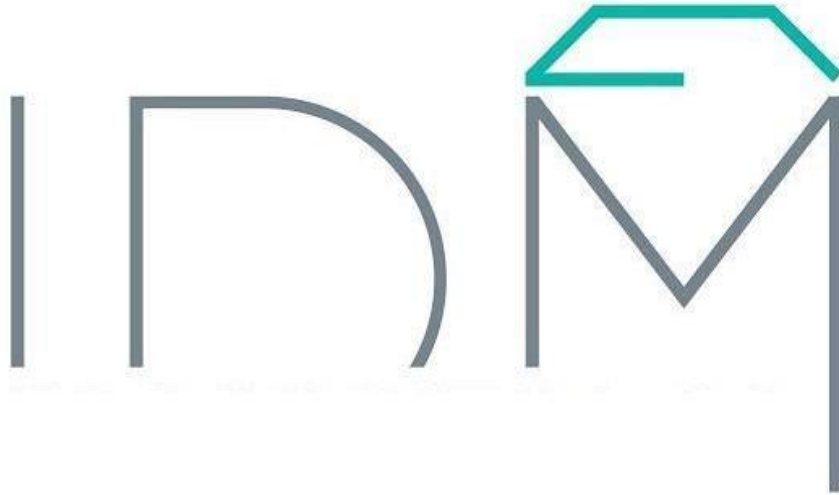


# INSTRUCTIONS FOR USE

Investigación y desarrollo en mecanizado médico S,L.



## BONE REGENERATION PRODUCTS



**Investigación y desarrollo en mecanizado médico S.L.**  
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## CAUTION – PLEASE READ CAREFULLY

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

## WARNING AND CONTRAINDICATIONS

All products are single-use and should not be reused. Their reuse could cause the loss of mechanical, chemical or biological characteristics. Its reuse could cause cross-contamination. There is a contraindication for the use of the products in case of patients with conditions that rule out the use of surgery for the placement of dental implants. Check the integrity of the packaging, and do not use it in case of alteration of the packaging. All materials used are biocompatible, however, some patients may have allergies or hypersensitivity to any of the materials and their components.

## STERILIZATION AND REUSE

Investigación y desarrollo en mecanizado médico S.L., recommends always carrying out a previous cleaning with products used in the dental sector, relying on ultrasound baths or automatic cleaning and disinfection methods prior to sterilization. Investigación y desarrollo en mecanizado médico S.L. does not supply the sterilized product, before sterilizing the products must be transferred from their original container to another suitable for this purpose. Its sterilization must be carried out in a wet steam autoclave at 134°C at a minimum of 3 minutes, according to UNE-EN-ISO 17665-1:2007, in sterilization bags 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. They are perfectly packaged and heat-sealed. A defect in this can lead to the loss of its decontamination and disinfection properties, so it is recommended to rule out its use. Under no circumstances should the material be removed from the original packaging and handled without the need for use.

## SERIOUS INCIDENT NOTICE

For patients/users/third parties in the European Union and in countries with an identical regulatory regime (Medical Device Regulation/EU), if, during the use of this device or as a result of its use, a serious incident occurs, please notify the manufacturer and your national authority. The contact information for the manufacturer of this device to report a major incident is as follows:

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

**Contact telephone +34 934 026 740**



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## GENERIC USE

Contain the bone graft in patients with bone mass deficiency by means of osteosynthesis 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 rehabilitation of the denture. Additionally, dental bone regeneration by bone grafting is a surgical procedure that seeks to replace lost bone. The transplanted bone can come from the patient themselves, from a donor, or from commercially available bone substitutes (of animal, plant, or synthetic origin), as long as they are compatible with the patient. Osteosynthesis plates are used to create a scaffold for the bone graft, and osteosynthesis screws or microscrews are used to fix the plate until osseointegration of the grafted bone is achieved. After this process, the plates and screws or microscrews are removed.

## SPECIFIC USES

### OSTEOSYNTHESIS PLATE

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

- *Biocompatible material with excellent acceptance by all bone and periodontal tissues.*
- *Polished material with low bacterial adhesion. You may be exposed to the oral environment.*
- *Malleable and ductile material. Allows very easy handling. Keeps fit. It can be preformed prior to use and can be sterilized later while maintaining its new shape.*

Thanks to its various designs, cutting the plate is very simple and can be done with scissors of any type. The design leaves many islets without material, which allows the osseosynthesis of material (acts as a formwork of material) and allows more or less pressure to be exerted with its retaining screws on the materials that are formed. But it also does not insulate the material as it has wide perforations, so it allows free cell passage between fabrics (inside the formwork with what is outside). There are several designs that allow for different behaviors in their malleability.

Nombre / Name		UDI-DI -BASIC
Osteosynthesis Plate	Osteotynthesis plate	843660239TITANIUMPLATE6P

### OSTEOSYNTHESIS SCREW

Made of Grade 5 Titanium. The ELEMENT osteosynthesis screw fixation system is used in reconstructive surgeries whose objective is to stabilize and join the ends of a broken bone after a fracture, an osteotomy or a nonunion in cases of previous fracture. The ELEMENT screw is also used in maxillofacial surgery for the fixation of plates, block grafts, as well as in the occlusive barrier technique.

#### **Tip Design**

The tip of our screw consists of a very self-piercing loop. It has a very active tip that allows it to advance into the bone with minimal pressure. Its great advantage is that thanks to its active tip and its aggressive coils with the simple rotation on its axis, it allows an advance penetrating the bone with very little pressure. That is why the tip facilitates the presentation of the screw in contact with the bone and with minimal pressure it does not move from its position (without even passing a previous drill). With the simple rotation on its axis and maintaining a minimum pressure, the screw advances in the direction of the bone

#### **Body Design**

The screw bodies are 4,6,8,10 and 12mm long and maintain an aggressive coil up to its head, ending with the last coil that fades and settles flat on its head.



### Head design

The head is very flattened and has two sides. The first is the one that continues to the body of the pin and is completely flat (to increase the contact surface between its surface, the membrane and the bone. In this way, the pressure exerted is distributed and we reduce the risk of fracture of a bone block or sheet. In addition, it is a large flat surface that stops the screw so that it does not continue to advance (if it were not flat it would put more pressure on the central area of the body and would make it easier for the screw to continue advancing, breaking the graft or causing a crack). The other side of the head is the area where we hold the screw. It is rounded at its upper edge so as not to generate a great unevenness in the bone and to make it more progressive. In its connection it has a Torx 6 and a unigrip, which are connections that allow two advantages over other connections:

- Minimal deformation of the connection when torque is applied
- It maximizes the contact surface between the screwdriver tip and the pin connection, so when connecting them it does not come out easily and allows it to be transported to its placement area. Being a deep Torx allows rotation to be applied without leaving its position.

<b>Product</b>	Osteosynthesis <b>Ø1.0mm.</b>	Osteosynthesis <b>Ø1.2mm.</b>
<b>Torque (Max)</b>	10N/m.	15N/m.

<b>Nombre / Name</b>		<b>UDI-DI -BASIC</b>
Osteosynthesis Screws	Osteosynthesis screw	843660239OSTEOSCREWZK

### MICRO OSTEOSYNTHESIS SCREW

Made of Grade 5 Titanium. The Osteosynthesis Microscrew is used for the fixation of membranes, absorbable and non-absorbable, with the ultimate aim of preventing micro-mobility of the graft during the healing process. Its design allows easy and simple use, so that with the first hammer impact the perforation of the cortical is ensured, as well as a quick and safe insertion that speeds up surgery and provides greater guarantee for regeneration.

#### Tip Design

The tip of our Osteosynthesis Microscrew consists of a very self-piercing coil, it has a very active tip that allows it to advance in the bone with minimal pressure, it allows it to enter implanted since its turns do not block its entry and due to its shape like an arrow it does not let the Microscrew come out of place. But its great advantage is that with the rotation in its axis it allows an advance penetrating the bone with very little pressure on the input axis. That is why the tip facilitates the presentation of the Microscrew in contact with the bone and with minimal pressure it does not move from its position. With the simple rotation on its axis and maintaining a minimum pressure of the Microscrew, it advances in the direction of the bone.

#### Body Design

The microscrew enters rotating and that presents a drawback at the end of a membrane. When we enter a screw with a coil and rotating to fix a membrane, it always happens to us that the membranes rotate and wrap around the coil (it would be the same as if we tried to screw a piece of fabric to a piece of wood, while turning the screw the coil also rotates the fabric). That is why after 4 turns the body continues with the same diameter, but without 2 turns so as not to rotate the membrane, but maintaining the advance of the osteosynthesis Microscrew at its tip. That is, the "motor" that makes the Microscrew advance is at its tip, and once the last coil passes the membrane, it no longer makes it rotate, although it continues to advance.

### Head design

The head is very flattened and has two sides. The first is the one that continues to the Microscrew body. It is completely flat to increase the contact surface between its surface, the membrane and the bone. In this way, the pressure exerted is distributed and we reduce the risk of tearing the membrane. In addition, it is a large flat surface which stops the Microscrew so that it does not continue to advance (if it were not flat it would put more pressure on the central area of the body and would make it easier for the Microscrew to continue advancing).

The other side of the head is the area where we take the Microtoornillo. It has a bevel on its upper edge so as not to generate a great unevenness in the bone and to make it more progressive. In its connection it has a torx 6 and a unigrip which are connections that allow two advantages over other connections:

- Minimal deformation of the connection when torque is applied
- maximizes the contact surface between the screwdriver tip and the connection of the osteosynthesis Microscrew, so when connecting them it does not come out easily and allows it to be transported to its placement area. Being a deep torx, it allows rotation to be applied without leaving its position.

Nombre / Name		UDI-DI -BASIC
Micro Screw Osteosynthesis	Microscrew	843660239MEMBRANPINC

\*A Clinical Performance and Safety Summary (SCCP) of abutments for dental implants will be available in the European Medical Device Database (EUDAMED).

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



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## MANUFACTURER DATA














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

The contact telephone number is (+34) 93 4026740

#### LEGEND LABEL SYMBOLS

The product information is given on its label where it is detailed:

Symbols	Description
	Logo Investigación y desarrollo en mecanizado médico S.L.
	Manufacturer
	Date of Manufacture
	Lot Catalog Reference
	Lot
	See QR Instructions for Use
	Do not use if the container is damaged
	Sterile Product ( Depends on the product )
	Do not reuse
	CE marking
	Product Family
	Quantity indicative
	UDI code linked to Data Matrix

Please read the instructions described above with special attention to ensure a safe and efficient use of the products supplied by **Investigación y desarrollo en mecanizado médico S.L.** .

The entire range of products is designed in such a way that it facilitates work, both in the clinic and in the prosthetic laboratory, while providing the best quality. The characteristics of the product and its compatibilities are expanded in the commercial catalog, if in doubt please contact us.



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