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 or dental abutment and a zirconia superstructure and will be attached to the implant or abutment using the included 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.

Elos Accurate® Hybrid Base™ – Model Type	Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
HBE-NBR35 & HBN-NBR35	Nobel Replace NP	3.5	3.5
HBE-NBR43 & HBN-NBR43	Nobel Replace RP	4.3	4.3
HBE-NBR50 & HBN-NBR50	Nobel Replace WP	5	5
HBE-NBR60 & HBN-NBR60	Nobel Replace 6.0	6	6
HBE-NBA30	Nobel CC 3.0	3	3
HBE-NBA35 & HBN-NBA35	Nobel CC NP	3.5	3.5 & 3.75
HBE-NBA43 & HBN-NBA43	Nobel CC RP	3.9	4.3 & 5
HBE-NBA60 & HBN-NBA60	Nobel CC WP	5.1	5.5
HBE-SBO33 & HBN-SBO33	Straumann Bone Level NC	3.3	3.3
HBE-SBO41/4.8 & HBN-SBO41/48	Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8
HBE-ATO30	Astra Tech 3.0	3	3
HBE-ATO35	Astra Tech 3.5/4.0	3.5 & 4	3.5 & 4
HBE-ATO45	Astra Tech 4.5/5.0	4.5 & 5	4.5 & 5
HBE-ATE30	Astra Tech EV 3.0	3	3
HBE-ATE36	Astra Tech EV 3.6	3.6	3.6
HBE-ATE42	Astra Tech EV 4.2	4.2	3.6 & 4.2
HBE-ATE48	Astra Tech EV 4.8	4.8	4.2 & 4.8
HBE-ATE54	Astra Tech EV 5.4	5.4	5.4

All digitally designed zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are only intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility.

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. 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 the abutment level the Elos Accurate® Hybrid Base™ copings presented in Table 2 are used as an interface between the dental abutment and the zirconia bridge.

Table 2.

Elos Accurate® Hybrid Base™ coping – Model Type	Abutment compatibility	Abutment diameter [mm]
HBN-ATU20	Astra Tech UniAbutment 20°	3
HBN-ATU45	Astra Tech UniAbutment 45°	3.5 & 4
HBN-AUE33	Astra Tech Uni Abutment EV	3
HBN-SSA35	Straumann Screw-Retained Abutment Ø3.5	3.6
HBN-SSA46	Straumann Screw-Retained Abutment Ø4.6	4.2
HBN-MUA45	Multi-unit NP/RP	4.8
HBN-MUA60	Multi-unit WP	5.4
HBN-DBA40	Ankylos Balance Base	4.2
HBN-CBA43	Camlog Bar Abutment 3.3/3.8/4.3	4.3

Elos Medtech Pinol A/S
Engvej 33
DK - 3330 Gørløse
www.elosmedtech.com

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.
- 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.
- The Hybrid Base™ and Prosthetic Screw have not been evaluated for safety, heating, migration or compatibility in the Magnetic Resonance Imaging (MRI) environment.
- 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.
- Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth
- When mounting the Prosthetic Screw, it is important to use a manual screwdriver before using any kind of torque wrench

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 Elos Accurate® Hybrid Base™ products may include: loss of integration and infection.

7. Use in MR (Magnetic Resonance) environment
The Elos Accurate® Hybrid Base™ has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Elos Accurate® Hybrid Base™ products in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

Sterilization:
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

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.

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. Before cementing, clean the surface thoroughly with alcohol.

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 self-adhesive dental cement on the the Hybrid Base™. Multilink® Hybrid Abutment Cement by Ivoclar Vivadent® 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.
3. Immediately remove excess cement from the Hybrid Base™.

11. 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 2 & 3).
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™ has to 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 self-adhesive dental cement on the the Hybrid Base™. 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™.

Table 2.

Elos Accurate® Hybrid Base™ – Model Type	Prosthetic screw	Recommended Screw torque
HBE-NBR35 & HBN-NBR35	AS-NBRM1808A-1	35 Ncm
HBE-NBR43 & HBN-NBR43	AS-NBRM2010A-1	35 Ncm
HBE-NBR50 & HBN-NBR50		
HBE-NBR60 & HBN-NBR60		
HBE-NBA30	AS-NBAM1407A-1	15 Ncm
HBE-NBA35 & HBN-NBA35	AS-NBAM1608A-1	35 Ncm
HBE-NBA43 & HBN-NBA43	AS-NBAM2007A-1	35 Ncm
HBE-NBA60 & HBN-NBA60		
HBE-SBO33 & HBN-SBO33	AS-SBOM1608A-1	35 Ncm
HBE-SBO41/4.8 & HBN-SBO41/48		
HBE-ATO30	AS-ATOM1408A-1	15 Ncm
HBE-ATO35	AS-ATOM1608A-1	20 Ncm
HBE-ATO45	AS-ATOM2010A-1	25 Ncm
HBE-ATE30	AS-ATEM1408A-1	25 Ncm
HBE-ATE36	AS-ATEM1608A-1	25 Ncm
HBE-ATE42	AS-ATEM1808A-1	25 Ncm
HBE-ATE48	AS-ATEM2008A-1	25 Ncm
HBE-ATE54		

Elos Medtech Pinol A/S
Engvej 33
DK - 3330 Gørløse
www.elosmedtech.com

Table 3.

Elos Accurate® Hybrid Base™ coping – Model Type	Prosthetic screw	Recommended Screw torque
HBN-ATU20	AS-ATUM1405A-1	15 Ncm
HBN-ATU45		
HBN-AUE33	AS-AUEM1805A-1	15 Ncm
HBN-SSA35	AS-SSAM1404A-1	15 Ncm
HBN-SSA46		
HBN-MUA45	AS-MUAM1403A-1	15 Ncm
HBN-MUA60	AS-MUAM1804A-1	15 Ncm
HBN-DBA40	AS-DBAM1605A-1	10 Ncm
HBN-CBA43	AS-CBAM1604A-1	15 Ncm

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

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

14. Storage and Handling
Elos Accurate® Hybrid Base™ should be stored at room temperature.

15. Disposal
The dental restoration must be disposed as biological waste.

16. 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


Elos Medtech Pinol A/S
Engvej 33
DK - 3330 Gørløse
www.elosmedtech.com