Universal Base

Instruction for use

Surgical & Prosthetic Guide

Powered by Elos Accurate®

English - Instruction for use (English)
Universal Base

1. Indications for Use
The Universal Base is intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Universal Base is used as an interface between a dental implant and a zirconia superstructure and will be attached to the implant using a prosthetic screw and attached to the zirconia superstructure by cementing.

The Universal Base is compatible with the implant systems listed in table 1:

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Tri-Channel NP	3.5	3.5
Tri-Channel RP	4.3	4.3
Tri-Channel WP	5	5
Tri-Channel 6.0	6	6
Conical Connection NP	3.5	3.5 & 3.75
Conical Connection RP	3.9	4.3 & 5
Conical Connection WP	5.1	5.5
External Hex NP	3.5	3.3
External Hex RP	4.1	3.75, 4 & 5
External Hex WP	5.1	5 & 6

The zirconia superstructures for use with the Universal Base are either intended to be sent and manufactured at an FDA registered Elos Medtech approved milling facility or to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

2. Product Description
The product consists of the Universal Base and Prosthetic Screw which are manufactured from biocompatible titanium alloy grade 5 ELI (Ti6Al4V ELI). The Prosthetic Screw is uncoated or coated with a biocompatible low friction coating. The product is available for a variety of implant platforms and sizes. For specific product descriptions, please refer to above table and individual product labels.

The Universal Base is directly or indirectly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitations together with a zirconia superstructure designed and manufactured according to CAD/CAM workflow described in section 10. The zirconia superstructure can be cemented on the Universal Base. The Universal Base Non-Engaging is intended for multiple tooth dental restorations. For multiple tooth dental restorations at abutment level the Universal Base Multi-units are used as an interface between the dental abutment and the zirconia bridge. The Universal Base Multi-units are compatible with the abutment systems listed in table 2.

Table 2.

Abutment compatibility	Abutment diameter [mm]
Multi-unit Abutment NP/RP	4.8
Multi-unit Abutment WP	5.4

A temporary restoration can be used prior to the insertion of the final restoration to maintain, stabilize and form the soft tissue during the healing phase. The temporary restoration may not be placed into occlusion. The Universal Base may be placed into occlusion when the implant is fully osseointegrated.

3. Contraindications
- The Universal Base Non-Engaging is not intended for implants having a divergence angle more than 30° relatively to each other with no more than 20° per implant.
- The Universal Base Engaging is not intended for zirconia restorations angled more than 20° relative to the axis of the implant.

4. Warnings
- The Universal Base components must never be changed or modified.
- The product is for single-use only.
- Reuse of the product can result in loss of functionality and/ or infections.
- The Universal Base must be attached to the implant or abutment using the compatible Prosthetic Screw (refer to table 2).
- Since the Universal Base and Prosthetic Screw are small they must be handled with caution to avoid the risk of swallowing or aspiration by the patient.
- Place implant-borne restorations in occlusion only when the implant is completely osseointegrated.
- Always place temporary restorations out of occlusion.
- Allergies to the titanium alloy grade 5 ELI (Ti6Al4V ELI) or contents of the alloy may very rarely occur.
- The Universal Base components must be used and handled only by dental professionals.
- The use of torque value higher or lower than the recommended for the implant system according to the manufacturer's instruction may result in damage to the Universal Base, the Prosthetic screw and/or the implant
- Universal Base Non-Engaging is not intended for single tooth dental restorations.
- When mounting the Prosthetic Screw, it is important to use a manual screwdriver before using any kind of torque wrench
- Use of any abutment device, dental cement, superstructure or other ceramic materials, scanners, milling units, tools and CAD/CAM software other than those specifically identified as compatible in the labeling, may result in incorrect fit and/or damage of dental restoration.
- Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth

5. Precautions
- In order to ensure the best possible conditions for successful working of an implant, it is strongly recommended that the laboratory that designs the superstructure and the surgeon and dentist who install the components all work closely together throughout the processing of the implant.
- Only dental surgeons who have undergone approved training in dental implantology should fit the final abutment. Only laboratory employees with the relevant training should design the final abutment.

6. Potential adverse events
Potential adverse events associated with the use of the Universal Base products may include loss of integration and infection.

7. MRI Safety Information

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MRI Safety Information

A person with an Universal Base Non-Engaging Abutment, associated dental implant and prosthetic screw may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Universal Base Non-Engaging
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil
Operation Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of passive implant devices may produce an image artifact that scales with the device size

8. Cleaning and sterilization

Cleaning:
The Universal Base, Prosthetic Screw and the zirconia superstructure are delivered non-sterile. Prior to installation of the prosthetic restoration in the patient's mouth, it must be sterilized.

FDA-cleared sterilization accessories (i.e., wraps, containers, or indicators) are to be used for the recommended sterilization parameters performed by the end user.

The recommended sterilization procedure is full cycle pre-vacuum steam sterilization at a temperature of 132 °C (270˚F) for 4 minutes. Dry time: 20 minutes.

9. Surgical planning and implant insertion

Elos Medtech is not providing implants. For surgical planning and implant insertion, follow the instruction for use and surgical guide issued by the original implant manufacture.

10. Prosthetic procedure (Approved milling facility)

Using digital workflow (intra-oral scanning):

1. For detection of the precise implant position during scanning, use the Elos Accurate® Scan Body. This must be selected to be compatible with the relevant implant/abutment platform.
2. Scan the patients teeth setup by use of a dental Intra oral scanner

Optional:

3. Create a digital working model in the design software.
4. Export the STL file from the design software and send the STL file to your 3D printer or external 3D print provider.
5. Place an Elos Accurate® Analog for printed models in the 3D printed working model. This must be selected to be compatible with the relevant implant/abutment platform.

Using semi-digital workflow (desktop scanning):

1. Obtain conventional impression of patient teeth setup and create working model with placed enclosed analog to representing the implant.
2. Place an Elos Accurate® Scan Body in the analog to identify the position and orientation of this representing the implant.
3. Scan the working model by use of a dental desktop scanner.

Designing the zirconia superstructure:
The zirconia superstructure must be designed using appropriate design software with appropriate library files installed. The material thickness should not be less than 0.5 mm (screw hole to outer surface). The gingival height should not exceed 5 mm. The maximum angulation should not exceed 20°. The post height should not be less than 4 mm for single unit restorations.

1. Import the digitized patient information from the intra oral scan to the design software.
2. Import library file and select relevant implant platform from the library in order to facilitate precise design of inner geometry of the dental restoration interfacing the Universal Base.
3. Design the zirconia superstructure in the design software.
4. The digital file of the zirconia superstructure must be sent to an Elos Medtech approved milling facility for manufacturing.
5. The zirconia superstructure and the Universal Base will be sent to the dental lab with a Prosthetic Screw for finalizing the prosthetic restoration.

11. Prosthetic procedure (Digital dentistry workflow)

Using digital workflow (intra-oral scanning):

6. For detection of the precise implant position during scanning, use the Elos Accurate® Scan Body. This must be selected to be compatible with the relevant implant/abutment platform.
7. Scan the patient's teeth setup by use of an Intra oral scanner by 3shape. Scanner Accuracy must be 10µm or better (i.e. Intraoral Trios-series).

Optional:

8. Create a digital working model in the design software.
9. Export the STL file from the design software and send the STL file to your 3D printer or external 3D print provider.
10. Place an Elos Accurate® Analog for printed models in the 3D printed working model. This must be selected to be compatible with the relevant implant/abutment platform.

Using semi-digital workflow (desktop scanning):

4. Obtain conventional impression of patient teeth setup and create working model with placed enclosed analog to representing the implant.
5. Place an Elos Accurate® Scan Body in the analog to identify the position and orientation of this representing the implant.
6. Scan the working model by use of a 3shape desktop scanner. Scanner Accuracy must be 10µm or better (i.e. Lab D900, D2000, E-series and D/R2000).

Designing the zirconia superstructure:
The zirconia superstructure must be designed using 3shape Dental System design software with the relevant Universal Base library files installed.

The Universal Base library file can be obtained via the 3Shape server in the software.

Operation manual for 3Shape Dental System can be accessed from: www.3shape.com.

The Elos Accurate library file has built-in design limitations and the user isn't allowed to exceed these limitations. The material thickness should not be less than 0.5 mm (screw hole to outer surface). The gingival height should not exceed 5 mm. The maximum angulation should not exceed 20°. The post height should not be less than 4 mm for single unit restorations.

6. Import the digitized patient information from the intra oral scan to the design software.
7. Import library file and select relevant implant platform from the library in order to facilitate precise design of inner geometry of the dental restoration interfacing the Universal Base
8. Design the zirconia superstructure in the design software.
9. Send the digital file of the zirconia superstructure to an CORiTEC 350i Pro milling machine by Imes-Icore with iCAM V5 smart CAM-software using preset settings and manufacture the part with an Ø1 mm radius tooling for dental zirconia according to manufacturer's instructions.
10. The zirconia superstructure must be created from 3M™ ESPE™ Lava™ Plus High Translucency Zirconia. Ones it has been produced it must be sintered according to manufactures instruction.

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12. Cementing

Preparing the dental restoration for cementing:

1. Blast inner geometry of the milled zirconia superstructure interfacing the Universal Base with aluminum oxide 50-150 µm and blasting pressure of 2 bar.
2. Clean the bonding surface of zirconia and Universal Base thoroughly with alcohol or KATANA™ Cleaner by Kuraray Noritake.

Note: Do not blast the Universal Base.

Cementing the dental restoration:

1. Seal the screw channels with wax.
2. Apply a primer to the bonding surface of zirconia and Universal Base and let it react according to manufactures instruction. Monobond Plus Primer by Ivoclar Vivadent® or CLEARFIL™ CERAMIC PRIMER PLUS by Kuraray Noritake is recommended.
3. Apply self-adhesive dental cement on the the Universal Base. Multilink® Hybrid Abutment Cement by Ivoclar Vivadent® or PANAVIA V5 cement by Kuraray Noritake is recommended. The manufacturer's instructions must be followed. Bond the milled dental restoration to the Universal Base placed in the working model. The milled dental restoration must fit the Universal Base without gaps and voids.
4. Immediately remove excess cement from the Universal Base.

13. Use and handling for the dentist

The dentist receives the final dental restoration / working model with the Prosthetic screw from the dental lab.

1. Identify and unpack the Prosthetic screw(s).
2. Clean, disinfect and sterilize dental restoration and Prosthetic screw(s) according to this instruction for use.
3. Remove the healing cap, closure screw or temporary restoration from patient's mouth.
4. Gently, insert the dental restoration into the patient's mouth in proper position to the implant(s) or abutment(s).
5. Place corresponding Prosthetic screw(s) in the dental restoration and tighten screw(s) to the recommended torque (refer to individual screw label or table 3 & 4).
6. In order to obtain the recommended torque a dental torque wrench with a suitable screwdriver must be used in accordance with the relevant manufacturer's instructions.
7. Additionally, if cementing of the dental restoration and the Universal Base must be done intraorally, place Universal Base in the milled dental restoration with correct rotation.
8. Seal the screw channels with wax.
9. Apply the above recommended primer and self-adhesive dental cement on the Universal Base and zirconia bonding surface. Follow the instruction for use of both the dental restoration material and cement material manufacturer.
10. Bond the milled dental restoration to the Universal Base. The milled dental restoration must fit the Universal Base without gaps and voids. Immediately remove excess cement from the Universal Base.

The recommended screw torque for the Universal Base is listed in table 3 & 4.

Table 3 Recommended screw torque - Universal Base

Implant Platform compatibility	Recommended Screw torque
Tri-Channel NP	35 Ncm
Tri-Channel RP	35 Ncm
Tri-Channel WP	35 Ncm
Tri-Channel 6.0	35 Ncm
Conical Connection NP	35 Ncm
Conical Connection RP	35 Ncm
Conical Connection WP	35 Ncm
External Hex NP	35 Ncm
External Hex RP	35 Ncm
External Hex WP	35 Ncm

Table 4 Recommended screw torque - Universal Base Multi-unit

Abutment Platform compatibility	Recommended Screw torque
Multi-unit Abutment NP/RP	15 Ncm
Multi-unit Abutment WP	15 Ncm

14. Instruction for use and maintenance of milling equipment

The original operating manual and maintenance guide for the CORiTEC 350I series by Imes-Icore can be requisitioned by contacting: support@imes-icore.de.

15. Further information

For additional information about the use of Elos Medtech products, please contact your local sales representative.

16. Validity

Upon publication of this instruction for use, all previous versions are superseded.

17. Storage and Handling

Universal Base should be stored at room temperature.

18. Disposal

The dental restoration must be disposed as biological waste.

19. Symbols

REF	Catalogue number
LOT	Batch code
	Manufacturer
	Consult instructions for use
	Do not re-use
Rx	Prescription only
	Do not use if package is damaged
NON STERILE	Non sterile
	Recommended torque
	Date of manufacture
MD	Medical Device

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UDI	Unique Device Identifier
	Keep dry
	Keep away from sunlight
	MR Conditional

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