INSTRUCTIONS FOR USE, REPROCESSING AND MAINTENANCE: ADVAN SURGICAL KIT

DESCRIPTION

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.

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.

INDICATIONS

The components of the Advan Kit are:

- screwdrivers;
- ratchets;
- ratchets adaptors;
- drills;
- reamers;
- deep measuring tools;
- direction markers;
- drill extension;
- mounting and carrying devices

and they could be used in combination with contra-angle.

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 ether-ketone (PEEK), silicone, Nickel (only for ZYGOMA Diamond drill 07FDZ04 and 07FDZ20).

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.
During cleaning do not use brushes on retention systems of Implant Direct Drivers.
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.
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.

COMPATIBILITY INFORMATION

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 esthetic results.

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).

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: 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.
Automated cleaning/disinfection: Not applicable.
Drying: Carefully dry each tool by means of compressed air (maximum 2 bar) using only filtered air (oil-free, low contamination with microorganism and particles). The presence of humidity on tools' surface may favor bacterial growth and compromise sterilization process. The drying of the parts is of utmost importance before storage and sterilization, because the accumulation of moisture on the products is harmful and may cause oxidation.
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 that 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 recommended, 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 that a steam sterilization cycle at 134°C, 2 bar, 4 minutes, 1 hour lasting has produced a sterile condition of the surgical kit; this condition has been certified by an accredited laboratory.
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 instru-

ment. Instruments with damaged sterile packaging should not be used. We recommend keeping a replacement instrument 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.

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 above provided have been validated by the manufacturer of the medical devices to be capable of preparing a medical device for reuse. It is user's responsability to ensure that the reconditioning, carried out with the equipment and materials available in the reconditioning facility, has 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 managed in an environmentally sustainable way, in compliance with local regulations. Hazardous waste from contaminated devices or sharp objects must be disposed in suitable 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.

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 Kit 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
	Sterilize using irradiation.
	Serial number
	Consult instructions for use.
	Do not use if the package is damaged and consult instructions for use.
	Non-sterile
	Not locking prosthetic component
	Octagon locking prosthetic component
	Hexagon locking prosthetic component
	Keep away from sunlight.
	Keep dry

Symbol	Description
	Medical device
	Manufacturer
	Batch code
	Catalogue number
	Do not re-use
	Use-by date
	Advan products covered by the CE Mark fulfill the requirements of the Directive 93/42/CEE. With notified Body number.
	Advan products covered by the CE Mark fulfill the requirements of the Directive 93/42/CEE.
	Multi packaging (the number reported in the symbol refers to the number of units in the packaging).

Advan s.r.l.

Via Linussio, 1
33020 Amaro (UD) - Italia
Tel. +39 0433.096245
info@advanimplantology.com

www.advanimplantology.com