INSTRUCTIONS FOR USE: ADVAN TITANIUM ABUTMENTS AND TEMPORARY ABUTMENTS / CAPS

PRODUCT DESCRIPTION

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 Cover screws for implant/prosthetic connections, Healing abutments/caps, EASY pre-finished titanium abutments, EASy Skin-Cap, MUA abutments, GFA abutments, Titanium bases for CAD/CAM rehabilitations (Ti-Base and Uni-Base).

INTENDED USE

Advan abutments are intended for insertion into Advan dental and zygomatic implants to support prosthetic restorations such as single crowns, bridges and total arch restorations. The EASy Skin-Caps are fixed to the EASy abutments to support prosthetic restorations such as crowns and bridges.

INDICATIONS

The prosthetic components connected directly or indirectly to the endosseous dental and zygomatic implant must be used as an aid for prosthetic rehabilitations. The temporary elements can be used before the insertion of the final elements to maintain, stabilize and shape the soft tissue during the healing phase; they cannot be placed into occlusion. The final abutments can be placed into occlusion in implants with sufficient primary stability or completely osseointegrated.

CONTRAINDICATIONS

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).

	Indication				Duration
Prosthetic component	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

WARNINGS AND PRECAUTIONS

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 (D3.3 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 INFORMATIONS

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	Compatibility label indication
Fixture GTB	GTB restorative component
Fixture TZERO	GTB restorative component
Fixture ONE CONICAL	ONE CONICAL restorative component
Fixture ONE INTERNAL	ONE INTERNAL restorative component
Fixture ZYGOMA	ZYGOMA restorative component
MUA	MUA restorative component
GFA	GFA restorative 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 (ENZYMAX®, 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 tools 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, readyto-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/m³ 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. 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. 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 fractionation
Sterilization time	4 minutes
Sterilization temperature	134°C
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.

Caution: 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 be-

fore the use of the abutment. Abutments with damaged sterile packaging should not be used. We recommend keeping a replacement abutment handy.

STORAGE

Store in dark, cool and dry place. It is recommended to keep the pouch closed until next surgical procedure.
Follow the instructions of the manufacturer of the pouches regarding storage conditions and expiration date of sterilized goods.

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.

1. Insert the abutment in the connection replica on the working model.
2. Verify that the retention elements of the replica-abutment connection are correctly aligned.
3. Fasten the abutment to the connection analog by hand tightening the retention screw.
4. Fabricate the cemented or screw-retained restoration using the abutment.
5. 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.
6. 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 prosthesized 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.

1. The abutment must be correctly positioned in the implant before tightening the screw.
2. 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).
3. Tighten the retaining screw using the torque wrench (Ref. 02-CT20). Apply the correct tightening torque as indicated in the product catalog.

Caution: 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.
Caution: 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

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 PHASE

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

SIDE EFFECTS

Potential side effects and temporary symptoms: Pain, swelling, phonetic difficulties, gingival inflammation.
More persistent symptoms: the risks and complications with implants include but are not limited to: (1) chronic pain associated with implant and its prothesis, (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.

FURTHER INFORMATION

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

DISPOSAL

Disposal must be managed in an environmentally sustainable way, in compliance with local regulations. Hazardous waste from contaminated devices or sharp objects must be disposed of in suitable containers that meet specific technical requirements

NOTES

Doctors who use the Advan product are required to have appropriate technical knowledge and training, in order to ensure its safe use. The Advan Product must be used in accordance with the instructions for use provided by the manufacturer. The doctor is responsible for the use of the device in accordance with these instructions for use and for determining the suitability of the device for the individual patient situation. The Advan Product is part of a complete program and must only be used in conjunction with its original components and tools distributed directly by Advan and all Advan national dealers. The use of third part products not distributed by Advan voids any warranty or other obligation, implicit or explicit, of Advan.

VALIDITY

These operating instructions replace all previous versions.

AVAILABILITY

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

SYMBOLS

The following table describes the symbols that can be found on the packaging label. Consult the packaging label for the symbols applicable to the product.

SYMBOLS GLOSSARY

Symbol	Description
	Manufacturer
	Date of manufacture
	Use-by date

Symbol	Description
	Batch code
	Catalogue number
	Sterilized using irradiation
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight
	Keep dry
	Do not re-use
	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)

Symbol	Description
MD	Medical device
	Single sterile barrier system with protective packaging inside
	Single sterile barrier system with protective packaging outside
	Distributor
UDI	Unique device identifier
R	Not locking prosthetic component
NR	Octagon locking prosthetic component
NR	Hexagon locking prosthetic component
CE 0123	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
CE	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

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