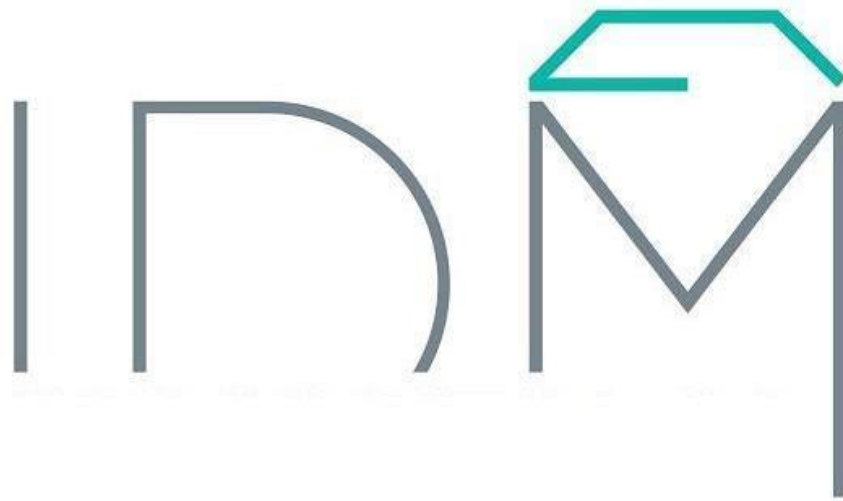


INSTRUCTIONS OF USE

Investigación y desarrollo en mecanizado médico S,L.



PROSTHETIC REINFORCEMENT MESH



Investigación y desarrollo en mecanizado médico S,L.
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INSTRUCTIONS OF USE

CAUTION – BY FAVOR READ SINCERELY

The products supplied by **Research and Development in Medical Machining S,L.** are intended to be used by qualified healthcare professionals (Dental Technicians, Doctors and Dentists). Safety and effectiveness of the products supplied by **Research and Development in Medical Machining S,L.**, be they screws, abutments or other surgical and prosthetic dental accessories, is only guaranteed when its use is limited to trained professionals. If in doubt, contact the manufacturer. All Products are designed for single use only and should not be reused. If they are reused, there is a risk that the product may be damaged or deteriorated. Product characteristics may lead to inadequacies in the prosthetic solution and/or other type of deterioration of the patient's health such as tissue infection. All components must be tested previously to the use in mouth of the patient to find out the adjustment is correct. He is responsible for the correct application of the products will be the prosthetic or clinical as appropriate, because so much the planning as the procedures are under his control. This is the reason why only dental specialists with the proper experience and training should work with **Medical Machining Research and Development** products S,L. If in doubt, please contact the manufacturer. During any use intraoral and handling all the products must be insured for avoid the aspiration due to its shape and size.

WARNING AND CONTRAINDICATIONS

All products are for single use and should not be reused. Reuse could cause loss of mechanical, chemical or biological characteristics. Its reuse could cause cross contamination. Check the packaging integrity, and do not use it in case of alteration of the same. All materials used are biocompatible, however, some patients may present allergies either hypersensitivity to any of the materials and their components.

STERILIZATION AND REUSE

Research and development in medical machining S,L., recommends always performing a prior cleaning with products for use in the dental sector, relying on ultrasonic baths or automatic cleaning methods and disinfection previous to its sterilization. **Research and development in medical machining S,L** supplies the sterilized product, before of should be sterilized transfer the products of his container original to another suitable for this purpose. Its sterilization must be carried out in a wet steam autoclave at 134°C for 3 minutes minimum, according to UNE-EN-ISO 17665-1:2007, in sterilization bags or boxes. If after its sterilization HE observe any deterioration in the container, No use the product.

STORAGE AND HANDLING

All products manufactured by **Research and Development in Medical Machining S,L.** It is presented perfectly packaged and heat-sealed. A defect in This may result in the loss of decontamination and disinfection properties, which is why it is recommended discard its use. Under no circumstances should the material be removed from the original packaging and handled without the need for utilization.

WARNING ABOUT INCIDENTS GRAVES

For patients/users/third parties in the Union European and in countries with a regime normative identical (Regulation /EU on medical devices), if, during the use of this device or as a result of its use, a incident serious, notify it to the manufacturer and So authority national. The information of contact of the manufacturer of this device for notify a incident serious is the following:

C/ Riera de Montealegre, 50, 08915 Badalona, Barcelona, Spain.
Phone of contact +34 934 026 740



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INSTRUCTIONS OF USE SPECIFIC

PROSTHETIC REINFORCEMENT PLATES

Made of Grade 2 Titanium. These plates are used for acrylic dental prostheses and their purpose is to stabilize and reinforce them, to avoid a fracture or in some cases to repair in case of previous breakage.

Design of the meshes

Made of Grade 2 Titanium, which gives it the following characteristics:

- Biocompatible material with excellent acceptance by all oral tissues.
- Polished material with low bacterial adhesion. Can be exposed to the oral environment.
- Malleable and ductile material. Allows for very easy manipulation. Maintains its shape. It can be preformed prior to use for prosthetic reinforcement; and can be subsequently sterilized while maintaining its new shape.

Body design

Thanks to its various designs, cutting the plate is very simple and can be done with any type of scissors. In two versions: 50 x 50mm and 25 x 50mm with perforations. Its characteristics provide it with high malleability and resistance. For reinforcing the base of the prosthesis. Large drilling diameter for a good bond with the resin.

They are generally used to reinforce removable prostheses, both complete and partial. Their function as reinforcement is to prevent fracture of the prostheses by providing extra reinforcement in the manufacture of the prostheses.

Reinforcement plates are a titanium metal filament with retentions that the dental technician decides to introduce when the prosthesis being manufactured could be subject to fragility and therefore crack or break. And it is embedded within the resin or acrylic with which the prosthesis is manufactured.

Description	Description	Ref.	Family	# Model Number
REINFORCEMENT MESH 50x50,v01	Reinforcement mesh 50x50,v01	ID00.33.551	REINFORCEMENT MESH	ID33
REINFORCEMENT MESH 50x25,v01	Reinforcement mesh 50x25,v01	ID00.33.521	REINFORCEMENT MESH	ID33
REINFORCEMENT MESH 50x50,v02	Reinforcement mesh 50x50,v02	ID00.33.552	REINFORCEMENT MESH	ID33
REINFORCEMENT MESH 50x25,v02	Reinforcement mesh 50x25,v02	ID00.33.522	REINFORCEMENT MESH	ID33

Name / Name		UDI-DI -BASIC
Prosthetic Reinforcement Mesh	<i>Prosthetic Reinforcement Mesh</i>	843660239REINFMESHRK

* A summary of safety and clinical performance (SSCP) of dental implant abutments will be available in the European Database on Medical Devices (EUDAMED).

<https://ec.europa.eu/tools/eudamed>



MANUFACTURER DATA














RESEARCH AND DEVELOPMENT IN MEDICAL MACHINING S,L. (IDM)

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

The contact telephone number is (+34) 93 4026740

LEGEND OF LABEL SYMBOLS

Product information is given on its label where it details:

<i>symbols</i>	<i>Description</i>
	<i>Logo Research and development in medical machining S ,L .</i>
	<i>Manufacturer</i>
	<i>Date of manufacture</i>
	<i>Catalog reference</i>
	<i>Batch</i>
	<i>Read the QR instructions for use</i>
	<i>Do not use if packaging is damaged.</i>
	<i>non-sterile</i>
	<i>Do not reuse</i>
	<i>CE mark</i>
	<i>Product family</i>
	<i>UDI code linked to Data Matrix</i>
	<i>Medical device</i>

Rogamos leer con especial atención las instrucciones descritas anteriormente para garantizar un uso seguro y eficiente de los productos suministrados por **Investigación y desarrollo en mecanizado médico S,L. .**

Toda la gama de productos está diseñada de forma que facilite el trabajo, tanto en clínica como en el laboratorio protésico, aportando al mismo tiempo la mejor calidad. Las características del producto y sus compatibilidades se amplían en el catálogo comercial, en caso de duda rogamos se pongan en contacto con nosotros.



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