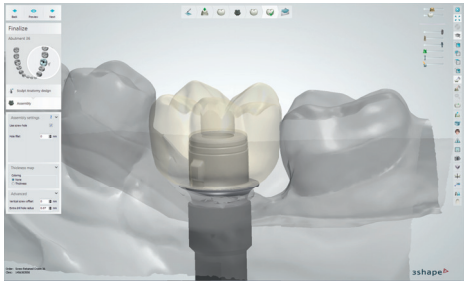
– Block out screw access hole and undercuts of the mounted Universal Base (e.g. with putty), in case the software does not support virtual blocking out.

– Scan spray may be applied.



2. Designing

– Design the implant crown using standard CAD tools.



3. Milling

– Send the design file to a milling unit or production facility that accepts the design files.

4. Finalization

– Once the restoration is produced, finalize it following the restorative material manufacturer's instruction.

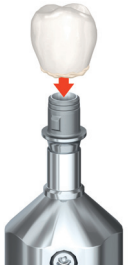
– Seal the screw channel with wax.

– Sandblast the contact surface of the Universal Base with aluminum oxide 50 µm at a maximum of 2 bar.

Caution: Do not sandblast the seating area. During the blasting procedure, use a protection analog to prevent any modification of the abutment/implant interface.

– Clean the surface as recommended by the bonding material manufacturer.

– Bond the restoration to the Universal Base according to the cement manufacturer's instructions. Use only self-adhesive dental cement/bonding material suitable for zirconium dioxide ceramics or PMMA (Polymethylmethacrylat).



Clinical procedure:

1. Remove the restoration from the implant analog.
2. Clean and disinfect the final restoration as applicable per restorative material manufacturer's instructions.
3. Remove the healing cap or temporary restoration.
4. Connect and tighten the restoration. It is recommended to verify the final abutment seating using radiographic imaging.
5. Tighten the Universal Base Abutment to **35 Ncm** using Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic.

Caution: Never exceed recommended maximum **35 Ncm** prosthetic tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Materials:

Universal Base Abutment and Abutment screw: Titanium alloy 90% Ti, 6%Al, 4%V.

Burn-out Coping: Polyoxymethylene (POM).

Cleaning and sterilization instructions:

Universal Base Abutment is delivered non-sterile and for single use. Final restoration should be cleaned and disinfected, as applicable per restorative material manufacturer's instructions, before intraoral use.

Warning: Do not use if package is damaged or previously opened.

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

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

Magnetic Resonance (MR) safety information:

Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

For additional information on Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Storage and handling:

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

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription device: Rx only
Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

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Rx Only

Non-sterile

Caution

Consult instructions for use

Do not re-use

Batch code

Do not use if package is damaged

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