

# ENGLISH | INSTRUCTIONS FOR USE OF AB DENTAL GERMANY UG (Haftungsbeschränkt) PROSTHETIC ACCESSORIES

**DISCLAIMER:** AB Dental Germany UG (Haftungsbeschränkt) products are intended for use only by certified dentists and authorized personnel with specific implant training. All devices are for prescription use only.

**CAUTION:** Federal (USA) law restricts the sale of this device to, or on the order of a licensed physician or dentist.

## GENERAL:

The Dental Implants and Dental Prosthetics System is consisting of Biocompatible Raw Material: Titanium Alloy Grade-23 which meets the International Standard ASTM F-136 Standard Specification of Wrought Titanium-6Aluminium-4Vanadium ELI Alloy for Surgical Implant Applications. The abutments are also available in PEEK, Gold alloy or Cobalt Chrome alloy Biocompatible Raw Materials. Dental Prosthetics products are attached to implants or screw retained abutments during the restoration procedure. The prosthetics products are available in implant standard and narrow platforms as well as screw retained platform and in verity of dimensions. Dental abutments/Attachments/Sleeves are for Single Use Only.

Dental abutments/attachments that bare Hexagon connection to the implant and sleeves are provided with a screw while healing caps, straight screw retained and straight attachments – that are non-engaged (rotational) have an integrated screw feature and therefore are not provided with a separate screw.

In order to install or remove the abutment for any reason, use prosthetic drivers T1 or T2.

## INDICATIONS:

AB Dental Germany UG (Haftungsbeschränkt) Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

AB Dental Germany UG (Haftungsbeschränkt) Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

## WARNINGS:

PEEK Temporary Abutments are not to exceed 29 days. Use of non-sterile components may lead to infection of tissues infectious diseases.

Small diameter implants and their corresponding angled abutments are not recommended for the posterior region of the mouth.

Narrow platform angled abutments (P4, P14, P64) should only be used in cases of low mechanical load. Placement in the molar region is not recommended.

## CAUTION:

Except from the scan abutment/bodies these products are single use products that must not be reprocessed. Re-processing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

## CONTRAINDICATIONS:

Customary observations should be made of the contraindications associated with implant materials used in oral surgery. The patient's general health and suitability for oral surgery must be assessed by the general practitioner.

- Insufficient bone, complicated grafting surgery.
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- Smoking, poor oral hygiene, nutrition, drug use, alcohol use.
- Illnesses like diabetes, Malnutrition, Haemophilia, autoimmune disorders.
- Involuntary tooth grinding during sleep, Bruxism.

## STORAGE AND HANDLING:

The products must be inspected prior to usage. The products should be stored at room temperature. Special care should be taken with the handling of the scan abutments, to avoid any mechanical damage. Worn out scan abutment/body must be discarded and not be used.

## CLEANING INSTRUCTIONS:

Rinse product in lukewarm distilled water for two and a half minutes. Sonicate for 10 minutes after cleaning the product with an ultrasonic cleaner and enzymatic detergent. Rinse with distilled water for three minutes.

## STERILIZATION INSTRUCTIONS:

Dental Abutments and Accessories are provided non-sterile. Prior to their use they must be clean and then sterilize in an autoclave:

Following the cleaning, seal the device in a single pouch and sterile in a steam autoclave for 15 minutes at a temperature of 270°F (132°C), dry time 15-30 minutes. Cooling time at room temperature is 10 minutes.

## MR SAFETY INFORMATION:

AB Dental Abutments have not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of AB Dental Prosthetic Device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## GENERAL CLOSURE TORQUES:

It is highly recommended to close products with calibrated torque wrench according to the following torques:

Product	Closure Torque
Healing abutment, Implant cover screw, Scan abutment/body	Manual torque – up to 15Ncm
Screw for final or temporary abutment	Standard Platform 30Ncm Narrow Platform 25Ncm
P14c	35Ncm
Sleeve screw for final straight screw retained abutment	Standard Platform 25Ncm Narrow Platform 20Ncm
Sleeve screw for final angular screw retained abutment	30Ncm

## Titanium Healing Caps

### P0

The healing caps made of Titanium alloy are intended for threading to the implant or screw retained abutments to maintain/facilitate the opening through the soft tissue until the restoration is completed.

The healing cap is secured to the implant using integrated hexagon feature.

## Temporary Abutments/Sleeves

### P3-PEEK/P4S-PEEK/P14-bT/P64-bT

Pre-fabricated abutments/sleeves made of Titanium alloy or PEEK are intended for shaping as required anatomically and cementation of the prosthetic crown/bridge on them.

Anti-rotation abutment for crown includes engaged Hexagon connection to the implant platform while rotational abutments are without Hexagon and intended for bridge restorations.

Abutment is secured with screw to the implant with the recommended closure torque according to the implant platform.

## Cement Retained Abutments

### Straight P3/P3S; Angular P4/P4S;

Pre-fabricated straight, angular, or anatomic shape abutments made of Titanium alloy are intended for shaping as required anatomically and cementation of the prosthetic crown/bridge on them. Anti-rotation abutment for crown includes engaged Hexagon connection to the implant platform while rotational abutments are without Hexagon and intended for bridge restorations.

Abutment is secured with screw to the implant with the recommended closure torque according to the implant platform.

## Screw Retained Abutments and Sleeves

### Straight P12/P16/P64; Angular P14/P64

Pre-fabricated straight or angular abutments made of Titanium alloy and are not intended to be shaped. The straight abutments don't include engaged Hexagon connection to the implant platform while the angular abutments include. Pre-fabricated Titanium alloy sleeves for the screw retained abutments are intended to be shaped as required anatomically and cementation of the prosthetic crown/bridge on them.

Pre-fabricated Cobalt-Chrome casting or plastic sleeves for the screw retained abutments are intended for creation of customized sleeves as required anatomically and cast the prosthetic crown/bridge on them. The Cobalt-Chrome sleeves can be cast only with appropriate Cobalt-Chrome metals while the plastic sleeves can be cast with noble or Cobalt-Chrome metals.

It is recommended not to exceed the casting temperature of the Cobalt-Chrome abutment above 1300°. The metal portion of the sleeves connection to the screw retained abutments or to the implants (in the case of P12) must be protected in case sand blast is used to rough the surface of the casted portion. Clean and sterilized the abutments before final use within the patient.

Abutment is secured with screws to the implant with the recommended closure torque according to the implant platform, while the sleeve secured with sleeve screw to the screw retained abutment according to the screw retained platform.

## Casting Abutments (Composed Abutments)

### P9

Pre-fabricated casting abutments made of Cobalt-Chrome or Gold alloys base and press on plastic sleeves and are intended for creation of customized abutments as required anatomically and cast the prosthetic crown/bridge on them. The Cobalt-Chrome based abutment can be cast only with Cobalt-Chrome metals while the Gold based abutments can be cast only with noble metals.

It is recommended not to exceed the casting temperature of the Cobalt-Chrome abutment above 1300° and the casting temperature of the Gold abutment above 1350°. The metal portion of the abutments connection to the implant must be protected in case sand blast is used to rough the surface of the casted portion.

Anti-rotation abutment for crown includes engaged Hexagon connection to the implant platform while rotational abutments are without Hexagon and intended for bridge restorations.

Abutment is secured with screw to the implant with the recommended closure torque according to the implant platform.

## Plastic Sleeves

### P2

The plastic sleeves casting abutments made of plastic are intended for creation of customized abutments as required anatomically and cast the prosthetic crown/bridge on them. The plastic sleeves can be cast with noble or Cobalt-Chrome metals.

Clean and sterilized the abutment before final use within the patient.

Anti-rotation abutment for crown includes engaged Hexagon connection to the implant platform while rotational abutments are without Hexagon and intended for bridge restorations.

Abutment is secured with screw to the implant with the recommended closure torque according to the implant platform.

## Ball/AB LOC Attachments

### Straight P5/P25; Angular P5/20 P25/20

Pre-fabricated straight or angular attachments made of Titanium alloy that incorporate an attachment/snap geometry are intended for overdenture, that snaps into a nylon cap/metal housing and is retained in the denture. Anti-rotation angular attachments include engaged Hexagon connection to the implant platform while straight attachments are without. The straight attachment is secured to the implant using integrated hexagon feature while the angular attachment is secured with screws to the implant. The recommended closure torque is according to the implant platform.

## Scan Abutments/Bodies

### P3,SC/P14,SC/P64,SC

The scan abutments/bodies intended to transfer the implant/Multiunit (screw retained abutment) position and orientation data (in patient mouth or cast model) to a digital file for later prosthetic restoration planning.

The scan abutments/bodies can be used as intraoral scan abutment or cast model scan abutment/bodies and intended for multiple use.

The scan abutments/bodies are made of Biocompatible PEEK with at least 2 flat surfaces for easy and accurate alignment/registration of scan image with the library model. The scan abutment/body correlate with the implant or screw retained connection. For better scanning precision we recommend locating the flat surfaces in palatal/lingual orientation. For use with angled implant/abutment, the short flat face on the scan abutment should be aligned with the slanted (Buccal) side of the base.

Scan abutment/body is secured with screw to the implant or screw retained abutment with the recommended closure torque according to the relevant platform.

The different scan abutments/bodies correspond with the respective platform (implants or screw retained) and differ in shapes/sizes. The scanning process should be performed as recommended by scanning/CADCAM system. It is important to choose the correct platform in software and corresponding type for the chosen restoration (engaging/non-engaging). After use the scan abutment can be loosened and placed

gently on the storage.

Scan abutments must be cleaned and sterile prior to use in patient mouth. Please follow cleaning/sterile instructions.

## Titanium Bases and Titanium Adhesive Sleeves

### P3, P14/P64

Pre-fabricated straight abutments/sleeves made of Titanium alloy or Cobalt-Chrome alloy are not intended to be shaped. Anti-rotation abutment for crown includes engaged Hexagon connection to the implant platform while rotational abutments are without Hexagon and intended for bridge restorations.

Abutment/Sleeve is secured with screw to the implant or screw retained abutment with the recommended closure torque according to the relevant platform.

## Analog/Digital Model Analog

### D1

The Digital Model Analogs are analogs for plastic printed model and will serve to simulate the implants or screw retained abutments location and orientation in the jaw model. These analogs and their screw will be made from Stainless Steel or Titanium alloy.

## CADCAM Libraries

The CADCAM Libraries are to be used with dedicated dental CAD software's that will allow transferring the data gathered from the patient mouth/jaw to the technician (via the software libraries) in order to create the prosthetics work.

The company CADCAM products have supported libraries for the leading CAD software's. These libraries were developed, tested and validated according to each software requirements.

The company holds the rights to change and update the libraries content according to the software manufacturers and the company CADCAM products portfolio.

The most updated libraries can be downloaded from the company website [search CADCAM Libraries at [www.ab-dent.com](http://www.ab-dent.com)].

Please refer to each software provider in order to install/upload the CADCAM libraries.

Please follow each CADCAM software instructions in order to create your required dental prosthetics restoration creation.

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	<b>Symbol for Do not reuse</b> ISO 15223-1:2012 (5.4.2)
	<b>Symbol for Caution</b> Indicated the need to consult the instructions for use for important cautionary
	<b>CE marking of conformity</b> Complies with the requirements of directive 93/42/EEC for medical device
	<b>Symbol for Batch code</b> Lot number
	<b>Consult instructions for use</b>
	<b>Date of manufacture</b>
	<b>Manufacturer</b>
	<b>Has not been subjected to a sterilization process</b>
	<b>Federal law restricts this device to sale by or on the order of a Dentist</b>

