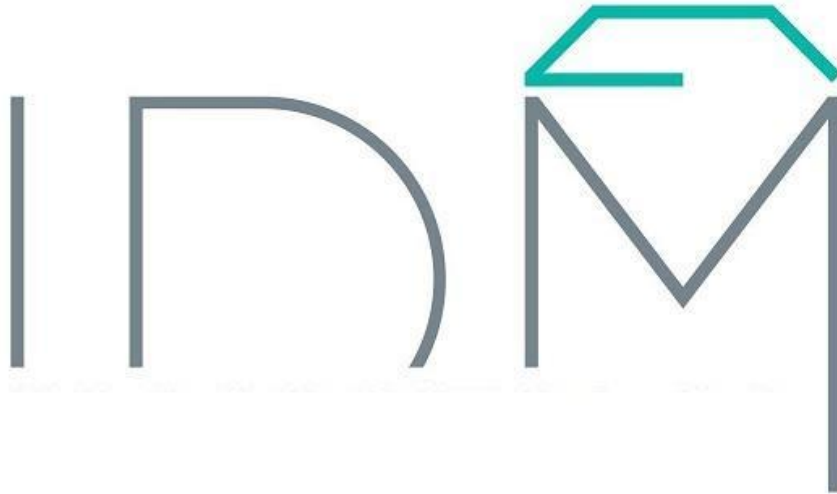


INSTRUCTIONS FOR USE

Investigación y Desarrollo en mecanizado medico S.L



DENTAL IMPLANT ACCESSORIES

Class I



Investigación y Desarrollo en mecanizado medico 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 SL are intended for use by qualified healthcare professionals (Dental Technicians, Doctors and Dentists).

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

All mouth-to-mouth products that are not tools are designed for single use only and should not be reused. If reused, there is a risk that damaged or impaired characteristics of the product 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 a proper fit. The clinician will be responsible for the correct application of the products, as both planning and procedures are under their control. This is why only dental specialists with the right experience and training should work with R&D machining products. Médico SL If in doubt, please contact the manufacturer.

During any 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 the 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 and disposable cloth. Visually inspect the cleanliness. All visible surfaces, internal and external, must be visually inspected. If necessary, clean them again until they are visibly clean.

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



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INDICATIONS

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

Target patients are those who are wholly or partially edentulous, who require oral rehabilitation. These restorations can be unitary, multiple or on dentures.

The main function is to replace teeth by restoring the morphology, function, comfort, aesthetics and health of the stomatological system, regardless of the degree of atrophy, alteration or injury of the same. 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 abutments, interfaces, etc., on dental implants in dental crown reconstructions. Use in the oral cavity will be less than 1 hour, unless it is only applied in a prosthetic laboratory, which in this 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 case of patients with disease 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 is 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 in case of being in the mouth the time is a few minutes.

COMPATIBILITY INFORMATION

All **Investigación y Desarrollo en mecanizado medico S.L** The components are available in different prosthetic connections. For compatibility with dental implants and analogues, please use our catalog.

STERILIZATION AND REUSE

Investigación y Desarrollo en mecanizado medico S.L, always recommends carrying out a previous cleaning with the usual cleaning products that exist in the dental field, also using ultrasonic baths or automatic methods of cleaning and disinfection 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 carried out in wet steam at 134°C for a minimum of 4 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

All the products manufactured by Investigación y desarrollo en mecanizado medico S.L. in 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 the loss of 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 use. **Investigación y Desarrollo en mecanizado medico S.L** The products are not sterile, it is recommended to sterilize them before use, if they go to the mouth, not those that are for use in the laboratory.

SERIOUS INCIDENT WARNING:

For patients/users/third parties in the European Union and in countries with the same regulatory regime (EU/Medical Device Regulation), if a serious incident occurs during the use of this device or as a result of its use, please notify the manufacturer and 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 +34 934 026 740



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INSTRUCTIONS FOR USE FOR SPECIFIC PRODUCTS

SCANBODY.

The Scanbody is a device used as a transfer attachment to establish the virtual 3D position of the implant in relation to the oral cavity and consists of three elements that are 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.

BURNABLE.

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

The calcinable ones are machined with Polyacetal Copolymer (POM-C) (residue-free) complying with FDA (Food and Drug Administration) and EEC 90/128 regulations. Polyacetal Copolymer is the ideal choice for machining precision parts: Low moisture absorption. High dimensional stability. Easy to machine. Low coefficient of friction. High strength and rigidity. It is available in Rotary format (for bridges or rehabilitations) and Anti-Rotary (for single pieces).

REPLICAS / ANALOGUES

Analogues are machined elements from refractory stainless steel to withstand the temperature in case a weld or medical grade titanium is necessary.

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 COPYING PRINT.

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

DISC PROTECTOR. To facilitate hygiene in the assembly of the prosthesis.

The protective disc is momentarily used to position the retentive cup on 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 Lockator type pillar

PROSTHETIC SCREW.

This is the screw used to secure the prosthetic abutment or the final prosthesis to the dental implant, ensuring the correct retention and mechanical stability of the prosthesis-implant assembly.



TOOLS

Conveyors

Wrenches of different shapes and dimensions for the transport of implant screws for use both manually and by means of a ratchet or handpiece.

Screwdrivers

Wrenches of different shapes and dimensions for tightening screws and implants for use both manually and by means of a ratchet or handpiece.

Screwdriver handles.

They are used to hold the various screwdriver bits.

Assembly key.

Used for the assembly of Lockator abutments

Ratchets

Mechanical devices whose mechanism allows, by means of the coupling of a screwdriver or conveyor, the opening of a screw or implant in a single direction.

Extensions.

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

Equipment extractor.

Extractor screws to remove screws or dental implants that have broken.

Screw Container Box

Box used as a screw tank

Product description	Basic UDI-DI
Scanbody.	843660239SCANBODY57
Calcinables	843660239CALCIAS
Analog or Implant Replica.	843660239ANALOGUEZH
Disc protector	843660239PROTECQJ
Spacer ring	843660239RINGK3
Prosthetic Screw	843660239PROSCREWKF
Conveyors	843660239CARRIERSX3
Tips	843660239TIPPJ
Screwdriver handles	843660239HANDLEDH
Mounting key	843660239KEYNB
Ratchets	843660239RATTLEMD
Extensions	843660239EXTENDERD8
Screw extractor kit	843660239EXTRACTORZN
Screw Container Box	843660239CAJACONTENVH

MANUFACTURER

All the products we market and distribute:

Investigación y Desarrollo en mecanizado medico 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 of this product is shown on the labeling:

Symbols	Description
	Logo Investigación y Desarrollo en mecanizado medico S.L
	Manufacturer
	Date of manufacture
	Catalog Reference
	Lot
	Read the QR instructions for use
	Do not use in case the packaging is damaged.
	Non-sterile
	Do not reuse
	CE mark
	Product Family
	UDI code linked to Data Matrix
	Medical device

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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