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INSTRUCTIONS FOR USE OF MEDICAL DEVICES FOR IMPLANTOLOGY

GENERAL INFORMATION

INDICATIONS

Read the following instructions for use before using Geass medical devices. These devices must only be used by surgeons and dentists who have experience in implant-restoration techniques and solutions. It is the responsibility of the licensed dentist or surgeon handling the products within their respective fields of expertise to have adequate knowledge about the product with regards to 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 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.

The following instructions for use do not relate to Geass endosseous implants, which have their own information sheet inside the packaging.

Geass medical devices are made of different materials, in compliance with the requirements of Directive 93/42 EEC, the Medical device Regulation (UE) 2017/745 and subsequent amendments, with UNI EN ISO 9001 - UNI EN ISO 13485 standards and IESS Group quality system requirements.

Any informative material for the use of Geass medical devices should be requested to the Customer Service: Telephone+39 0432 669191 - fax +39 0432 665323

- e-mail: servizioclienti@geass.it - website: www.geass.it. 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 of personally verifying the fitness of the product for its intended purpose and procedures. Carefully read the information contained in the "Warnings and conditions of sale" section in all Geass catalogs and manuals.

WARNINGS

The surgeon must determine patient suitability for oral surgery interventions and the appropriate surgical technique.

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.

Geass medical devices should only be used together with other components and/or devices belonging to the Geass implant prosthesis system.

The restorative product obtained on implants must not involve any support by natural teeth, as the various biomechanical characteristics of the support may easily lead to fractures in the restoration or to problems of osseointegration.

Any use other than that described in the Geass informative material is considered "misuse" and frees the manufacturer from any obligation or responsibility.

Do not use devices that appear to be damaged upon visual inspection. Verify that the device and its parts do not show any signs of oxidation, corrosion, wear or bent parts. The devices must be used only if they are perfectly intact, complete and functional in all their parts.

Medical devices that are used in the oral cavity must be secured (fixed) to prevent accidental falling into patient airways.

For cleaning, disinfection and sterilization phases, please follow instructions contained in the relative dedicated section.

Medical devices that are not reusable can be sterilized only once. A second sterilization and/or reuse is not allowed, as this may cause infection of the tissues, alteration to the mechanical properties of the material and therefore a loss in device performance.

PACKAGING

All Geass medical devices are decontaminated and packaged non-sterile. Therefore, before their use, they must be removed from the original packaging, packed in autoclavable material and then sterilized using validated procedures. They are sold as a single unit, unless otherwise specified on the product label. The transparent blister or medical pack permits immediate recognition of the component/s and provides optimal protection of the products up to their use under normal storage conditions. The package comes with adhesive labels which contain traceability data.

These adhesive parts can be removed and applied to the patient's clinical file.

ADVICE FOR STORAGE

Place the cleaned and sterilized medical devices in a dry place at room temperature, away from dust and light. Indicate the date of sterilization and expiry, calculated based on the timing provided by current regulations, on the medical pack.

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.

PROSTHETIC COMPONENTS

GENERAL INDICATIONS

Geass prosthetic components have been specially designed for the restoration of Geass implants, as a support to devices suitable for cemented or screwed oral rehabilitation in partially or totally edentulous patients.

PRECAUTIONS

Close collaboration between the surgeon, prosthetist and dental technician is essential in order to suitably produce restorative products with a correct load distribution. It is also crucial to plan the implant prosthesis treatment. Refer to the procedures described in the prosthetic manual to implement the restorative product.

It is however necessary to check in advance:

- the angle of the implant axis,
- the vertical space between the two arches,
- the size of the soft tissues, without underestimating the interdental space.

Make sure all components are free of any organic or non-organic residue before inserting them in the implant seat. It may be useful to take an X-ray to verify correct connection of the abutment with the implant.

WARNINGS

Geass prosthetic components are not reusable. The implant-abutment contact surfaces must not be sanded or treated in any way. Do not submerge the prosthetic components in hydrofluoric acid, sulphuric acid or other corrosive chemical agents, as this may cause alterations of the device or of its surface. The abutments with parts in PMMA should not be used for tests on patients. Each implant line has unique features and has been developed in order to connect the implant and the prosthetic components in an accurate manner. The combined use of prosthetic components differing from those of the dedicated implant line or which are an incorrect size for perfect coupling to the system can cause mechanical defects, tissue damage, reduction or failure of the implant integration or unsatisfactory esthetic results. It is therefore necessary to carefully check the following factors:

- correspondence of the prosthetic component with the implant seat;
- the type of prosthesis to be implemented;
- height of the abutment collar according to the gingival thickness;
- tightening torque of the connecting screw.

The prosthetic components must be tightened using a torque-controlled screwdriver according to the instructions contained in Table 1. During tightening, avoid lateral flexing which could break the instrument or cause damage to the components that are being handled.

Table 1. Tightening of the prosthetic components

Line	*Prosthetic component*	*Maximum torque*
All lines	- Abutments and components in PMMA - Scan Body	4 N•cm
All lines	- Cover screws - Healing abutments - Copings - Temporary abutments - Lingual screws - Accessories for Step, Leven and Mua abutments (healing abutment, copings, temporary abutments, App abutment)	15 N•cm
All lines	Components tilted hole	25 N•cm
way Mix	Components for definitive prosthesis	25 N•cm
way Milano	Components for definitive prosthesis ø 3.4-3.8 mm	25 N•cm
	Components for definitive prosthesis ø 4.5-5.5 mm	35 N•cm
way Roma	Components for definitive prosthesis	35 N•cm
way Venezia	Components for definitive prosthesis	35 N•cm
way Rock	Components for definitive prosthesis	35 N•cm
way Slim	Components for definitive prosthesis	25 N•cm
Omny	Components for definitive prosthesis	25 N•cm
Kentron	Components for definitive prosthesis	25 N•cm
Every	Components for definitive prosthesis	25 N•cm
Omny Classics	Components for definitive prosthesis	35 N•cm

Connection screw tightening not in compliance with the Geass prosthetic protocol does not guarantee the mechanical hold of the implant-abutment system.

During preparation of the component in the laboratory, do not use the same fixing screw that will be used for the final tightening of the abutment on the implant: use the screws supplied as replacement parts for this purpose.

During the customisation procedures through milling, use a mask to protect the airways and a visor for eye protection. These procedures must be performed in an extraoral site using a diamond bur with irrigation.

SPECIFIC INDICATIONS

Temporary abutments: must not be used for the production of permanent restorative products, and must be replaced by the definitive prosthesis within 30 days.

Step, Leven and Mua abutments: must not be used on individual elements but only on structures of 2 or more elements. The accessories in PEEK supplied in the package together with the abutment are single-use and serve only to facilitate its positioning.

Abutments in golden alloy: for melting, use an alloy with a composition as similar as possible to that of the abutment in gold alloy: Au 60% - Pt 24,9% - Pd 15% - Ir 0.1%; Melting range: 1350-1460°c. Do not use cast alloys with casting temperature above 1200°C.

Abutments in Co Cr: for casting, use an alloy with composition as similar as possible to the abutment in Co Cr: Co 66% - Cr 28% - Mo 6%.

Temperature of solidus-liquidus 1307-1417°C, melting point: 1440°C.

Abutments and components in PMMA: use the IESS Performa Torque for tightening in the laboratory. After obtaining the final component, follow the instructions in Table 1 for tightening.

Linkers: should not be used for temporary restoration. The Linkers for Way Mix and Omny can be provided in the Large and Small version, respectively indicated for the posterior and anterior regions.

Retentive caps for mobile prosthesis: the black caps must be replaced with definitive caps at the end of rebasing.

ROTATING DENTAL INSTRUMENTS AND RELATED ACCESSORIES

GENERAL INDICATIONS

The devices must be correctly inserted into the handpiece, making sure that they are properly gripped. Verify the correct direction of rotation of 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 Geass manuals and catalogs. 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.

SPECIFIC INDICATIONS

Drills: reusable medical devices in stainless steel to be used to create a controlled osteotomy. PRECAUTIONS: 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 micromotor, while preventing bending that can lead to fractures or oversized holes. To avoid damage to the drills during cleaning and disinfection, keep them separate from different material devices. WARNINGS: they can be used for up to a maximum of 4 applications and only if perfectly intact upon visual inspection. Round burs and EBM drills can be used for up to a maximum of 15 applications. 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.

Drill stops: must only be used with the Geass drills to reach the planned perforation depth. They should not be used in the event of a post-extraction technique or surgical guide.

Stops in metallic material: reusable medical devices in stainless steel. Following surgical protocol, carefully choose the type of stop according to the drill which will be used. Stops for twist drills should only be used with twist drill equipped with black notches on the shank near the identification measurements.

Extension for drills: reusable medical device in stainless steel, to be used to easily reach the intervention area between two adjacent dental elements. Should only be used with Geass rotating instruments.

Punches: reusable medical devices in stainless steel used to remove the soft tissues. WARNINGS: 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 punches should not

be used since they are no longer able to carry out their function. In particular, the use of punches that are no longer sharp causes damage to the soft tissues and may therefore lead to complications.

DRIVERS, INSERTS AND ACCESSORIES FOR HANDLING

GENERAL INDICATIONS
Reusable medical devices in stainless steel and/or titanium to be used for the handling of Geass implants and components.

PRECAUTIONS
Choose the driver or the insert that is suited to the implant platform and make sure that the devices perfectly match the seat of the components before starting handling.
Carefully note the position of the drivers and the inserts while screwing, tightening or unscrewing the devices so that the rotation axis of the instrument coincides with the axis of the handled device.

SPECIFIC INDICATIONS
Drivers and inserts equipped with an o-ring: the o-ring is made of polymeric material and must always be 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.
Digital screwdriver: must be used with the appropriate insert for handling implants and prosthetic components. Always check that coupling with the insert is correct.
Newton torque wrench: see the specific instructions sheet supplied in the packaging.

SURGICAL INSTRUMENTS

GENERAL INDICATIONS
Reusable medical devices in steel and/or titanium intended to be used in the context of implant treatments with Geass implants and prosthetic components. Refer to the respective catalogs or manuals for the specific intended use.

CLEANING, DISINFECTION AND STERILIZATION

During cleaning, disinfection and maintenance phases, check the device and its parts do not present any 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 devices during cleaning and disinfection operations, separate them from devices in different materials.
All medical devices are supplied disinfected and in non-sterile packaging. They must be removed from original packaging, packaged in autoclavable material and then sterilized before use, according to instructions provided here below.

PREPARATION OF INSTRUMENTS FOR CLEANING AND DISINFECTION CYCLES

PRE-TREATMENT
Reusable devices must be disinfected/sterilized by starting manual cleaning and drying procedures within 2 hours of use to ensure effectiveness.
Devices should be rinsed in cold tap water and any deposits should be removed with a soft plastic bristle brush.

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 (e.g. DC1® supplied by KOMET at 3% for 15 mins). For an enhanced cleaning effect, use the ultrasonik 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 less 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. Sterilization is also necessary before first use.

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).
All NON-STERILE products can be autoclaved (EN 13060 and EN 285) according to validated procedures.
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.
Any other procedures used by the operator must be validated.

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 2.
The number of pieces placed inside the autoclave must correspond with validated load capacity, to guarantee homogeneous vapor penetration.

WARNINGS
Do not sterilize medical devices in a hot air oven or using a quartz balls sterilizer.
As the abutments or PMMA parts therein are made of a non-autoclavable material and are intended solely for use in the dental laboratory, they cannot be sterilized in an autoclave: they are already ready for use.
Carefully follow the directions given by the sterilizer manufacturer.

Cold sterilization
Thermosensitive prosthetic components (Table 2) must be sterilized in accordance with the normal applicable and validated procedures for non-autoclavable products. Carefully follow the instructions for use given by the cold sterilizer manufacturer, especially the instructions concerning the concentration, temperature and contact time.

STORAGE AND MAINTENANCE

After sterilization, place the labelled and sealed sterilization 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.

Table 2. Sterilization of medical devices

Thermosensitive	*Autoclavable*	
Cold sterilization	*Rubber cycle sterilization 121°C*	*Iron cycle sterilization 134°C*
- Scanbody Bluecam Sirona® L	- Contra angle adapter - Tapper	- Indicator pin - Anchor pin - Endosteal elevator - Double cutting chisel
	- Beak insert - W-fix insert - K-start insert - Omny insert - Classics insert - Over insert - OT Equator insert - Insert extension	- Microesam insert - Stepper insert - Insert tilted holes
	- W-start screwdriver - I Move screwdriver - Universal screwdriver	- Performa screwdriver - Screwdriver
	- W-start driver - Beak driver - K-start driver - Omny driver - Classics driver	- Microesam driver - Performa driver - Driver tilted holes
	- Esthetic-Temp abutment in Peek - Single-Temp abutment in Peek - Multi-Temp abutment in Peek - Single-Temp Reflect abutment in Peek - Multi-Temp Reflect abutment in Peek - Mounter extractor - Healing ring	- Healing abutment - Single-Temp abutment - Multi-Temp abutment - Multi-App abutment - Custom abutment - Rotative abutment - Reflect abutment - Compact abutment - Shoulderless abutment - Equator abutment - Spherical abutment - Precision straight and angled abutment - Roller straight and angled abutment - Leven straight and angled abutment - Mua straight and angled abutment - Slender straight and angled abutment - Syal straight and angled abutment - Elpy straight and angled abutment - Syal Base Regular and Wide - App Mua abutment - Abutment pin - Ti-Base Sirona - Linker
	- Cap for Basic coping - Scanbodies	- Pick-up coping - Overdenture coping - Basic coping - Esam coping - Pin for coping
	- Holder spare part	- Cover screw - Fixing screw
		- Analogs
		- Drills - Drill stop - Drill extension - Tissue Punch - Pilot

SYMBOL KEY

Manufacturer

Catalog Number

Batch code

Non-sterile

Do not re-sterilize

Do not re-use

Caution

Compliance of medical devices with Directive 93/42/CEE and subsequent amendments For Class IIa and IIb devices
0123

Conformity of medical devices with the Medical Devices Regulation (EU) 2017/745. For Class I devices

Medical device

Unique Device Identifier