Elos Accurate® Hybrid Base™

Instruction for use

Surgical & Prosthetic Guide

English - Instruction for use (English)
Elos Accurate® Hybrid Base™

1. Indications for Use
The Elos Accurate® Hybrid Base™ is intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Hybrid 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 Elos Accurate® Hybrid Base™ is compatible with the implant systems listed in table 1:

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Nobel Replace NP	3.5	3.5
Nobel Replace RP	4.3	4.3
Nobel Replace WP	5	5
Nobel Replace 6.0	6	6
Nobel CC 3.0	3	3
Nobel CC NP	3.5	3.5 & 3.75
Nobel CC RP	3.9	4.3 & 5
Nobel CC WP	5.1	5.5
Straumann Bone Level NC	3.3	3.3
Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8
Astra Tech 3.0	3	3
Astra Tech 3.5/4.0	3.5 & 4	3.5 & 4
Astra Tech 4.5/5.0	4.5 & 5	4.5 & 5
Astra Tech EV 3.0	3	3
Astra Tech EV 3.6	3.6	3.6
Astra Tech EV 4.2	4.2	3.6 & 4.2
Astra Tech EV 4.8	4.8	4.2 & 4.8
Astra Tech EV 5.4	5.4	5.4
Brånemark NP	3.5	3.3
Brånemark RP	4.1	3.75, 4 & 5
Brånemark WP	5.1	5 & 6

The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are either intended to be sent and manufactured at a 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 Elos Accurate® Hybrid Base™ and Elos Prosthetic Screw which are manufactured from biocompatible titanium alloy grade 5 ELI (Ti6Al4V ELI). The Elos 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 Elos Accurate® Hybrid 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 Elos Hybrid Base™. The Hybrid Base™ Engaging is intended for single tooth dental restorations and the Hybrid Base™ Non-Engaging is intended for multiple tooth dental restorations. For multiple tooth dental restorations at abutment level the Elos Accurate® Hybrid Base™ copings are used as an interface between the dental abutment and the zirconia bridge. The Elos Accurate® Hybrid Base™ copings are compatible with the abutment systems listed in table 2.

Table 2.

Abutment compatibility	Abutment diameter [mm]
Astra Tech UniAbutment 20°	3
Astra Tech UniAbutment 45°	3.5 & 4
Astra Tech Uni Abutment EV	3
Straumann Screw-Retained Abutment Ø3.5	3.6
Straumann Screw-Retained Abutment Ø4.6	4.2
Multi-unit NP/RP	4.8
Multi-unit WP	5.4
Ankylos Balance Base	4.2
Camlog Bar Abutment 3.3/3.8/4.3	4.3

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 Hybrid Base™ may be placed into occlusion when the implant is fully osseointegrated.

3. Contraindications
- The Elos Accurate® Hybrid 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 Elos Accurate® Hybrid Base™ Non-Engaging with straight chimney (HBN-XXXXXH-1) is not intended for intra-oral cementation.
- The Elos Accurate® Hybrid Base™ Engaging is not intended for zirconia restorations angled more than 20° relative to the axis of the implant.

4. Warnings
- The Elos Accurate® Hybrid 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 Elos Accurate® Hybrid Base™ must be attached to the implant or abutment using the compatible Prosthetic Screw (refer to table 2).
- Since the Hybrid 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 Elos Accurate® Hybrid 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 Hybrid Base™, the Prosthetic screw and/or the implant
- Elos Accurate® Hybrid 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

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employees with the relevant training should design the final abutment.

6. Potential adverse events

Potential adverse events associated with the use of the Elos Accurate® Hybrid Base™ products may include loss of integration and infection.

7. Use in MR (Magnetic Resonance) environment

MRI Safety Information

A person with an Elos Accurate® Hybrid Base™.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	Elos Accurate® Hybrid Base™.
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 Elos Accurate® Hybrid Base™, Elos 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 Hybrid 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 Elos Accurate® Hybrid Base™ will be sent to the dental lab with an Elos 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 Elos Accurate library files installed.

Elos Accurate library file can be downloaded from:
https://elosdental.com/libraries.

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 Hybrid Base™
8. Design the zirconia superstructure in the design software.

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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.

12. Cementing

Preparing the dental restoration for cementing:

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

Note: Blasting of Hybrid Base™ is not necessary, but if blasted make sure to protect the implant/abutment interface.

Cementing the dental restoration:

1. Seal the screw channels with wax.
2. Apply a primer to the bonding surface of zirconia and Hybrid 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 Hybrid 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 Hybrid Base™ placed in the working model. The milled dental restoration must fit the Hybrid Base™ without gaps and voids.
4. Immediately remove excess cement from the Hybrid 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 Hybrid Base™ must be done intraorally, place Hybrid 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 Hybrid 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 Hybrid Base™. The milled dental restoration must fit the Hybrid Base™ without gaps and voids. Immediately remove excess cement from the Hybrid Base™.

The prosthetic screw compatibility for the Elos Accurate® Hybrid Base™ is listed in table 3 & 4.

Table 3 Prosthetic screw compatibility - Hybrid Base™

Implant Platform compatibility	Prosthetic screw	Recommended Screw torque
Nobel Replace NP	AS-NBRM1808A-1 AS-NBRM1808POS	35 Ncm
Nobel Replace RP	AS-NBRM2010A-1 AS-NBRM2010POS	35 Ncm
Nobel Replace WP		
Nobel Replace 6.0		
Nobel CC 3.0	AS-NBAM1407A-1 AS-NBAM1407POS	15 Ncm
Nobel CC NP	AS-NBAM1608A-1 AS-NBAM168POS	35 Ncm
Nobel CC RP	AS-NBAM2007A-1 AS-NBAM207POS	35 Ncm
Nobel CC WP		
Straumann Bone Level NC	AS-SBOM1608A-1 AS-SBOM1608POS	35 Ncm
Straumann Bone Level RC		
Astra Tech 3.0	AS-ATOM1408A-1 AS-ATOM148POS	15 Ncm
Astra Tech 3.5/4.0	AS-ATOM1608A-1 AS-ATOM168POS	20 Ncm
Astra Tech 4.5/5.0	AS-ATOM2010A-1 AS-ATOM2010POS	25 Ncm
Astra Tech EV 3.0	AS-ATEM1408A-1 AS-ATEM148POS	25 Ncm
Astra Tech EV 3.6	AS-ATEM1608A-1 AS-ATEM168POS	25 Ncm
Astra Tech EV 4.2	AS-ATEM1808A-1 AS-ATEM188POS	25 Ncm
Astra Tech EV 4.8	AS-ATEM2008A-1 AS-ATEM208POS	25 Ncm
Astra Tech EV 5.4		
Brånemark NP	AS-BRAM1607A-1 AS-BRAM167POS	35 Ncm
Brånemark RP	AS-BRAM2007A-1 AS-BRAM207POS	35 Ncm
Brånemark WP	AS-BRAM2507A-1 AS-BRAM257POS	35 Ncm

Table 4 Prosthetic screw compatibility - Hybrid Base™ Coping

Abutment Platform compatibility	Prosthetic screw	Recommended Screw torque
Multi-unit NP/RP	AS-MUAM1403A-1 AS-MUAM1403POS	15 Ncm
Multi-unit WP	AS-MUAM1804A-1 AS-MUAM1804POS	15 Ncm
Ankylos Balance Base	AS-DBAM1605A-1	10 Ncm
Camlog Bar Abutment 3.3/3.8/4.3	AS-CBAM1604A-1	15 Ncm
Astra Tech Uni Abutment EV	AS-AUEM1805A-1	15 Ncm
Astra Tech UniAbutment 20°	AS-ATUM1405A-1	15 Ncm
Astra Tech UniAbutment 45°		
Straumann Screw-Retained Abutment Ø3.5	AS-SSAM1404A-1	15 Ncm
Straumann Screw-Retained Abutment Ø4.6		

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

Elos Accurate® Hybrid Base™ should be stored at room temperature.

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18. Disposal

The dental restoration must be disposed as biological waste.

19. Symbols

	Catalogue number
	Batch code
	Manufacturer
	Consult instructions for use
	Do not re-use
	Prescription only
	Do not use if package is damaged
	Non sterile
	Recommended torque
	Date of manufacture
	Medical Device
	Unique Device Identifier
	Keep dry
	Keep away from sunlight
	MR Conditional

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