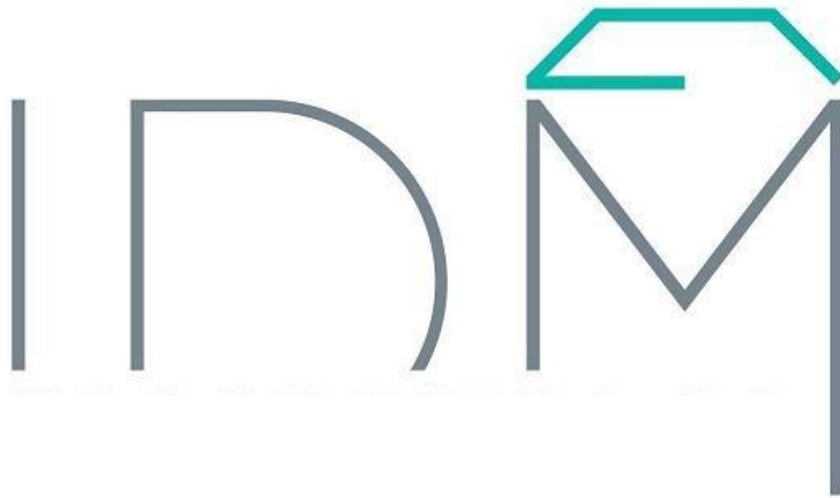


INSTRUCTIONS FOR USE

Investigación y desarrollo en mecanizado médico S,L.



ABUTMENTS FOR DENTAL IMPLANTS



Investigación y desarrollo en mecanizado médico S,L.
Riera de Montealegre, 50 08915 Badalona (Spain)
<https://element-dental.com> 0034 93 402 67 40



INSTRUCTIONS FOR USE

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 Prosthetists, 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 products. Whether they are screws, abutments or other dental surgical and prosthetic accessories, is only guaranteed when their use is limited to adequately trained professionals. In case of doubt, please contact the manufacturer. All products are designed for single use only and must not be reused. If reused, there is a risk that damaged or deteriorated product characteristics may lead to insufficiencies in the prosthetic solution and/or other deterioration of the patient's health such as tissue infection. All components should be tested prior to use in the patient's mouth for proper fit. The clinician will be responsible for the correct application of the products, because both the planning and the procedures are under his/her control. This is the reason why only dental specialists with the appropriate experience and training should work with products from Investigación y desarrollo en mecanizado médico S.L. In case of doubt, please contact the manufacturer.

During any intraoral use and handling all products must be secured to avoid aspiration due to their shape and size.

INDICATIONS

The dental abutments are used for prosthetic restorations of dental implants in order to recover phonation, aesthetic or chewing functions of the teeth.

WARNINGS AND CONTRAINDICATIONS

The reuse of single-use products entails a possible deterioration of their characteristics which implies the risk of tissue infection and / or deterioration of the patient's health. There is a contraindication to use the products in case of patients with illness or bad conditions to be submitted in a surgery to place dental implants. Check the integrity of the packaging, and do not use it if it is altered. All the materials used are biocompatible however some patients may have allergies or hypersensitivity to any of the materials and their components.

COMPATIBILITY INFORMATION

All the Investigación y desarrollo en mecanizado médico S.L. components are available in different prosthetic connections. To know the compatibility with dental implants and analogues please use our catalogue.

STERILIZATION AND REUSE

Investigación y desarrollo en mecanizado médico S.L. , recommends always to make a previous cleaning with the common cleaning products that exists in the dental field, also using ultrasonic baths or automatic cleaning and disinfection methods prior to sterilization. Before sterilizing the products must be transferred from their original packaging to another suitable for this purpose. If sterilization is necessary, it must be done in a humid steam at 134°C for a minimum of 3 minutes, according to UNE-EN-ISO 17665-1: 2007 in sterilization bags or boxes. If after sterilization any deterioration is observed in the packaging do not use the product.



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STORAGE AND HANDLING

The product is perfectly packaged and heat-sealed. A defect in this package can lead to loss decontamination and disinfection properties. Therefore, it is recommended to discard the use. Under no circumstances should the material be removed from the original packaging and handled without the need of use. Investigación y desarrollo en mecanizado médico S,L. products are non-sterile, it is recommended to sterilize them before use.

NOTICE REGARDING SERIOUS INCIDENTS:

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

C / Riera de Montealegre, 50, 08915 Badalona, Barcelona, Spain.
Contact telephone number +34 934 026 740

INSTRUCTIONS FOR USE FOR SPECIFIC PRODUCTS

SCREWS

Made in Titanium. Intended to fix any prosthetic element with the implant. To obtain a good result it is essential to fulfil the following conditions:

Use a suitable driver to tighten or untighten the screw. Check that the driver fits into the socket of the screw. The screwdriver must be positioned in the longitudinal axis of the prosthesis / implant assembly. The first time a prosthesis is assembled, and for future revisions, a new screw must be used. Do not use screws from the prosthetic laboratory in clinical use. Make sure to use the appropriate reference for each case.

The recommended torque for definitive prosthesis is the next:

Metric thread	M2,5	M2	M1,8	M1,6	M1,4	TORX	UNIGRIP	SQUARE	HEXAGON
Torque	30 N.cm	20 N.cm	20 N.cm	20 N.cm	15 N.cm	30 N.cm	30 N.cm	30 N.cm	20 N.cm

HEALING ABUTMENTS

Made in Titanium. Soft and manual tightening is recommended. The height of this element will be that which ensures its correct function and prevents the transmission of chewing efforts. It is recommended don't reuse the healing abutments.

OVERDENTURE ABUTMENTS _Locators

Made in Titanium. It is necessary to verify the compatibility with the implant to which it is going to be used. We recommend an X-ray once screwed at the level of the junction with the implant and on the axis perpendicular to that junction, to check the good fit of the set. It is convenient to position the patient in a way that, in case the screw fall during the screwing / unscrewing, this fall occurs on an area where it can be recovered.

IMPRESION COPING

The impression abutment is used to transfer the exact position of the implant to the model by taking an impression. It is essential to check the compatibility of the product with the implant to which it is going to be attached. It can be used as an open bucket or as a closed bucket.



PROVISIONAL ABUTMENTS

Manufactured in Titanium. Temporary abutments are designed to be used in the upper or lower jaw to support tooth replacements in order to restore masticatory function. The abutments, in combination with endosseous implants, are used as a base for the fixation of tooth replacements in both jaws. Their use is indicated for temporary restorations of cemented supra-constructions to replace single teeth.

TITANIUM BASES_Ti BASE

The Titanium base is used for prosthetic restorations prepared by dental technicians in the laboratory. The main use of the titanium base is to support the restoration made in CAD / CAM. It can also be used as a connector between screw-retained full crowns (of any material) and an implant. To use this product in digital dentistry, the Investigación y desarrollo en mecanizado médico S,L. library and its scan abutments are required. To improve the adhesion of the cement, it is recommended to clean and degrease the surfaces before cementation. Any cement can be used. Always follow the cement manufacturer's instructions. The ceramic surface in the cementation zone must be sandblasted and cleaned / degreased.

TRANSEPIHELIAL ABUTMENTS

Made in Titanium. It is necessary to verify the compatibility with the implant model. Avoid damage in the connection area in case of carving or machining. We recommend an X-ray once screwed in at the level of the junction with the implant and also on the axis perpendicular to that junction to check the good fit of the set.

HEALING PLUGS

Manufactured in Titanium. Dental implant abutments are designed for use in the upper or lower jaw to support tooth replacements to restore masticatory function. or lower jaw to support tooth replacements to restore masticatory function. The abutment and healing cap are designed to be used as temporary components in an endosseous implant to allow soft tissue healing.

	UDI-DI Básico
Screw <i>Tornillos</i>	843660239SCREWJQ
Healing Abutments <i>Pilar de Cicatrización</i>	843660239HEALINGABUTUD
Overdenture Abutments <i>Pilar Locator</i>	843660239OVERDABUTW6
Impresion Coping <i>Transfer</i>	843660239IMPRESOPINGQ3
Provisional Abutment <i>Pilar Provisional</i>	843660239PROVISABUT3U
Ti Base <i>Interfase</i>	843660239TIBASEJP
Transepithelial Abutment <i>Pilar Transepitelial</i>	843660239TRANS.ABUTJH
Healing Plugs <i>Tapón Cicatrización</i>	843660239HEALINGPLUGYE

MANUFACTURER

All the products that commercialize and distribute:

INVESTIGACIÓN y DESARROLLO EN MECANIZADO MÉDICO S,L. (IDM), have been manufactured in:
C/ Riera de Montealegre, 50, 08915 Badalona, Barcelona, España.
The contact phone number is (+34) 93 4026740















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LABEL SYMBOLS

The information of this product is showed in the labelling:

Symbols	Description
	Logo Investigación y desarrollo en mecanizado médico S,L.
	Manufacturer
	Reference of the catalogue
	Batch
	Read instructions for use QR
	Don't use in case packaging is damaged
	No sterile
	Don't reuse
	CE mark
	Product family
	UDI code linked to Data Matrix
	Medical Device

*A Summary of Safety and Clinical Performance (SSCP) of Abutment for Dental Implants will be available at the European Database on Medical devices (EUDAMED) .

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

Please read the instructions described above carefully to guarantee 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 a way in order to facilitate the work in the clinic and in the prosthetic laboratory providing the best quality. The features of the product and its compatibility are expanded in the commercial catalogue, in case of doubts please contact us.