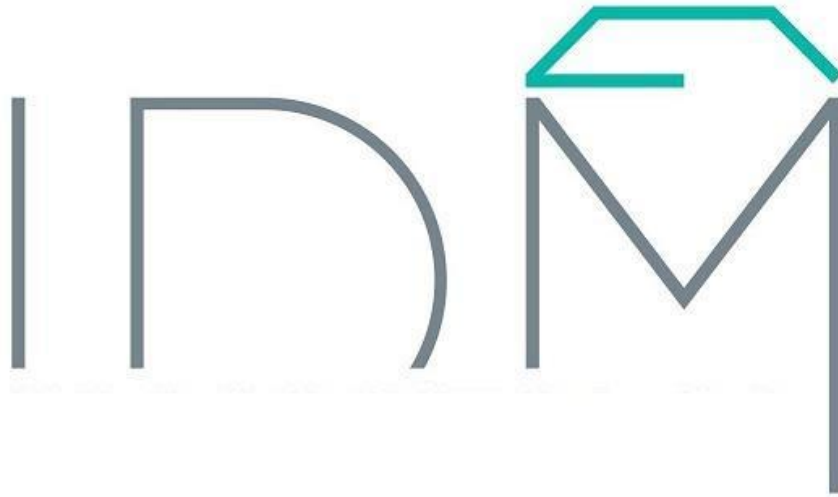


# INSTRUCTIONS FOR USE

Investigación y desarrollo en mecanizado médico S,L.



## ACCESSORIES FOR DENTAL IMPLANTS

### Class I



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

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## **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 Technicians, Doctors and Dentists).*

*The safety and effectiveness of the products supplied by Investigación y desarrollo en mecanizado médico S,L. , whether scanbodies , replicas, castables, screws, pillars, or accessories or tools , see specific instructions for use below, are only guaranteed when their use is limited to properly trained professionals. If in doubt, contact the manufacturer.*

*All oral products that are not tools are designed for single use and should not be reused. If reused, there is a risk that damaged or deteriorated characteristics of the product may lead to deficiencies in the prosthetic solution and/or other deterioration of the patient's health, such as tissue infection. All components should be tested before use in the patient's mouth for proper fit. The clinician will be responsible for the correct application of the products, since both the planning and the procedures are under his or her control. This is why only dental specialists with appropriate experience and training should work with R&D machining products. Medico SL If in doubt, please contact the manufacturer.*

*intra -oral use and handling , all products must be secured to prevent aspiration due to their shape and size.*

*Reusable devices such as tools should be cleaned and disinfected as soon as possible after each use. Disassemble all components, if applicable. Rinse with cold tap water to remove coarse contamination. Bathe in an enzymatic detergent solution (e.g. ENDOZIME®, Ruhof Corporation 6.0-7.5 pH) prepared according to manufacturer's instructions for 5 minutes. Scrub thoroughly with a soft brush and/or tube cleaner; especially very narrow lumens should be rinsed with an enzymatic detergent solution using a syringe. Rinse with cold tap water for at least one minute. Bathe in a detergent solution (e.g., LIQUI-NOX®, Alconox , Inc. 8.5 pH) prepared according to the manufacturer's instructions for 5 minutes. Scrub thoroughly with a soft brush and/or tube cleaner. Rinse thoroughly with deionized/reverse osmosis water. Apply an ultrasonic bath for a minimum of 10 minutes in an enzymatic detergent solution. Rinse thoroughly with deionized/reverse osmosis water. Dry with a clean, soft, absorbent, disposable cloth. Visually inspect cleanliness. All visible surfaces, internal and external, must be visually inspected. If necessary, wipe them again until they are visibly clean.*

*After this, the devices must be sterilized again according to these instructions.*



## **INDICATIONS**

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

*The target patients are those who are totally or partially edentulous, who require oral rehabilitation. These rehabilitations can be single, multiple or over dentures.*

*The main function is to replace teeth, restoring the morphology, function, comfort, aesthetics and health of the stomatological system, regardless of the degree of atrophy, alteration or injury thereof. Specifically, these products are accessories that will help replace what would be the crown or tooth.*

*The products covered by this File are the instruments and accessories to be able to properly mount the pillars, interfaces, etc., on the dental implants in the reconstructions of the dental crown. Use in the oral cavity will be less than 1 hour, unless it is only applied in a prosthetic laboratory, which in that case is non-invasive and does not enter the oral cavity.*

## **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 for the use of the products in the case of patients with illness or poor conditions who are going to undergo surgery to place dental implants. Check the integrity of the packaging and do not use it if it has been altered. All the materials used are bio-compatible, however, some patients may have allergies or hypersensitivity to some of the materials and their components, however the risk is very unlikely because if it is in the mouth the time is only a few minutes.*

## **COMPATIBILITY INFORMATION**

*All research and development in medical machining S, L. Components are available in different prosthetic connections. To find out compatibility with dental implants and analogues, use our catalogue.*

## **STERILIZATION AND REUSE**

*Research and development in medical machining S, L., always recommends carrying out prior cleaning with the usual cleaning products that exist in the dental field, also using ultrasonic baths or automatic cleaning and disinfection methods prior to sterilization. Before sterilizing the products, they must be transferred from their original packaging to another suitable for this purpose. If sterilization is necessary, it must be carried out in humid steam at 134°C for a minimum of 4 minutes, according to UNE-EN-ISO 17665-1:2007 in sterilization bags or boxes. If any damage to 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. of this File do not have specific temperature and humidity conditions. However, it is advisable to store them at a temperature between 15-35 °C and between 40-70% humidity. Products should be protected from direct sunlight and any artificial ultraviolet light. The product comes perfectly packaged and heat-sealed. A defect in this package may lead to loss of decontamination and disinfection properties. Therefore, it is recommended to discard use. Under no circumstances should the material be removed from the original packaging and handled without need for use. Research and development in medical machining S,L. The products are not sterile, it is recommended to sterilize them before use, if they are put in the mouth, but not those that are for use in the Laboratory.*

## **NOTICE REGARDING SERIOUS INCIDENTS:**

*For patients/users/third parties in the European Union and in countries with identical regulatory regime (Medical Devices Regulation/EU), if during the use of this device or as a consequence of its use a serious incident occurs, please notify the manufacturer and to its 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**

### **SCANBODY.**

*The Scanbody is a device used as a transfer accessory to establish the virtual 3D position of the implant in relation to the oral cavity and is made up of three elements: the titanium base, the PEEK body and the titanium insertion screw.*

*The Scanbody sits directly on the implant connection or on a transepithelial element, depending on the model, serving as a reference during the intraoral CAD/CAM scanning process, or in the laboratory, to subsequently carry out the design and machining of the prosthetic restorations.*

### **CALCINABLES.**

*The castable is defined as the mechanized component of meltable plastic that, once positioned on the coronal part of the implant, will serve as an initial base to model the shape of the final structure, which will be cast in the corresponding metal .*

*The castables are machined with Polyacetal Copolymer (POM-C) (without residue) complying with FDA ( Food and Drugs) regulations Administration) and EEC 90/128. Polyacetal \_ Copolymer , it is the ideal option for the machining of precision parts: Low moisture absorption. High dimensional stability. Easy to machine. Low coefficient of friction. High resistance and rigidity. It is available in Rotating format (for bridges or rehabilitations) and Anti-Rotating (for unitary pieces).*

### **REPLICAS / ANALOGUES**

*The analogues are machined elements of refractory stainless steel to withstand the temperature in case welding is necessary or medical grade titanium.*

*They are used to replicate the implant/ transepithelial /digital in the laboratory plaster model, which is why they are also known as “replicas”. Reuse is not recommended.*



## **SCREW COPYNG PRINT.**

*It is the screw that is used to fix the impression coping abutment , see previous point.*

## **PROTECTIVE DISC.**

*To facilitate hygiene during the assembly of the prosthesis. The protective disc is used momentarily to position the retentive cup over the implant or ball abutment. It is located on the abutment/implant and makes it difficult for the patient's fluids to enter the cup.*

## **SPACER RING.**

*Ring used to facilitate hygiene in the assembly of the Locator type abutment*

## **TOOLS**

### **Conveyors**

*Keys of different shapes and dimensions for transporting implant screws to use both manually and by means of a ratchet or hand piece.*

### **Screwdrivers**

*Wrenches of different shapes and dimensions for tightening screws and implants to use both manually and by means of a ratchet or hand piece.*

### **Screwdriver handles.**

*They are used to hold the different screwdriver bits.*

### **Assembly wrench.**

*It is used for mounting Locator type pillars.*

### **Ratchets**

*Mechanical devices whose mechanism allows, by attaching a screwdriver or protractor, the tightening of a screw or implant in a single direction.*

### **Extenders.**

*They are used as an extension of screwdrivers and wrenches to be able to assemble the accessories.*

### **Extractor kit.**

*Extractor screws to be able to extract screws or dental implants that have broken .*

<b>Product description</b>	<b>Basic UDI-DI</b>
Scan body .	843660239SCANBODY57
Burnable	843660239CALCIAS
Analog or Replica of implant.	843660239ANALOGUEZH
Protective disc	843660239PROTECQJ
spacer ring	843660239RINGK3
Conveyors	843660239CONVEYORSX3
Tips	843660239TIPPJ
Screwdriver handles	843660239HANDLEDH
mounting wrench	843660239KEYNB
ratchets	843660239RATTLEMD
Extensions	843660239EXTENDERD8
Screw Extractor Kit	843660239EXTRACTORZN

## MAKER

All the products we market and distribute:














**INVESTIGACIÓN Y DESARROLLO EN MECANIZADO MÉDICO S,L. (IDM)**,  
manufactured in:

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

The contact telephone number is (+34) 93 4026740

## LABEL SYMBOLS

The information about this product is shown on the labeling:

<b>symbols</b>	<b>Description</b>
	<i>Investigación y desarrollo en mecanizado médico S,L.</i>
	<i>Maker</i>
	<i>Manufacturing date</i>
	<i>Catalog reference</i>
	<i>Batch</i>
	<i>Read the instructions for use QR</i>
	<i>Do not use if the packaging is damaged.</i>
	<i>not sterile</i>
	<i>do not reuse</i>
	<i>CE marking</i>
	<i>Product family</i>
	<i>UDI code linked to Data Matrix</i>
	<i>Medical device</i>

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.