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INSTRUCTIONS FOR USE INSTRUMENTS

LIMITATION OF LIABILITY
Read the following instructions for use before using IESS Group medical devices. The sale of these medical devices is restricted by or on the order of a licensed dentist or surgeon who has experience in implant-restoration techniques and solutions. It is the responsibility of all the operators handling the products in the context of their respective field of activity to have adequate knowledge about the product on the basis of the most recent technological standards. This allows for correct use of the products and prevents health and safety risks to the patient, the user and other relevant persons. The authorised dentist or surgeon must determine the suitability of the patient for oral surgery interventions and the appropriate surgical technique; they must also determine the suitability of the product chosen for intended use, therefore taking on every form of risk and responsibility in relation to such. Product processing, handling and application in the surgery or dental laboratory are outside the control of the manufacturer and therefore fall under the responsibility of the user. Any use other than that described in the informative material is considered “misuse”, releasing the manufacturer from any obligation or liability.

GENERAL INFORMATION
The following instructions for use refer exclusively to the instruments of the IESS Group implant prosthesis system.
IESS Group medical devices are made of different materials, in compliance with the requirements of Medical device Regulation (UE) 2017/745, with UNI EN ISO 9001 - UNI EN ISO 13485 standards and the IESS Group quality system requirements.
Any informative material for the use of IESS Group medical devices should be requested to the Customer Service: Telephone +39 0432 669191 - fax +39 0432 665323 - e-mail: servizioclienti@iess.dental - website: www.iess.dental.
The information contained therein represents the current state of the art known at the time of product marketing. This does not exonerate the user from the responsibility to personally verifying the suitability of the product for its intended purpose and procedures.
Carefully read the information contained in the “Warnings and conditions of sale” section in all IESS Group catalogs and manuals.

PRODUCT DESCRIPTION
The instruments are non-sterile devices to be used only in conjunction with IESS Group dental implants and prosthetic components; they are intended for temporary use in the oral cavity, less than 60 minutes. For specific indications, please refer to the respective instructions for use of the implant or prosthetic component.

INDICATIONS
The IESS Group instruments are indicated for use in procedures for implant placement or the application of related prosthetic components in fully or partially edentulous patients.

CONTRAINDICATIONS
The same contraindications apply as stated in the Instructions for Use for IESS Group dental implants. In addition, they are contraindicated in case of known allergies or hypersensitivity to the chemical ingredients of the following materials: titanium and its alloy (Ti6Al4V), stainless steel, tungsten carbide, cobalt, silicone, polyurethane (PU), polyoxymethylene (POM).

REACTIONS TO THE INTERVENTION AND SIDE EFFECTS
After the surgical intervention some disorders may occur, such as: pain, swelling, phonation difficulties, inflammation of the soft tissues, bone resorption, dehiscence, aesthetic problems, damage to the adjacent natural elements or nerves, paraesthesia, dysesthesia, infections, fistulas, hyperplasia, lack of integration, bone fracture, breakage of the implant or prosthesis. These effects may depend on the correct surgical technique adopted and/or incorrect planning of the implant treatment.

INTENDED USE
The IESS Group instruments are divided into four types according to their use.
ROTATING CUTTING INSTRUMENTS:
Drills (stainless steel): reusable medical devices in stainless steel to be used to create a controlled osteotomy. They have different morphology and should be selected according to the protocol: twist, final, lanceolate, enlargers, countersinks, pilot, tappers, bone profilers.
Round burs (stainless steel, tungsten carbide, cobalt): reusable medical device, to create a cortical incision in preparation for the next drill.
EBM drills (stainless steel, tungsten carbide, cobalt): reusable medical device, to create the bone window during sinus lift surgery.
Tissue punches (stainless steel): reusable medical devices used to remove the soft tissues.

ACCESSORIES FOR ROTARY CUTTING INSTRUMENTS
Drill stops (medical grade titanium or stainless steel): reusable medical devices, they must only be used with drills to achieve the programmed drilling depth.
Drill extension (stainless steel): reusable medical device, to be used to easily reach the intervention area between two adjacent dental elements.

DRIVERS AND INSERTS:

Devices intended for applying or transmitting torque to instruments, implants or prosthetic components.
Drivers (stainless steel): used for the handling and inserting of IESS Group implants and components, characterised by contra-angle connection.
Inserts (stainless steel): used for the handling and inserting dental implants or tightening the prosthetic components, to be used manually or in combination with torque wrenches.
Drivers and inserts equipped with o-ring (stainless steel, silicone, polyurethane): the o-ring is made of polymeric material to retain other devices.
Digital screwdriver (medical grade titanium, silicone, polyurethane): must be used with the appropriate insert for handling implants and prosthetic components.

SURGICAL INSTRUMENTS:
Mounter (stainless steel): allows the implant to be picked and positioned in the implant site. It can be used with a digital screwdriver and torque wrench.
Mounter extractor (stainless steel): screwed in the mounter in place of the screw, allows it to be removed if it gets stuck in the implant seat.
Inserts for osteotome (medical grade titanium): are indicated for sinus floor elevation, are indicated for fracturing the sinus floor by repeatedly tapping it, for partial sinus floor elevation in cases of insufficient vertical maxillary bone.
Handle and joint for osteotomes (stainless steel): are used in the preparation of the implant bed to be used in combination with osteotome inserts.
Wideners (medical grade titanium): are indicated for the condensation of the trabecular bone, radially strengthening the cancellous bone in order to improve the primary stability of the implant.
Parallel pins (medical grade titanium, polyurethane), depth probe (medical grade titanium): are indicated for visual control or physical guidance of the position, depth and direction of the osteotomy or implant.
Anchor pin (medical grade titanium): are used to fix the surgical template in guided surgery.

PRECAUTIONS/WARNINGS
The dentist must ensure conditions that prevent inhalation/ingestion of devices that are used intraorally. Inhalation/ingestion may cause infection or unforeseen physical injury.
Rotating instruments must be inserted into the handpiece correctly, ensuring that they are held effectively; check the correct direction of rotation of the instruments.
Use handpieces and/or contra-angles that are clean and in perfect hygienic and functional condition. Do not exceed the maximum speed indicated in the information material provided by IESS Group. The torque must not exceed 50 N•cm. In the event of cracks or deformations on the shank of the rotating tools, check the efficiency of the micromotor.

ROTATING CUTTING INSTRUMENTS
Before use, check that the drill is of a suitable type, length and diameter. A non-controlled osteotomy may cause damage to the hard and soft tissues or to anatomical areas. It is therefore necessary that the surgeon follow the instructions described in the surgical protocol of the chosen implant line. During the osteotomy, maintain the axial position between the cutting portion and the anchoring shank of the contra-angle, while preventing bending that can lead to fractures or oversized holes. Use the cutters and taps with clockwise rotation; apply a “back-and-forth” motion to facilitate cooling and cutting. To avoid damage to the drills during cleaning and disinfection, keep them separate from different material devices.
They can be used for up to a maximum of 4 applications and only if perfectly intact upon visual inspection. Worn, damaged, oxidised or corroded drills should not be used since they are no longer able to carry out their function. In particular, the use of drills that are no longer sharp causes bone necrosis from overheating and can therefore lead to implant failure. Overheating of the implant site may cause irreversible lesions of the tissues. It is therefore necessary to use a suitable cooling system during site preparation. Handle cutting instruments with care to avoid injury to the operator.
Some supplies may contain up to 1% cobalt (EC number 231-158-0). It is therefore advisable to take this into account if you have particularly sensitive/vulnerable patients or breast-feeding women. Studies show that the release of this element from steel surgical instruments is negligible.
Twist drills: Due to the design and function of the drills, the instrument tip may be longer than the implant insertion depth. This value is given in the specific information material provided by the IESS Group and must be taken into account when planning the treatment.
Round burs and EBM drills: they can be used for up to a maximum of 15 applications. They contain cobalt (EC number 231-158-0) in a ratio of a minimum 4% and a maximum of 10% of the cutting edge alone. It is therefore advisable to take this into account if you have particularly sensitive/vulnerable patients or breast-feeding women. Studies show that the release of this element from steel surgical instruments is negligible.

ACCESSORIES FOR ROTATING CUTTING INSTRUMENTS
Drill stops: must only be used with IESS Group drills. They should not be used in the event of a post-extraction technique or surgical template. Following surgical protocol, carefully choose the type of stop according to the drill which will be used. It is recommended to always check that the stop is engaged at the desired height. An incomplete insertion may reduce the preparation depth. For insertion and removal, please refer to the IESS Group information material.
Drill extension: must only be used with IESS Group rotating instruments.
Tissue punches: they can be used for up to a maximum of 4 applications and only if perfectly intact upon visual inspection. Worn, damaged, oxidised or corroded tissue punches should not be used since they are no longer able to carry out their function. In particular, the use of tissue punches that are no longer sharp causes damage to the soft tissues and may therefore lead to complications.

DRIVERS AND INSERTS
Always check that the coupling between drivers and inserts is correct. Pay attention to the correct selection of the instrument according to the component to be handled (e.g. tilted hole). When tightening, observe the torque value indicated in the information material.
Drivers and inserts equipped with o-ring: make sure it is always present. If the o-ring is missing, not intact or incorrectly positioned, the components that need to be handled might fall. During maintenance, check the o-ring and its conformity.

PACKAGING
All IESS Group medical devices are decontaminated and packaged non-sterile, therefore, before their use, they must be removed from their original packaging, packaged in autoclavable material and then sterilised using validated procedures. They are sold as a single unit, unless otherwise specified on the product label. The transparent blister pack or medical pouch allows for immediate recognition of the component(s) and ensures optimal protection of the product(s) until used under normal storage conditions. The packaging comes with adhesive labels bearing traceability data, these stickers can be removed.

STORAGE RECOMMENDATIONS
Store clean, sterilised medical devices in a dry place at room temperature, protected from dust and sunlight. Indicate on the medical pouches the date of sterilisation and the expiry date calculated according to the times provided by the current regulations.

ECOLOGICAL INFORMATION AND DISPOSAL
The medical devices are not biodegradable. If they are used correctly, they do not give rise to any environmental damage. The medical devices must be treated according to current regulations. The material must be disposed of by authorised companies.

CLEANING AND STERILIZATION INSTRUCTIONS
During cleaning, disinfection and maintenance, check the device and its parts for signs of oxidation, corrosion, wear or bent elements. If the device is not intact, complete and functional in all its parts, it must be replaced.
To prevent damage to the devices during cleaning and disinfection, keep them separate from devices made of different materials.
IESS Group instruments are supplied non-sterile. Before their use, they must be removed from the original packaging, and then cleaned and sterilised. The devices can be cleaned manually or using automatic washing equipment. Each device must then be sealed in a sterilization pouch and sterilised.
To avoid damage to the devices during cleaning and disinfection, keep them separate from devices made of different material.
The following cleaning and sterilization processes have been validated according to international standards:
• Automatic and manual cleaning: ISO 15883
• Sterilization: ISO 17665-1
In accordance with EN ISO 17664, it is the responsibility of the user/cleaner/sterilizer to ensure that such treatment/reconditioning is carried out using suitable equipment, materials and personnel to ensure the effectiveness of the processes. Any deviation by the user/cleaner/sterilizer from the following instructions must be validated to ensure the effectiveness of the process.
Note: Carefully follow the instructions for use by the manufacturer of the cleaning solution/detergent and/or equipment and accessories used to clean and/or dry the devices.

PRELIMINARY CLEANING
Immerse the devices in an aldehyde-free cleaning and disinfecting solution (e.g. in a container with DC1® supplied by KOMET at 2% for 30 min). If other cleaning and disinfection agents are used, the manufacturer’s instructions must be followed.

MANUAL CLEANING
Rinse devices under cold running water. Proceed with chemical disinfection using a suitable

liquid in an aldehyde-free cleaning (e.g. DC1® supplied by KOMET at 3% for 15 mins). For an enhanced cleaning effect, use the ultrasonic bath, at a maximum temperature of 45°C (to prevent the hardening of substances containing proteins). Action time start immediately after immersion of the last instruments. If other cleaning and disinfection agents are used, the manufacturer's instructions must be followed.
Rinse the instruments with cold tap water for at least 10 seconds until all detergent solution has been removed and dry thoroughly. Dry the device with a clean, soft, lint-free disposable cloth. Make sure that the devices are completely dry after drying and do not have any residual moisture that could lead to corrosion.

CLEANING AND AUTOMATIC DISINFECTION
Rinse the devices under cold running water. Insert the devices into a basket with lid. The use of a basket dim 80x40x30 mm, containing 6 devices for each cycle, is suggested.
Proceed with cleaning and automatic thermodisinfection.
The use of a thermodisinfector satisfying the requirements of ISO 15883 is recommended.
During IESS Group validation, the following washing cycle has been used:
•Pre-wash for 3 minutes with filtered water at mains temperature (CW)
•Wash for 10 minutes at 65°C with Smeg Deterliquid C2 4ml/l (5 litres of charged water)
•Neutralisation for 3 minutes CW with Smeg Acidglass C2 2ml/l (5 litres charged water)
•Rinse for 3 minutes with deionised water (DW)
•Thermodisinfection for 5 minutes at 90°C
•Program duration = 41 minutes
Dry with a sterile, lint-free disposable cloth if moisture remains after the drying cycle

STERILIZATION
After disinfection, medical devices must be sterilized in autoclave (EN 13060 e EN 285) in accordance with validated procedures.

Steam sterilization in an autoclave
Seal each device in a sterilization pouch suitable for steam sterilization (temperature resistance at least up to 137 °C sufficient steam permeability), which meets the following requirements: EN ISO 11607 and/or DIN 58953-7.
Label the sterilization pouch with the necessary information to identify the device (such as product name, article number and/or batch number, if applicable).
The following steam sterilizer was utilised during IESS Group validation: "SERENA 18" model.
IESS Group has validated the following parameters according to the requirements of current sterilization standards (EN ISO 17665). Sterilization should be carried out according to these validated procedures.

Table 1

Cycle	Minimum temperature	Minimum sterilization time	Minimum drying time
Pre-vacuum cycle[1]	134°C	5 minutes	10 minutes
Pre-vacuum cycle[1]	121°C	15 minutes	10 minutes

[1] Sterilization processes validated to achieve a Sterility Assurance Level (SAL) of 10-6 in accordance with EN ISO 17665-1.

Set the sterilization cycle for medical devices according to Table 1. The number of pieces placed inside the autoclave must correspond with validated load capacity, to guarantee homogeneous vapor penetration. Carefully follow the directions given by the sterilizer manufacturer.
WARNINGS: do not sterilize medical devices in a hot air oven or using a quartz balls sterilizer.

Table 2. Sterilisation of medical devices

Autoclavable	
Rubber cycle sterilisation 121°C	*Iron cycle sterilisation 134°C*
- Beak insert - W-fix inset - Omny insert - Classics insert - OT Equator insert - Insert extension	- Microesam/Nanoesam insert - Stepper insert - Insert tilted holes - Performa insert - Insert for angulated MUA - Implant removal insert
- W-start screwdriver - I-Move screwdriver - Universal screwdriver	- Performa screwdriver
- W-start driver - Beak driver - Omny driver - Classics driver	- Microesam/Nanoesam driver - Every driver - Performa driver - Driver tilted holes
- Holder spare part - Contra-angle adapter - Tapper	- Drills - Drill stop - Drill extension - Tissue punch - Pilot drill - Bone profiler - Guide for bone profiler
Indicator pin	- Mounter - Mounter extractor - Angled adapter for osteotome - Osteotome insert - Wideners - Fixing pin - Depth probe

STORAGE AND MAINTENANCE
After sterilization, place the labelled and sealed sterilisation pouch in a dry place at room temperature (+5°C to +30°C), away from direct sunlight, water and heat sources. Pouches should only be opened immediately before re-use. Sterilization pouches are normally able to maintain sterility inside unless the pouch is damaged. Care should therefore be taken not to use components if the pouches in which they were stored are damaged and to re-sterilize them in new pouches before re-use. The shelf life of sterilized products in pouches should not exceed that recommended by the pouch manufacturer.

SERIOUS INCIDENT WARNING
(For the patient/user/third party in the European Union and countries with identical regulatory regime - Medical Devices Regulation 2017/745/EU)
If a serious incident has occurred during or in connection with the use of this device, report it to the manufacturer and the appropriate national authority.

BASIC UDI-DI INFORMATION
The following table shows the basic UDI-DI information of the devices described in these operating instructions.

PRODUCT	BASIC UDI-DI
Drills and accessories	805299004DRILLD4
Drivers and accessories	805299004DRIVERHC
Surgical instruments	805299004INSTRUMENTSVH
Inserts, screwdrivers, mounter and accessories	805299004INSERTJV

SYMBOL KEY

Manufacturer

Date of Manufacture

LOT Catalogue number

REF Batch code

NON STERILE Non sterile

Consult Instruction for Use

Caution

Contains hazardous substances

MD Medical Device

UDI Unique Device Identifier

CE 0426 Conformity of medical devices with the Medical Devices Regulation (EU) 2017/745 for class IIa medical devices.

CE Conformity of medical devices with the Medical Devices Regulation (EU) 2017/745 for class I medical devices.

Note: for the applicable CE mark for each device, please refer to the product label.