IESS GROUP Srl
Via Madonna della Salute 23 - 33050 Pozzuolo del Friuli UD - I -
tel. +39 0432 669191 - www.iess.dental

EN - ENGLISH

INSTRUCTIONS FOR USE: GEASS ENDOSSEOUS IMPLANTS: OMNY

LIMITATION OF LIABILITY Read the following instructions for use before using Geass endosseous dental implants. 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 operators handling the products within their respective field of activity to have adequate knowledge of the product, based on 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 patient suitability for oral surgery and the appropriate surgical technique; they must also determine the suitability of the product chosen for intended use, taking on every form of risk and responsibility to this effect. Product processing, handling and application in the surgery or dental laboratory are beyond the manufacturer's control and therefore fall under the responsibility of the user. Any use other than what is described in information material is considered "misuse" and relieves the manufacturer of any obligation or responsibility.

PRODUCT DESCRIPTION Geass endosseous implants have been designed for oral-surgical use; they are implantable devices made of titanium for medical use with a Synthegra surface, available in a range of models, diameters and lengths to satisfy diverse anatomical requirements. Implants of the Omny line are supplied with a cover screw and multifunction component, both made of titanium for medical use.

INTENDED USE
Omny dental implants are for insertion in the oral cavity, to provide anchorage or support for connected prosthetic devices.

INDICATIONS

Dental implants Geass endosseous dental implants are single-use devices intended for surgical placement in the bone of the mandibular and/or maxillary dental arches, to provide support for fixed and/or removable restorations and thus restore original features and masticatory function. They are indicated for permanent use, for partially or completely edentulous patients.
Cover screw To be used with the implant during healing to protect the platform and the implant cavity from bone growth.
Multifunction component specially designed for both the restoration and the impression taking of Omny implants, as a support for an oral rehabilitation device in partially or completely edentulous patients. The component may be used as a temporary abutment, as a coping or as a permanent abutment.

CONTRAINDICATIONS The following are considered contraindications for an implant-restoration treatment: metabolic bone disorders, osteoporosis, cancer, bleeding disorders, diseases of the immune system, endocrine disorders, severe liver and kidney diseases, uncontrolled diabetes, infectious diseases (AIDS), allergy to metals, psychosis and neurological disorders, drug and alcohol abuse, smoking, lack of cooperation and motivation of the patient, radiation therapy, heart disease, treatment with anticoagulant drugs and critical pharmaceuticals (e.g. bisphosphonates), chemotherapy, pregnancy, parafunctions in the oral cavity, bruxism, uncontrolled periodontal disease, poor oral hygiene, inflammation and/or local infections and unfavourable bone anatomical situations.

REACTIONS TO OPERATION AND SIDE EFFECTS After the surgical operation some discomfort may be experienced, such as: pain, swelling, phonation difficulties, inflammation of the soft tissues, bone resorption, dehiscence, aesthetic problems, damage to the adjacent natural elements or nerves, paresthesia, 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.

LIMITATIONS OF USE Geass medical devices should only be used with other components and/or devices belonging to the same implant prosthesis system. Omny endosseous dental implants with a diameter of 3.5 mm or less are exclusively indicated for edentulous treatment of the lower incisors and the upper laterals. The use of XL Omny implants is not intended for D1 bone. IESS Group declines all liability for uses other than those indicated. In the event of use of reconstructive techniques, comply with instructions supplied by the reconstructive material manufacturer and indications in literature.

WARNINGS In order to correctly execute surgical procedures involving Geass endosseous dental implants, it is essential for each Professional to have necessary surgical preparation. For application, proceed according to the surgical protocol and information tools provided by IESS Group. An erroneous surgical procedure may result in the failure of implant therapy and/or the loss of bone support tissue. The Surgeon must always ascertain the suitability of the selected endosseous implant for intended use and the prosthesis to be made, undertaking all forms of risk and responsibility. They must always assess the indispensable premises for proceeding with prosthetic treatment, such as excellent primary stability and adequate bone values. The insertion and restoration of Geass endosseous implants must be carried out in compliance with biological and biomechanical principles, to avoid the failure of implant therapy and/or the loss of support tissue. In certain cases, Omny endosseous implants are indicated for immediate restoration. The restoration of a single element with immediate loading is not recommended as the procedure has not yet been validated by scientific literature. Before inserting any component within the implant cavity, clean it of all organic and non-organic residue. Omny endosseous dental implants must not be inserted with a torque exceeding 50 N•cm. The cover screw must be tightened to a maximum torque of 15 N•cm. According to its use, the multifunction component must be tightened to a maximum torque of: 15 N•cm if used as a coping or temporary abutment; 25 N•cm if used as a permanent abutment.

PACKAGING AND STERILISATION Packaging includes two adhesive labels for implant traceability purposes and which, in compliance with current regulations, must be applied to the patient's implant passport. Do not use the medical device if the packaging is damaged or open.
Dental implants and cover screw
Geass endosseous dental implants are medical devices sterilized by ionizing radiation; they are single-use devices and must be used by the indicated expiry date. Second sterilization and/or reuse is not allowed as this may cause alteration to the mechanical, chemical and microbiological properties of the material and therefore a loss in the performance of the device.
Multifunction component
The multifunction component is supplied sterile. If used in a moment subsequent to the implant insertion intervention, remove it from the original packaging and proceed with cleaning and disinfection. Subsequently package the multifunction component in autoclavable material and proceed with the sterilization in an autoclave using validated procedures in accordance with regulations in force using the following parameters: 134°C for 5 minutes in a device in conformity with DIN EN 13060. Do not sterilize the multifunction component in a hot air oven or through a quartz balls sterilizer; carefully follow the indications given by the manufacturer of the sterilizer.

STORAGE Geass endosseous dental implants must be kept at room temperature, in a dry place away from direct sunlight and heat sources. The expiry date refers to the product in its closed packaging and which has been correctly stored.

ECOLOGICAL INFORMATION AND DISPOSAL Geass endosseous implants are not biodegradable. If used correctly, they do not give rise to any ecological damage and must be treated according to current regulations. The material must be disposed of by authorized companies.

MATERIALS
Dental implants: Commercially pure grade 4 titanium (0.05% max nitrogen, 0.08% max carbon, 0.0125% max hydrogen, 0.5% max iron, 0.4% max oxygen, the remainder titanium) compliant with the standards ISO 5832-2 and ASTM F67; 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 carbon, 0.03% max nitrogen, 0.012% max hydrogen, the remainder titanium) compliant with the standards ISO 5832-3 and ASTM F136.
Cover screw and multifunction stump: titanium alloy Ti6Al4V ELI (5.5-6.50% aluminium, 3.5-4.5% vanadium, 0.25% max iron, 0.13% max oxygen, 0.08% max carbon, 0.03% max nitrogen, 0.012% max hydrogen, the remainder titanium) compliant with the standards ISO 5832-3 and ASTM F136.

DOCUMENTATION Information material for the use of Geass dental endosseous implants must be requested from our commercial representatives, area dealers, or directly from the head office. Customer Service: telephone +39 0432 669191 – fax 39 0432 665323 - e-mail: servizioclienti@iess.dental - website: www.iess.dental. Information contained therein refers to the state of the art as known at the time of product commercialisation. This does not exonerate the user from the responsibility of personally verifying the fitness of the product for its intended purpose and procedures.

NOTIFICATION OF SERIOUS INCIDENTS (For patients/ users/ third parties in the European Union and Countries with an identical regulatory framework - Regulation 2017/745/EU on Medical Devices). If a serious incident occurs during or in concomitance with the use of this device, it must be reported to the manufacturer and competent national authority.

INFORMATION TO BE PROVIDED TO PATIENT The patient must be provided with information on contraindications, warnings, precautions, undesired effects and complications that may occur with the use of Geass devices. The Omny implant system has not been assessed in terms of safety and compatibility in the MR environment. It has not been tested for overheating, migration or image artefact in the MR environment. The safety of the Omny implant system in an MR environment is not known. Geass dental implants come with an implant passport containing important information for patients on the device. The dentist must fill out the passport with specific information on the patient and devices used for rehabilitation, and return it to the patient. When the European Medical Devices Data Base will be available, the SSCP (Summary of Safety and Clinical performance) of Geass dental implants will be available at https://ec.europa.eu/tools/eudamed. The document will be entitled SSCP.04.xx (current version)

PRODUCT	BASIC UDI-DI CODE
Dental implants	805299004DENTALIMPLANT65

Code. 40542 – Rev.3 – 2024-03

KEY OF SYMBOLS

Manufacturer

Manufacture date

REF Catalogue number

LOT Batch code

STERILE R Sterilised with ionising rays

Single sterile barrier system with internal protective packaging

Non resterilisable

Non reusable

Usable before the date

Do not use if packaging is damaged and read the IFU

Store away from the sun's rays

Store in a dry place

Read instructions for us

MD Medical Device

UDI Unique Device Identifier

CE 0426 Compliance of medical devices with the Medical Devices Regulation (EU) 2017/745