

## INSTRUCTIONS FOR USE: ADVAN PROSTHETIC COMPONENTS

### PRODUCT DESCRIPTION AND INDICATIONS

The Advan prosthetic line, made up of secondary components and related prosthetic and/or accessory components, is used for the restoration of Advan dental and zygomatic implants of different types, endosseous diameters, lengths and implant/prosthetic connections. These components are available in various shapes and sizes to meet any patient need. These instructions for use are valid for Analogs, Scan abutments, Transfer, Cover screws, Healing abutments/caps, Temporary abutments, EASy abutments, EASy Skin-Caps, Multi-Unit Abutments, Gingival Former Abutments, Titanium bases for CAD/CAM rehabilitations (Ti-Base and Uni-Base), MORPHO abutments, Millable abutments in Ti.

Prosthetic elements connected directly or indirectly to the dental endosseous, zygomatic, and extra-oral implant should be used as an aid for prosthetic rehabilitations. Provisional elements may be used prior to insertion of definitive elements to maintain, stabilize, and shape soft tissue during the healing phase; they may not be inserted in occlusion. Definitive prosthetic components can be used in occlusion in implants with sufficient primary stability or fully osseointegrated.

Refer to the surgical guidelines for implants and prosthetic components.

### INTENDED USE

Advan prosthetic components are intended for assembly with Advan dental, zygomatic, and extra-oral implants to support prosthetic restorations such as single crowns, bridges, and full dentures. EASy Skin-Caps are attached to EASy abutments to support temporary prosthetic restorations such as crowns and bridges.

Prosthetic component	Indication				Duration
	Crown	Bridge	Full arch	Overdenture	
Cover screw					Temporary
Healing abutment					Temporary
EASy abutment	✓	✓	✓		Unlimited
EASy Skin Cap	✓	✓			Temporary
MUA		✓	✓	✓	Unlimited
GFA	✓	✓	✓	✓	Unlimited
Titanium base	✓	✓	✓	✓	Unlimited

### CONTRINDICATIONS

Allergies or hypersensitivity to the chemical components of the following materials used: titanium (Ti), titanium alloy (Ti6Al4V ELI), polyether etherketone (PEEK) or polymethyl methacrylate (PMMA).

### POTENTIAL COMPLICATIONS

Potential complications include all the activities in which the body is exposed to severe physical strain that should be avoided immediately after the insertion of dental implants. It is recommended that the physician or other authorized personnel informs the patient regarding the precautions and potential complications, as below reported, which may occur as a consequence of the surgical procedure for implanting the components. It is also recommended to invite the patient to promptly contact the physician in case of any loss of performance of the implant or of the prosthetic components. The risks and complications with implants include but are not limited to:

Potential side effects and temporary symptoms: pain, swelling, phonetic difficulties, gingival inflammation.

More persistent symptoms: (1) chronic pain associated with implant and its prosthesis, (2) swallowing, (3) permanent paraesthesia, (4) dysesthesia, (5) localized or systemic infection, (6) oroantral or oronasal fistulas, (7) jaw, bone oral denture fracture, (8) aesthetic problem, (9) nerve injury, (10) exfoliation, and (11) hyperplasia.

## WARNINGS/CAUTIONS

Advan prosthetic components are part of an overall concept and must be used only with the original components and surgical instruments, following the instructions and recommendations of the relevant surgical manual.

Patients may ingest or aspirate the component. Make sure that the screwdriver and the screw are properly engaged to avoid aspiration or ingestion. The secondary titanium parts must not be veneered directly with ceramic. Perform the prosthesis of the implant exclusively with secondary components and Advan parts compatible with the implant used. Failure to follow the procedures outlined in these instructions can result in any or all of the following complications:

- suction of a component
- swallowing of a component
- follow-up treatment

Always place temporary restorations in sub-occlusion. Use temporary cement to cement the temporary or protective caps. Treat dental cement or any other material used to cement prosthetic components as specified by the manufacturer. Choose a protective cap suitable for the patient's anatomical situation and the desired result. Advan titanium abutments and temporary abutments/caps are disposable devices. Insert the restoration on an occluded implant only when the implant is completely osseointegrated. Angled abutments are not recommended in areas with high mechanical load on small diameter implants (Ø3.3 mm). Products containing plastic components (PEEK and PMMA) must be stored away from direct sunlight.

For screw-retained abutments (MUA Abutments), do not use the alignment pin to screw the abutment to avoid damage to the occlusal threads (MUA components are packaged with their own carrier and need their own driver to properly tighten on the implant). The alignment pin should only be used for axial alignment. The carrier can be used to transport and screw the component but it's mandatory to tighten the component using the torque wrench and the dedicated driver.

## COMPATIBILITY INFORMATION

Advan dental and zygomatic implants and prosthetic lines are available in numerous configurations. The abbreviations on the label applied to each product allow you to easily identify the compatibility of a particular secondary component with the implant that you are restoring. The name of the implant and the prosthetic component contain an identifier for the connection, summarized in the following table.

Connection	Indication of compatibility
Fixture GTB	GTB prosthetic component
Fixture ONE CONICAL	ONE CONICAL prosthetic component
Fixture ONE INTERNAL	ONE INTERNAL prosthetic component
Fixture MARK	MARK prosthetic component
Fixture SyEASY	SyEASY prosthetic component
Fixture miniMAX	miniMAX prosthetic component
Fixture ZYGOMA	ZYGOMA prosthetic component
GFA	GFA prosthetic component
MUA	MUA prosthetic component

## CLEANING AND STERILIZATION

All sterile abutments must not be reprocessed after their first (and only) use.

Regarding non-sterile abutment, Advan recommends the following instructions. Before inserting the restoration into the patient's oral cavity, the product must be disassembled into its various parts, cleaned and sterilized. Advan recommends the following cleaning and sterilization procedure of the abutments non-sterile before use:

1. Place the components in an appropriate solution of high-quality decontamination medium (ENZYMAL<sup>®</sup>, 0.8% v/v with demineralized water), at 35°C contained in a suitable support (i.e., becker), the components must be totally covered by the solution. Allow 10 minutes before removing.

2. Carefully rinse the components under clean running or distilled water to remove any trace of detergent (i.e., enzymatic).

**Warning:** use sterile water unless the drinking water is low contamination (meeting the following requirements Pharmacopoeia European monograph 0169: max 10 microorganisms/ml, max 0.25 endotoxins/ml).

3. Place the components in a solution as in point 1 inside a suitable support (i.e., becker) and then put the support in an ultrasonic washing machine for 10 minutes at 35°C.

**Note:** the components must be opportunely positioned to avoid collisions between container itself; appropriate supports are recommended (i.e. becker).

4. Carefully rinse the components under clean running or distilled water to remove any trace of detergent (i.e., enzymatic).

**Warning:** use sterile water unless the drinking water is low contamination (meeting the following requirements Pharmacopoeia European monograph 0169: max 10 microorganisms/ml, max 0.25 endotoxins/ml).

5. Immediately after manual cleaning, or not more than 30 minutes place the components in an appropriate solution of high-quality disinfection medium (PROSEPT® Burs, ready-to-use solution), contained in a suitable support (i.e., becker), the components must be totally covered by the solution. Put the support in an ultrasonic washing machine for 1 minute at 20°C before removing.

**Warning:** the use of automatic cleaning and disinfection equipment is not recommended as it could compromise the integrity of the components due to possible collisions that could occur during the automatic washing and disinfection phases (the same level of control that can be achieved manually cannot be guaranteed during these phases).

6. The best means of drying is compressed air. Its action allows water to be physically removed from surfaces. The presence of moisture on the surface of components can promote bacterial growth and compromise the sterilization process. Drying components is of utmost importance before storage and sterilization, as moisture accumulation on products is harmful and can cause oxidation. It is recommended to dry each component thoroughly by means of compressed air (range 1.5 - 2 bar) using only filtered air (oil-free and with low contamination of microorganisms and particles, meeting the following Pharmacopoeia European max. 0.1mg/m<sup>3</sup> oil). Manual drying must provide a sufficient surface area, an air gun, cloths and absorbent paper material with low particle release. Alternatively, cloths that do not release filaments or dust must be used. During the drying phase, the cleanliness of the components must be verified and checked.

7. 1.Place the components into a sterilization pouch, which fulfil the following requirements: EN ISO 11607 (e.g., medical grade paper); suitable for steam sterilization.

8. 1.The use of an autoclave for steam sterilization of the prosthetic components is recommend, which fulfil the following requirements: EN ISO 17665. Carefully observe the instructions and recommendations of steam sterilizer manufacturer. Follow the instructions for maintenance and calibration of the autoclave. It has been validated, in accordance with EN ISO 17665, that one sterilization cycle (using the parameters given in the table) produced sterility of the surgical kit; this condition has been certified by an accredited laboratory.

	Vacuum fractionatium
Sterilization time	4 minutes
Sterilization temperature	134C°
Minimum pressure	2 bar
Drying time	20 minutes

The heating time and vacuum fractionation (at least three steps) can vary between 25 and 30 minutes, depending on autoclave conditions. The maximum sterilization temperature is 138°C. The actual drying time required depends on parameters for which the operator is solely responsible (e.g., configuration and loading density, state of the sterilizer) and must therefore be determined by the operator. In any case, the drying time should not be less than 20 minutes.

**Warning:** do not autoclave this product in its original packaging.

9. If not already present on the sterilization pouch, it is recommended to place a chemical indicator inside the autoclave during the process to confirm sterilization effectiveness.

10. When removing the components from the sterile package, follow the aseptic principles. The sterile packaging must not be opened until immediately before the use of the component. Components with damaged sterile packaging should not be used. We recommend keeping a replacement component handy.

**Warning:** Use the devices immediately after sterilization. Do not store sterilized devices.

**Note:** Users must ensure that the sterilizer and all sterilization accessories (sterilization sheets, envelopes, sterilization trays, biological and chemical indicators) are correctly calibrated and approved for the intended sterilization cycle. The user must consult the recommendations for sterilization of the manufacturer of the restoration material. If there are visible signs of humidity (damp spots on the sterile package, stagnant water in the load) at the end of the sterilization cycle, repackage and resterilize using a longer drying time.

**Note:** To avoid voltage cracks in the temporary copings made of PMMA for cementable abutments, do not use the following: alcohol, UV radiation, sterilization by irradiation (gamma ray sterilization), immersion in liquid for over an hour or temperatures above 60°C.

Advan Cover screw, Healing Abutment, MUA and GFA abutments are packaged sterile. The intact sterile packaging protects the sterilized abutment from external agents and, if properly stored, guarantees sterility up to the expiration date. When removing the abutment from the sterile package, follow the aseptic principles. The sterile packaging must not be opened until immediately before the use of the abutment. Abutments with damaged sterile packaging should not be used. We recommend keeping a replacement abutment handy.

## **SURGICAL PROCEDURE**

Use and treatment of Advan abutments by the dental technician: to make a cap or crown, follow standard procedures according to the instructions of the material manufacturer.

### RESTORATION DESIGN WITH TRADITIONAL WORKFLOW:

**Warning:** During polishing or other procedures always protect the prosthetic connection of the abutment by fixing the component itself to the correct connection replica. It is recommended not to use the screws contained in the abutment package, dedicated to fixing the prosthetic rehabilitation on the patient, but to use working screws.

- Insert the abutment in the connection replica on the working model.
- Verify that the retention elements of the replica-abutment connection are correctly aligned.
- Fasten the abutment to the connection analog by hand tightening the retention screw.
- Fabricate the cemented or screw-retained restoration using the abutment.
- To ensure the correct transfer of the abutment position from the master model to the patient, an individualized template can be made on the model. In the case of single crowns, the template is fixed with the support of the lateral teeth, while in the case of bridges the secondary components are fixed to each other with a splint.
- Always use the corresponding screwdriver to remove the prosthetic components from the implant replica

### RESTORATION DESIGN USING DIGITAL WORKFLOW FOR ADVAN CEMENTABLE EASy ABUTMENTS:

If you adopt a digital workflow, you can scan the Scan Abutment of the corresponding implant connection to report the correct position of the implant connection to the CAD software. The EASy Skin Cap can be used directly as a Scan Body for the EASy Abutments sleeve. Follow steps 5 - 6 of the traditional workflow, described above, after designing the restoration in the CAD software.

**Important:** EASy abutments can be used with both digital and traditional workflow. If these components are previously modified, they can only be prosthodontized with a traditional workflow or after direct scanning of the modified abutment sleeve.

### DESIGN OF MULTIPLE RESTORATIONS WITH DIGITAL WORKFLOW FOR ADVAN SCREW-RETAINED ABUTMENTS:

Use the corresponding Scan Abutments to simplify the precise design of the interface between the screw-retained Advan abutments and the meso-structure. If applicable, follow steps 5 - 6 of the traditional workflow, described previously after designing the restoration in the CAD software.

**Important:** It is recommended to always use titanium bases (Ti-Base or Uni-Base) in order not to lose the Advan guarantee on prosthetic connections.

### USE AND TREATMENT OF ADVAN ABUTMENTS BY THE DENTIST:

The dentist receives the master model with the original abutment from his dental laboratory. At this step it is necessary to remove the cover cap, the healing abutment or the temporary prosthetic restoration. Remove the restoration from the working model. Clean and sterilize the restoration as explained in sections 7 and 8. Insert the prosthetic restoration into the patient's mouth. MUA Straight abutments are tightened using a dedicated driver (MUA Driver). GFA abutments are tightened using the GTB / ONE CONICAL implant driver (GDD series or GDM series driver). All other prosthetic elements are inserted and tightened with the Prosthetic Driver (EG series or EGM series driver). Abutments with pre-assembled screw can be inserted into the patient's mouth using the Prosthetic Driver (EG series or EGM series driver). All other elements should be positioned carefully using tweezers. Insert the sterilized abutment into the implant and make sure that the retentive elements of the abutment-connection are correctly aligned.

- The abutment must be correctly positioned in the implant before tightening the screw.
- Make sure to fix the abutment on the implant with the appropriate screw (refer to the indications in the product catalog for the exact correspondence between the abutments and the retaining screw).

- Tighten the retaining screw using the torque wrench (Ref. 02-CT20). Apply the correct tightening torque as indicated in the product catalog.

**Warning:** Torques greater than::

- 25 Ncm for GTB / TZERO / ONE CONICAL components
- 35 Ncm for GFA primary components
- 25 Ncm for GFA secondary components
- 35 Ncm for ONE INTERNAL / ZYGOMA components can cause failure of the abutment and/or implant.

Torques lower than the recommended values can cause loosening of the abutment, with consequent possible failure of the same and/or the implant. It is recommended to always use new fixation screws to fix the final components in the patient.

**Warning:** Do not remove the screw once it has been tightened to 25 Ncm (35 Ncm for the GFA primary components or ONE INTERNAL / ZYGOMA components) to prevent wear of the screw itself. Do not remove the final abutments without engagement after they have been tightened to 25 Ncm (35 Ncm for the GFA components or ONE INTERNAL / ZYGOMA components) and/or after taking the impression to avoid the loss of the orientation of the abutments between the patient and the working model.

#### RETAINING SCREW CHANNEL CLOSURE:

**Important:** Before fixing the restoration on the abutment or cap, the screw channels must be sealed with wax or sealing composite (e.g. gutta-percha or composite restoration material). This allows for subsequent removal of the abutment or coping if the prosthesis needs to be replaced.

Device modification: In the traditional workflow, if necessary, the abutments can be modified by the technician or chair-side according to the anatomical conformation of the patient. It is not possible to modify the MUA and GFA components. In a digital 4 Advan Titanium Abutments and Temporary Abutments / Caps workflow it is not possible to modify the Ti-Base and Uni-Base components (with the exception of the Uni-Base components with TALL sleeve, which allows to shorten the sleeve maintaining compatibility with Advan genuine libraries for the digital workflow).

#### **HEALING FASE**

Advan cover screws and healing abutments allow the implant connection to be closed for submucosal healing or soft tissue modelling during transmucosal healing. After the soft tissue healing phase, they are replaced with the appropriate temporary or final restoration.

#### **STORAGE**

Store the prosthetic components in a dry environment, out of direct sunlight and at room temperature. Follow the envelope manufacturer's instructions regarding storage conditions and expiration date of sterilized products.

#### **GENERAL HANDLING, CARE AND MAINTENANCE OF THE SURGICAL INSTRUMENTS**

**Warning:** The clinical success of the surgical procedure of prosthetic component placement requires the use of instruments in perfect condition.

Care and maintenance of instruments are critical to successful treatment. Sterilized instruments not only protect patients and staff from infection and cross-infection, but are also essential to the total treatment outcome.

Due to the small size of the components, care should be taken to ensure that the components are not swallowed or aspirated by the patient. A rubber dam is recommended to prevent inhalation of loose parts.

Please read the instructions on technical sheet for surgical kit use and maintenance.

#### **FURTHER INFORMATION**

For more information on the use of Advan products, contact Advan customer service.

#### **DISPOSAL**

Disposal must be handled in an environmentally sustainable manner, in accordance with local regulations. Hazardous waste from contaminated devices or sharps must be disposed of in appropriate containers that meet specific technical requirements.

#### **NOTES**

Physician who use the Advan product are required to have adequate technical knowledge and training, in order to ensure its safe use. The Advan product must be used in accordance with the manufacturer's instructions for use. The physician is responsible for using the device in accordance with these instructions for use and for determining the suitability of the device for the patient's individual situation. The Advan product is part of a complete program and should be used only in conjunction with its original components and instruments distributed directly by Advan and all national Advan dealers. Use of third-party products not distributed by Advan voids any warranty or other obligation, implied or express, of Advan.

#### **VALIDITY**

These operating instructions supersede all previous versions.




















## AVAILABILITY







Some Advan implant system items may not be available in all countries.

## SYMBOLS

The following table describes the symbols that can be identified on the packaging and on the device label. Refer to the packaging label for symbols applicable to the product.

### Symbols glossary

Symbol	Description	Symbol	Description
	Do not re-sterilize		Unique device identifier
	Non-sterile		Not locking prosthetic component
	Do not use if package is damaged and consult instructions for use		Octagon locking prosthetic component
	Keep away from sunlight		Hexagon locking prosthetic component
	Keep dry		Advan products covered by the CE mark fulfill the requirements of the Directive 93/42/CEE concerning medical devices and falls within Classes IIa, IIb
	Do not re-use		Advan products covered by the CE mark without the identification number fulfill the requirements of the EU Regulation 2017/745 (MDR) concerning medical devices and falls within Class I
	Consult instructions for use or consult electronic instructions for use		
	Caution		
	Multi packaging (the number reported in the symbol refers to the number of units in the packaging)		
	Medical device		
	Single sterile barrier system with protective packaging inside		
	Single sterile barrier system with protective packaging outside		
	Distributor		

Symbol	Description
	Manufacturer
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Sterilized using irradiation



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