INSTRUCTIONS FOR USE:
REPROCESSING AND MAINTENANCE OF ADVAN SURGICAL KIT

PRODUCT DESCRIPTION AND INDICATIONS

The Advan Kit is supplied along with its integrating instruments. Case for the storage of surgical and/or prosthetic instruments during their use, cleaning and sterilization. Being manufactured in autoclavable polymer, it presents silicone supports for conditioning and safe fastening each instrument. It also presents markings that guide instrument use during procedures. The instruments are supplied together with the Advan Kit, however they are packaged in a separate pouch with indication of the lot code and description; to position them in the kit, operate in accordance with the configuration table.
Components of the Advan Kit are:

- screwdrivers;
- torque wrench;
- ratchet adapters;
- drills;
- reamers;
- depth probe;
- direction indicators;
- drills extensions;
- carrying and mounting devices.

These instruments can be used in conjunction with the handpiece.
Refer to surgical guidelines regarding implants and prosthetic components.

INTENDED USE

The Advan Kit is intended to be used only by highly skilled medical staff, trained in dental, zygomatic and extra-oral implantology. The instruments supplied with the Advan Kit are to be used to permit an easy preparation of the implant site and placement of dental, zygomatic or extra-oral implant.

CONTRAINDICATIONS

Allergies or hypersensitivity to the chemical components of the following materials used: steel (AISI steels 400 and 630 series), titanium alloy (Ti6Al4V ELI grade 23), polyether etherketone (PEEK), silicone, Nickel (only for ZYGOMA Diamond drill 07FDZ04 and 07FDZ20).

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 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.

WARNINGS/CAUTIONS

The Advan dental, zygomatic and extra-oral implantology instruments are part of an overall concept and must be used only with the original components, following the instructions and recommendations of the relevant surgical manual. It is strongly recommended that Advan surgical instruments are used only with Advan implants, as combining components that are not dimensioned for correct mating (coupling) can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory aesthetic results.
Using the Handpiece Contra-Angle Tools Adapter 02-AC50, do not apply tightening torque exceeding 50 Ncm to avoid adapter or connected instrument, damaging. Strictly follow the instructions for use and maintenance of the Torque Wrench 02-CT20.
All the instruments and related components are reusable, excepted for the zygomatic diamond drill (Ref. 07FDZ04 – 07FDZ20) and the sleeve, and supplied non-sterile (see label), being unitarily packaged. The instruments must be correctly cleaned and sterilized before their first use, do not autoclave the instruments in their original packaging. The instruments are supplied together with the Advan Kit; however, they are packaged in a separate pouch with indication of the lot code and description; to position them in the kit, operate in accordance with the configuration table.
Patients may ingest or aspirate the component; make sure that the screwdriver and the screw are properly engaged to avoid aspiration or ingestion. During cleaning do not use brushes on retention systems of Implant Direct Drivers.

The surgical tray should not be put in contact with used contaminated instruments. We recommend to clean the surgical box with denatured alcohol and check its cleanliness. Avoid use of corrosive disinfectant liquids and ultrasonic cleaning, for the surgical tray. Whichever cleaning method is used, the personnel in charge of the operations should always use suitable protective clothing and equipment. Refer to the instructions provided with the cleaning agents for correct handling and use.
After surgery, all instruments are contaminated due to the contact with blood, saliva and potentially infected organic substances. Therefore, all instruments must be properly cleaned, disinfected and sterilized before each use.
In addition to these guidelines, please follow the legal regulations valid in your country, as well as the hygiene rules of dental offices or hospitals, so that any changes in the law regarding reusable medical devices and their reprocessing can be covered.

REPROCESSING INSTRUCTIONS
After surgery, all instruments are contaminated due to the contact with blood, saliva and potentially infected organic substances. Therefore, all instruments must be properly cleaned, disinfected and sterilized before each use.

INITIAL TREATMENT AT THE POINT OF USE:
Immediately after use, or not more than 30 minutes, remove gross soil by means of absorbent paper wipes.

CONTAINMENT AND TRANSPORTATION:
It is recommended that instruments are reprocessed as soon as is reasonably practical following use, or not more than 30 minutes. To avoid mechanical damages, do not mix heavy devices with delicate ones. Pay particular attention to drills' cutting edges.

PREPARATION BEFORE FOR CLEANING:
Disassemble the tools if composed by more than one part. Disassemble kit boxes.

MANUAL CLEANING:
1. Immediately after use, or not more than 30 minutes, place the tools 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 tools must be totally covered by the solution. Allow 10 minutes before removing. Pay attention that there is no contact between the instruments;

2. Using a soft plastic brush (e.g. soft nylon brush), carefully clean each tool to remove any organic residual;
Warning: do not use brushes on retention systems
Warning: do not clean any instruments using metal brushes or steel wool.

3. 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 potable water is low contamination (meeting the following requirements Pharmacopoeia European monograph 0169: max 10 microorganisms/ml, max 0.25 endotoxins/ml).

4. Place the tools 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 minute at 35°C.
Note: the instruments must be opportunely positioned to avoid collisions between instruments and container itself; appropriate supports are recommended (i.e. becker);

5. 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 potable water is low contamination (meeting the following requirements Pharmacopoeia European monograph 0169: max 10 microorganisms/ml, max 0.25 endotoxins/ml).
Warning: prolonged immersion time and/or excessive solution concentration can cause corrosion of the instruments; always comply with the recommendations for immersion time provided by the producer of the disinfectant solution.

MANUAL DISINFECTION:
Immediately after manual cleaning, or not more than 30 minutes place the tools in an appropriate solution of high-quality disinfection medium (PROSEPT® Burs, ready-to-use solution), contained in a suitable support (i.e., becker), the tools must be totally covered by the solution. Put the support in an ultrasonic washing machine for 1 minute at 20°C before removing. Pay attention that there is no contact between the instruments.
Warning: to avoid corrosion, do not rinse rotating instruments with water at this stage of reprocessing.
Warning: the use of automatic cleaning and disinfection equipment is not recommended as it could compromise the integrity of the instruments contained in the surgical kit 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).

DRYING:
The best means of drying is compressed air. Its action allows water to be physically removed from surfaces, especially for hollow objects or tubes.

The presence of moisture on the surface of instruments can promote bacterial growth and compromise the sterilization process. Drying instruments 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 instrument thoroughly by means of compressed air (range 1.5 - 2 bar) using only filtered air (with low contamination of microorganisms and particles, and oil-free 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 instruments must be verified and checked.

MAINTENANCE:
At the end of each cleaning, disinfection and drying cycle, the instruments must be subjected to a visual inspection in order to make sure that they are macroscopically clean. Damaged instruments must be discarded to prevent the reuse of blunt or damaged tools. This visual control is absolutely essential for any instrument that affects the result of the operation. A blunt, corroded or contaminated instrument can damage or infect healthy tissue.
Note: the visual inspection is as important as cleaning, disinfection, drying and sterilization.

Instruments that are not totally clean must undergo another cleaning, disinfection and drying cycle. Damaged instruments always have to be discarded. Inspection and function: We recommend to check frequently the wear conditions of surgical instruments and immediately replace the worn-out ones. In particular:

1. cutting tools: it is very important to check the cutting performance before each use; replace the tools that cannot guarantee adequate cutting performance, leading to inaccurate cut and bone overheating. We recommend to do not use more than 10 times on hard bone and not more than 50 times on medium/soft bone;
2. coupling parts of tools: parts of the tools that are mechanically coupled are subjected to wear (screwdrivers, hand-piece tools, drill extension, hand-piece connections). We recommend to check after each cleaning, disinfection and sterilization cycle the wear of screwdriver's retention systems and replace those which may not guarantee the correct retention anymore;
3. we recommend to check periodically the calibrated instruments to ensure their proper functionality (e.g. torque wrench).

PACKAGING:
Place the instruments back in the correspondent slot inside the surgical tray. The surgical kit must be placed into a sterilization pouch, which fulfil the following requirements: EN ISO 11607 (e.g. medical grade paper); suitable for steam sterilization; sufficient protection for instruments as well as for maintenance of sterilization packaging against mechanical damage (the pouch protects the kit during sterilization and keeps it sterile until further use).
Pack the surgical tray with sterilization pouch and put it inside the autoclave in a horizontal position; do not turn it upside down to ensure the proper drying.

STERILIZATION:
This product is reusable and supplied non-sterile, being unitarily packaged. This product must be correctly cleaned, disinfected and sterilized before each use.
Warning: do not autoclave this product in its original packaging.
The use of an autoclave for steam sterilization of the surgical tray is recommend, which fulfil the following requirements: EN ISO 17665 series. 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.
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.
It is recommended to sterilize the instruments arranged in the appropriate position inside the surgical tray. Pack the surgical tray with sterilization pouch and put it inside the autoclave in a horizontal position; do not turn it upside down to ensure the proper drying.
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. 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 re-sterilize.
When removing the instruments from the sterile package, follow the aseptic principles. The sterile packaging must not be opened until immediately before the use of the instrument. Instruments with damaged sterile packaging should not be used. We recommend keeping a replacement instrument handy.

STORAGE
Store the kit and all surgical instruments in a dry environment, out of direct sunlight and at room temperature. It is recommended to keep the pouch closed until the next surgical procedure. Follow the envelope manufacturer's instructions regarding storage conditions and expiration date of sterilized products.

FURTHER INFORMATION
Advan surgical instruments are made of materials suitable for surgical use and for severe conditions occurring during cleaning, disinfection and sterilization. We recommend not to exceed with disinfection and sterilization processes (too higher disinfectant concentrations, temperatures, times, etc.) since it may reduce tools' lifetime. We recommend to follow the manufacturer's instructions for all products used in combination with Advan surgical instruments. Instruments that have not been used must be, in any case, washed and sterilized before the next use; new instruments provided in original packaging by Advan must be washed and sterilized before use. The instructions provided above have been validated by the manufacturer of the medical devices to be capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieved the desired result. This normally requires verification and/or validation and routine monitoring of the process. 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.

LIFECYCLE
The Advan Kit is recommended for up to 50 uses, as long as the conditions of use indicated by Advan are respected. Concerning the cutting tools lifecycle please refer to paragraph inspection and function point 1. Anyway, regardless of the number of times that the instrument has been used, the professional must always evaluate its condition after each use. The end of life of instruments is normally determined by wear and damage due to surgical use. All devices must be inspected for functionality before sterilization. If non-operational, they must be disposed of according to internal processes. All instruments marked disposable must not be reprocessed after their first (and only) use.

NOTE
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 surgical kit 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
	Manufacturer
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Sterilized using irradiation

Symbol	Description
	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)
	Medical device
	Single sterile barrier system with protective packaging inside
	Single sterile barrier system with protective packaging outside
	Distributor

Symbol	Description
	Unique device identifier
	Not locking prosthetic component
	Octagon locking prosthetic component
	Hexagon locking prosthetic component
	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
	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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