Elos Accurate® Customized Abutment

Instruction for use

Surgical & Prosthetic Guide

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Electronic IFU can be accessed at: www.elosmedtech.com/ifu
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English - Instruction for use (for US only)

Elos Accurate® Customized Abutment

Secondary brand name: Elos Accurate® Custom Ti Abut.

1 Indications for Use

The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.

The Elos Accurate® Customized Abutments are compatible with the implant systems listed in table 1:

Table 1.

Elos Accurate Customized Abutment – Model Type	Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
AB-NBR35	Nobel Replace NP	3.5	3.5
AB-NBA30	Nobel CC 3.0	3	3
AB-NBA43	Nobel CC RP	3.9	4.3 & 5
AB-NBA60	Nobel CC WP	5.1	5.5
AB-SBO33	Straumann Bone Level NC	3.3	3.3
AB-SBO41	Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8

All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments 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® Customized Abutment and Elos Prosthetic Screw which are manufactured from biocompatible titanium alloy grade 5 ELI ($TiAl_6V_4$ ELI). The Elos Accurate® Customized Abutment is created from the Abutment Blank. The Elos Prosthetic Screw can be layered 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.

3 Contraindications

- The Elos Accurate® Customized Abutment is not intended for restorations requiring an angle more than 30° to the axis of the implant.
- Allergies to the alloy or contents of the alloy may very rarely occur.
- The Elos Accurate® Customized Abutment cannot be combined with implants of a different implant type or manufacturer than stated on the label.

4 Warnings

- Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.
- Only the compatible Elos Prosthetic Screw must be used to secure the Elos Accurate® Customized Abutment to the implant. Use of other screws than the Elos Prosthetic Screw may result in loss of functionality and/or infections.
- The use of torque value higher than the recommended may result in damage to the Elos Accurate® Customized Abutment, the Elos Prosthetic Screw and/or the implant. The use of torque values lower than those recommended may result in loosening of the Elos Accurate® Customized Abutment, which may result in damage to the Elos Accurate® Customized Abutment and/or the implant.
- The interface of the Elos Accurate® Customized Abutment, which being connected to the implant, must never be changed or modified. Modifications of the interface may result in loss of functionality and/ or infections.
- The Elos Accurate® Customized Abutment is for single use only. Reuse can result in loss of functionality and/ or infections.
- Since the final abutments are small, they must be handled with caution to avoid the patient swallowing or inhaling them. It is recommended that they are handled using forceps.

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 structure and applies porcelain 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® Customized Abutment products may include: failure to integrate, loss of integration and infection.

7 Use in MR (Magnetic Resonance) environment

The Elos Accurate® Customized Abutment 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® Customized Abutment 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® Customized Abutment and Elos Prosthetic Screw are delivered non-sterile. Prior to instalation of the prosthetic restoration in the patient's mouth, it must be cleaned with water and brush followed by sterilization.

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

Impression techniques:

Impression of the teeth setup could be done by conventional impression technique or by intra oral scanning.

Conventional impression:

1. Obtain conventional impression of patient teeth setup.
2. Create working model and place the enclosed model analog.
3. Place preferable an Elos Accurate® Scan Body in the model analog.
4. By use of an Elos Accurate® Scan Body, scan the working model.

Intra oral scanning:

For precise detection of implant position during intra oral scanning, use an Elos Accurate® Scan Body compatible with the original implant system.
The working model can be created from the intra oral digital scan by 3D-printing.

Designing the Elos Accurate® Customized Abutment:

The Elos Accurate® Customized Abutment must be designed using FDA approved design software as outlined below. Guidelines for minimum material

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thicknesses, minimum post height, minimum collar height and maximum angles are shown in figure 1. The screw head must not be exposed when designing the Elos Accurate® Customized Abutment.

1. In order to identify the position and orientation of the respective implant, import the digitized patient information from the intra oral scan to the design software by use of an Elos Accurate® Scan Body.
2. Use appropriate library file and select relevant implant platform from the library.
3. Design the Elos Accurate® Customized Abutment in the design software.
4. The digital file of the Elos Accurate® Customized Abutment must be send to an Elos Medtech approved milling facility for manufacturing.
5. The Elos Accurate® Customized Abutment will be sent to the dental lab with a prosthetic screw for finalizing the prosthetic restoration.

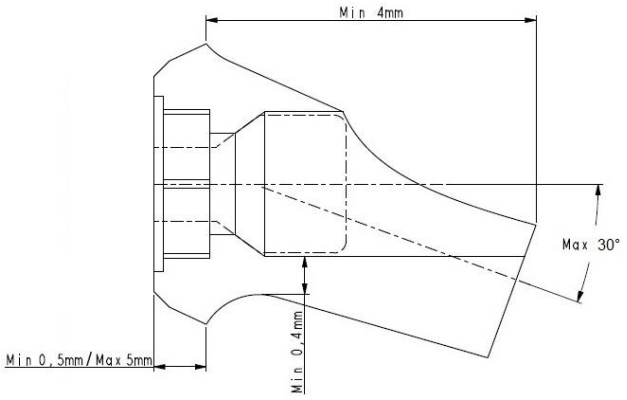

Figure 1

Finalizing the prosthetic restoration:

1. Place the Elos Accurate® Customized Abutment in the working model with the model analog and a process screw.
2. Complete the crown/bridge restoration following routine laboratory procedures.

Clinical procedure:

1. The final prosthetic restoration is attached to the implant using the corresponding Elos Prosthetic Screw.
2. The Elos Prosthetic Screw is tightened to therecommended torque (refer to individual screw label or table 2).
3. In order to obtain the recommended torque a dental torque wrench with a suitable screw driver must be used in accordance with the relevant manufacturer's instructions
4. The screw channel must always be sealed after the abutment is attached to the implant.

Table 2.

Elos Accurate Customized Abutment – Model Type	Elos Prosthetic screw	Recommended Screw torque
AB-NBR35	AS-NBRM1808POS	35 Ncm
AB-NBA30	AS-NBAM1407POS	15 Ncm
AB-NBA43	AS-NBAM207POS	35 Ncm
AB-NBA60		
AB-SBO33	AS-SBOM1608POS	35 Ncm
AB-SBO41		

11 Caution

U.S. Federal Law restricts this device to sale by or on order of a dentist or physician.

12 Further information

For additional information about the use of Elos Medtech products, please contact your local sales representative or send an email to: dentalsupport@elosmedtech.com

13 Validity

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

14 Disposal

The prosthetic restoration must be disposed as biological waste.

15 Signs and symbols

Catalogue number

Batch code


Manufacturer


Consult instructions for use


Do not re-use

Prescription only

Non sterile

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