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INSTRUCTIONS FOR USE OF PROSTHETIC COMPONENTS

GENERAL INFORMATION

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 Medical device Regulation (UE) 2017/745, with UNI EN ISO 9001 - UNI EN ISO 13485 standards and the IESS Group quality system requirements, see dedicated section for more information.
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 of personally verifying the fitness of the product for its intended purpose and procedures.

CHARACTERISTICS AND INSTRUCTIONS

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. Geass prosthetic components contain the screw/s required for use or fixing in the package.

When choosing which prosthetic component to use, 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 (see table 1);
- specific indications for each type of component, given in the following paragraphs.

COVER SCREWS (medical grade titanium) Supplied with the implant, they can also be bought separately. Cover screws preserve the implant seat during the soft tissues healing, in case of two-stage surgical procedure.
HEALING ABUTMENTS (medical grade titanium) To guide the healing of periimplant soft tissues, in order to create the best emergency profile for the restoration; choose the proper height, according to the mucosal thickness.
TEMPORARY ABUTMENTS (SINGLE TEMP: medical grade titanium, MULTI TEMP: pure titanium grade 4, ESTHETIC TEMP: PEEK) To create temporary restoration with an aesthetic function, avoiding functional load. They are supplied with long screws for the construction of the temporary restoration and short screws for fixing. Must not be used for the production of permanent restorative products, and must be replaced by the definitive prosthesis within 30 days.
COPINGS (medical grade titanium) To transfer the axial and angular position of the implant from the patient to the laboratory, through a custom or a standard impression tray.
SCANBODY (medical grade titanium, PEEK) To transfer the position of the implant from reality to the CAD software in three dimensions; they always have to be matched up with the proper library. If used in laboratory, they must be tightened with the Performa Torque spanner; if used on the patient (intraoral digital scanning) they must be tightened with the Performa screwdriver.
DEFINITIVE TITANIUM ABUTMENTS. To create the definitive fixed restoration; select the straight or the angulated version, according to the implant axis. Engaging abutments must be used in case of single elements, non-engaging abutments in case of multiple elements. The product must be milled in laboratory, in order to adapt its morphology to the customized prosthesis, according to the treatment plan.
Abutments can be reduced in height until obtaining the dimensions suitable to the specific case, as long as it does not go below the head of the screw; never adjust the abutments below the shoulder, so that the mechanical characteristics are not compromised.
The Step, Leven, Reflect, Mua, Syal abutment can in no way be modified in order to maintain functionality.
Moreover:
- THE STEP, LEVEN, REFLECT and MUA ABUTMENT must not be used on individual elements but only on structures of 2 or more elements. The accessory possibly supplied in the package together with the abutment is single-use and serve only to facilitate its positioning.
- LINKER: should not be used for temporary restoration; they are available in the Large and Small version, respectively indicated for the posterior and anterior regions.

DEFINITIVE CASTABLE ABUTMENTS For the creation of the final fixed restoration, using in laboratory the casting and overcasting techniques, according to the type and material. Pay particular attention to the characteristics of material:
- ABUTMENTS IN CoCr: for casting, use an alloy with composition as similar as possible to the abutment in CoCr: Co 66% - Cr 28% - Mo 6%.

Temperature of solidus-liquidus 1307-1417°C, melting point: 1440°C.
- ABUTMENTS AND COMPONENTS IN PMMA: use the Performa Torque spanner for tightening in the laboratory. After obtaining the final component, follow the instructions in Table 1 for tightening

Table 1. Tightening of the prosthetic components

Line	*Prosthetic component*	*Maximum Torque*
All lines	- Abutments and components in PMMA - Scanbody	4 N•cm
All lines	- Cover screws - Healing abutments - Copings - Temporary abutments - Lingual screws - Accessories for Step, Leven, Syal and Mua abutments (healing abutment, copings, temporary abutments, App abutment)	15 N•cm
All lines	Tilted hole components for Step, Leven, Mua	15 N•cm
All lines	Tilted hole components, excluded for Step, Leven, Mua	25 N•cm
Way Mix, way Slim, Omny, Kentron, Every	Components for definitive prosthesis, included Mua e Syal	
Way Milano	Components for definitive prosthesis ø 3.4-3.8mm	25 N•cm
	Components for definitive prosthesis ø 4.5-5.5mm	35 N•cm
Way Roma, way Venezia, way Rock, Omny Classics, Ergon, Hexa, Esedra Dual	Components for definitive prosthesis	35 N•cm

MATERIALS

DEFINITIVE, SINGLE-TEMP TEMPORARY ABUTMENTS AND COPINGS: titanium alloy Ti6Al4V ELI (5.5-6.5% aluminium, 3.5-4.5% vanadium, 0.25% max iron, 0.13% max oxygen, 0.08% max carbonium, 0.05% max nitrogen, 0.012% max hydrogen, titanium balanced) according to ISO 5832-3 and ASTM F136 standards.
MULTI-TEMP TEMPORARY ABUTMENTS: grade 4 commercial pure titanium (0.05% max nitrogen, 0.08% max carbon, 0.0125% max hydrogen, 0.5% max iron, 0.4% max oxygen, titanium balanced) according to ISO 5832-2 and ASTM F67 standards.
DEFINITIVE EQUATOR ABUTMENTS: TiN coating, titanium nitride.
ESTHETIC-TEMP TEMPORARY ABUTMENTS AND SCANBODIES: medical grade PEEK (polyether-ether-ketone).
CoCr FUSION ABUTMENTS: cobalt-chromium alloy (26-30% chromium, 5-7% molybdenum, 0.75% max iron, 1% max manganese, 1% max silicon, 1% max nickel, 0.25% max nitrogen, 0.14% max carbon, cobalt balanced) according to ISO 5832-12 and ASTM F1537 standards.
CASTABLE ABUTMENTS: PMMA (polymethyl-methacrylate).

WARNINGS

Do not use devices that appear to be damaged upon visual inspection. The devices must be used only if they are perfectly intact, complete and functional in all their parts.
The dentist must make sure to avoid unintentional dropping of medical devices into the patient's airway.
Geass prosthetic components are not reusable and can be sterilised 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. For cleaning, disinfection and sterilization phases, please follow instructions contained in the relative dedicated section.

PROSTHETIC PLANNING

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

CORRESPONDENCE BETWEEN PROSTHETIC COMPONENTS AND DEDICATED IMPLANT LINE

Geass prosthetic components should only be used together with other devices belonging to the Geass implant prosthesis system. 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. 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.

MANUFACTURE OF PROSTHESES

Refer to the procedures described in the IESS Group informative material to implement the restorative product. 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.
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. 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.
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. IESS Group cannot guarantee that the mechanical properties of products modified in this way will be maintained. Any use other than that described in the IESS Group informative material is considered "misuse" and frees the manufacturer from any obligation or responsibility.

TIGHTENING

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. 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..

PRESENCE OF HAZARDOUS SUBSTANCES

Fusion abutments CoCr contain cobalt (EC number 231-158-0) in a ratio of a minimum 63% and a maximum of 69%. It is therefore advisable to take this into account if you have particularly sensitive/vulnerable patients or breast-feeding women.

PACKAGING

Geass prosthetic components are single-use and non-sterile; before their use, please follow instructions contained in the section dedicated to cleaning and sterilization. They are sold as a single unit, unless otherwise specified on the product label. The packaging permits immediate recognition of the product and provides optimal protection 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.

CLEANING AND STERILIZATION INSTRUCTIONS

Geass prosthetic components are single-use and non-sterile. Before their use, they must be removed from the original packaging, and then cleaned and sterilized. The devices can be cleaned manually or using automatic washing equipment. Each device must then be sealed in a sterilization pouch and sterilized.
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 steam sterilized in autoclave (EN 13060 e EN 285) in accordance with validated procedures.
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.

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. 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. 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.

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.

Table 2. Sterilisation of medical devices

Thermosensitive	*Cold sterilization*	Scanbody Bluecam Sirona L
Autoclavable	*Rubber cycle sterilization 121°C*	- 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 - Healing ring - Cap for Basic coping - Scanbodies
	Iron cycle sterilization 134°C	- 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 - Pick-up coping - Overdenture coping - Basic coping - Esam coping - Pin for coping - Cover screw - Fixing screw

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.

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.

INFORMATION TO BE PROVIDED TO PATIENT
The patient should be provided with information on contraindications, warnings, precautions, side effects, and complications that may occur with the use of Geass devices.
The GEASS implant-prosthesis system has not been evaluated in terms of safety and compatibility in the MRI environment. It has not been tested for overheating, migration or artefactual imaging in the MRI environment. The safety of the GEASS implant-prosthesis system in the MRI environment is unknown.
Upon availability of the European Medical Device Database, the Summary of Safety and Clinical Performance (SSCP) of Geass prosthetic components will be available at https://ec.europa.eu/tools/eudamed.
It will be available for each type of implantable device. For prosthetic components it will be referred to as SSCP.01.xx (current revision).

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
Definitive abutments and fixing screws	805299004DEFINITIVEZ9
Temporary abutments, healing abutments and cover screws	805299004TEMPORARYMT
Copings and accessories, scanbodies	805299004IMPRESSIONWC

SYMBOL KEY


Manufacturer


Date of Manufacture

Catalogue number

Batch code

Non sterile


Do not re-sterilize


Consult Instruction for Use


Caution


Contains hazardous substances

Medical Device

Unique Device Identifier

Conformity of medical devices with the Medical Devices Regulation (EU) 2017/745