INSTRUCTIONS FOR USE

Investigación y desarrollo en mecanizado médico S,L.

CUSTOM PLATES / MESHES

CAUTION – PLEASE READ CAREFULLY

The products supplied by **Investigación y desarrollo en mecanizado médico S,L.** are intended for use by qualified healthcare professionals (Dental Technicians, Physicians, and Dentists). The safety and efficacy of the products supplied by **Investigación y desarrollo en mecanizado médico S,L.**, whether screws, abutments, or other surgical and prosthetic dental accessories, is only guaranteed when their use is limited to properly trained professionals. If in doubt, please contact the manufacturer. All products are designed for single use and must not be reused. If reused, there is a risk that a damaged or deteriorated product may lead to failures in the prosthetic solution and/or other harm to the patient's health, such as tissue infection. All components must be tested prior to intraoral use in the patient to verify correct fit. The clinician (dentist) is responsible for the correct application of the products, as both planning and procedures are under their control. This is why only dental specialists with appropriate experience and training should work with products from **Investigación y desarrollo en mecanizado médico S,L.** If in doubt, please contact the manufacturer. During any intraoral use and handling, all products must be secured to prevent aspiration due to their shape and size.

WARNINGS AND CONTRAINDICATIONS

All products are for single use only and must not be reused. Reuse may cause loss of mechanical, chemical, or biological properties. Reuse may cause cross-contamination. Check the integrity of the packaging and do not use it if it is damaged. All materials used are biocompatible; however, some patients may present allergies or hypersensitivity to any of the materials and their components.

STERILIZATION AND REUSE

Investigación y desarrollo en mecanizado médico S,L. recommends always performing a prior cleaning with products used in the dental sector, supported by ultrasonic baths or automatic cleaning and disinfection methods prior to sterilization. **Investigación y desarrollo en mecanizado médico S,L.** supplies the product NON-STERILIZED. Before sterilizing, the products must be transferred from their original packaging to one suitable for that purpose. Sterilization must be carried out in a moist steam autoclave at 134°C for a minimum of 3 minutes, in accordance with UNE-EN-ISO 17665-1:2007, in sterilization pouches or boxes. If any deterioration of the packaging is observed after sterilization, do not use the product.

STORAGE AND HANDLING

All products manufactured by **Investigación y desarrollo en mecanizado médico S,L.** are presented perfectly packaged and heat-sealed. A defect in the packaging may result in the loss of decontamination and disinfection properties, so it is recommended to discard its use. Under no circumstances should the material be removed from its original packaging and handled without the need for use.

NOTICE ON SERIOUS INCIDENTS

For patients/users/third parties in the European Union and in countries with an identical regulatory framework (EU Regulation on medical devices), if a serious incident occurs during or as a result of the use of this device, notify the manufacturer and the relevant national authority. The contact information of the manufacturer of this device for reporting a serious incident is as follows:

C/ Riera de Montealegre, 50, 08915 Badalona, Barcelona, Spain.

Contact telephone: +34 934 026 740

SPECIFIC INSTRUCTIONS FOR USE

CUSTOMIZED PLATES FOR BONE REGENERATION

Manufactured in Titanium TI6AI4V ELI_ ISO 5832-3 and Zirconia. The purpose is to contain the bone graft in patients with bone mass deficiency using custom or customized plates and screws or microscrews to fix it until osseointegration is achieved, which will allow the placement of dental implants during the process of total or partial dental rehabilitation. Additionally, dental bone regeneration through bone grafting is a surgical procedure that seeks to replace lost bone. The transplanted bone may come from the patient themselves, from a donor, or from commercially available bone substitutes (of animal, plant, or synthetic origin), provided they are compatible with the patient. Osteosynthesis plates are used to create a scaffold for the bone graft, and osteosynthesis screws or microscrews serve to fix the plate until osseointegration of the grafted bone is achieved. After this process, the plates and screws or microscrews are removed.

CUSTOMIZED SUBPERIOSTEAL PLATES

Manufactured in Titanium TI6AI4V ELI_ ISO 5832-3. The subperiosteal plate/mesh is designed by the clinician (dentist) based on a high-resolution CBCT; to adapt to the shape of the maxillary or mandibular bone, being placed under the periosteum (the membrane covering the bone) but above the bone itself. It is used as an alternative in cases where the amount of bone is insufficient for a traditional endosseous implant.

Design and Manufacturing:

Manufactured in Titanium TI6AI4V ELI (ISO 5832-3), which gives them the following characteristics:

- **Biocompatibility:** Biocompatible material that guarantees excellent acceptance by all oral tissues.
- **Low Bacterial Adhesion:** Polished surface that minimizes bacterial adhesion, allowing them to be safely exposed to the oral environment if necessary.
- **Rigidity and Malleability:** Rigid material that allows simple and predictable manipulation, maintaining the designed shape without deformations.
- **3D Customized Design:** Three-dimensionally designed and preformed by the clinician (dentist) using specific software, precisely adapting to the morphology and dimensions of each patient's bone defects.
- **Sterilizable:** Can be sterilized afterward without losing their original shape or design, being stably fixed with osteosynthesis screws.

Manufactured in high-purity, surgical-grade Zirconia (ZrO_2), which gives them the following characteristics:

- **Superior Biocompatibility:** Highly biocompatible material with an excellent response from all oral tissues, minimizing adverse reactions.
- **Aesthetic Properties:** White/ivory color similar to the tooth, which offers aesthetic advantages by not showing through the mucosa in case of exposure or in thin areas.
- **Low Bacterial Adhesion:** High-density, polished surface that significantly reduces bacterial adhesion, and can be exposed to the oral environment with low risk of contamination.
- **Rigidity and Stability:** Rigid material that perfectly maintains the designed shape, offering excellent space maintenance for guided bone regeneration.
- **3D Customized Design:** Three-dimensionally designed and preformed by the clinician (dentist) using a computer, precisely adapting to the specific morphology and dimensions of each patient's bone defects.
- **Sterilizable:** Can be sterilized afterward while maintaining their original shape and design, being retained with osteosynthesis screws (generally metallic or of the same material).

BODY DESIGN

For Bone Regeneration Plates

Thanks to custom designs made by the clinician (dentist), regardless of the bone defect, being preformed and custom-designed they are useful for regenerating any type of defect. Their perforations vary according to the needs and indications of the defect and the clinician; and they are individually crafted for each case. Their characteristics provide ease of use, handling, and high resistance. Their function is as formwork and barrier for the retention of the grafted bone material, and once the integration time has passed, they are removed.

They are plates with perforations and specific dimensions for each patient and defect; and with holes for the placement of self-tapping osteosynthesis screws, which retain it mechanically. The design is decided by the clinician prior to manufacturing, according to the defect and the anatomical circumstances previously obtained from a high-resolution CBCT. These plates are intended to retain the grafted material and form custom formwork to precisely regenerate oral bone defects, and they remain in the mouth for 6 to 8 months until the bone tissue has completed its biological cycle of neoformation. It is at this point that both the plate and the screws are permanently removed so that osseointegrated implants can be placed, and the masticatory, functional, and aesthetic functions of the patient can be rehabilitated.

For Subperiosteal Plates

A subperiosteal plate is a personalized metal structure designed to adapt to the bone surface of the maxilla or mandible, placed under the periosteum. Its design varies according to the patient's anatomy, but generally presents the following characteristics:

Structural Characteristics

1. **Material:**
   - Manufactured in **Titanium TI6AI4V ELI (ISO 5832-3) and Zirconia (ZrO_2)**, which guarantees strength, durability, and compatibility with tissues.
2. **Shape and Design:**
   - Designed beforehand by the clinician (dentist) to measure using 3D scans of the patient's maxillary or mandibular bone for validation and subsequent manufacturing.
   - It has a **plate or lattice mesh structure**, which allows better integration with the surrounding tissue and reduces the weight of the implant, and also contains perforations for the placement of osteosynthesis screws, which vary according to the retention needs and indications included in the clinician's design.
   - It has **extensions or connections/abutments** that pass through the gum and emerge in the oral cavity to screw and support the dental prosthesis.
3. **Location and Fixation:**
   - Placed **above the bone and below the periosteum**, without the need for perforations in the bone.
   - Anchored by specific supports designed to distribute the masticatory load uniformly.
   - Fixation is achieved through its anatomical fit, with the use of anchor or osteosynthesis screws.

Product Description	Basic UDI-DI	#Model Number	Class	Material
Bone Regeneration Plate	843660239CUSTOMMESHVY	ID34	IIb	Titanium per ISO 5832-3. Yttria-stabilized tetragonal polycrystalline zirconia // ZrO_2 + Y_2O_3
Subperiosteal Plate	843660239CUSTOMMESHVY	ID34	IIb	Titanium per ISO 5832-3.

MANUFACTURER DATA

INVESTIGACIÓN y DESARROLLO EN MECANIZADO MÉDICO S,L. (IDM)
C/ Riera de Montealegre, 50, 08915 Badalona, Barcelona, Spain.
Contact telephone: (+34) 93 4026740

LABEL SYMBOL LEGEND

Product information is provided on its label where the following is detailed:

Symbol	Description
	Logo of Investigación y desarrollo en mecanizado médico S,L.
	Manufacturer
#	Family Number
REF	Product Reference
Nº	Work Number
CLIENTE	Do not use if packaging is damaged.
De	Prescriber Name
	Do not use if packaging is damaged.
	Do not reuse
MD	Medical Device
Quantity	Packaged Units

*We kindly ask you to read carefully the instructions described above to ensure a safe and efficient use of the products supplied by **Investigación y desarrollo en mecanizado médico S,L.** The entire product range is designed to facilitate work, both in the clinic and in the prosthetic laboratory, while providing the best quality. The product characteristics and compatibilities are detailed in the commercial catalogue; if in doubt, please contact us.*