INSTRUCTIONS FOR USE

Investigación y desarrollo en mecanizado médico S.L.

DENTAL PROSTHESES

PRODUCTS COVERED BY THIS IFU: Crown and bridge frameworks · Monolithic crowns · Inlays, onlays and veneers · Implant-supported prosthesis frameworks.

Risk class: IIa – Regulation (EU) 2017/745, Rule 5, Annex VIII.

Manufacturer : INVESTIGACIÓN Y DESARROLLO EN MECANIZADO MÉDICO, S.L.
Riera Montealgre 50, 08915 Badalona – Barcelona – España | SNR: ES-MF-000032558

1. PRODUCT DESCRIPTION

The products covered by these Instructions for Use are dental restorations and prostheses manufactured individually using CAD/CAM (computer-aided design and manufacturing) technology, in accordance with the written prescription of a qualified healthcare professional, for specific adaptation to each patient.

1.1 Crown and Bridge Structures (UDI-DI: 843660239CORONAYPUENTE58 — ID36)

Milled prosthetic substructures intended to be covered with ceramic or composite material by the dental technician. This includes single-unit and multi-unit structures for fixed partial dentures on prepared natural teeth.

1.2 Monolithic Crowns (UDI-DI: 843660239MONOLITICASP9 — ID37)

Fully anatomical restorations manufactured from a single homogeneous material (zirconia, lithium disilicate or other certified biocompatible materials) that do not require additional ceramic layering. They are cemented directly onto the natural or prepared stump.

1.3 Inlays, Onlays and Veneers (UDI-DI: 843660239INONCARILLASDU — ID38)

Indirect partial restorations. Inlays and onlays are used in the posterior region to replace lost tooth structure; veneers are thin laminates for the buccal surface of anterior teeth for functional and/or aesthetic purposes.

1.4 Implant-Supported Prosthetic Structures (UDI-DI: 843660239ESPRSOIMPWN — ID39)

Metal or zirconia substructures designed to be screw-retained or cemented onto osseointegrated implant abutments. These include structures for single crowns, implant-supported bridges and abutment bars for removable implant-supported dentures.

Product description	Basic UDI-DI	#	Class	Material	Commercial Ref.
CROWN AND BRIDGE STRUCTURES	843660239CORONAYPUENTE58	ID36	IIa	Cobalt Chrome	ID00.36.100
MONOLITHIC CROWNS	843660239MONOLITICASP9	ID37	IIa	Zirconium, Lithium Disilicate	ID00.37.100
I INLAYS, ONLAYS AND VENEERS	843660239INONCARILLASDU	ID38	IIa	Lithium Disilicate, Zirconium	ID00.38.100
IMPLANT-BASED PROSTHESIS STRUCTURES	843660239ESPRSOIMPWN	ID39	IIa	Cobalt Chrome	ID00.39.100

2. INTENDED USE

These products are intended for the functional and aesthetic restoration of the mouth in patients who have lost one or more teeth, or who have suffered partial or total destruction of one or more teeth. They are custom-made medical devices for dental use, intended exclusively for professional use, and must be prescribed and fitted by a qualified dentist or oral surgeon.

For use exclusively by healthcare professionals (qualified dentists / dental surgeons / dental technicians).
This product is custom-made for a specific patient. Not suitable for use on any patient other than the one for whom it was prescribed.

3. INDICATIONS FOR USE

- Restoration of damaged, fractured or extensively decayed teeth using crowns or inlays/onlays.
- Replacement of missing teeth using tooth-supported or implant-supported bridges.
- Aesthetic improvement of anterior teeth using veneers.
- Single or multiple implant-supported restoration on osseointegrated implants.

4. CONTRAINDICATIONS

- Known allergy or hypersensitivity to any of the product's materials (zirconia, lithium disilicate, metal alloys such as CrCo or TiGr5). Refer to the technical data sheet for the specific material.
- Severe untreated traumatic occlusion or uncompensated parafunctions (bruxism), unless otherwise determined by the prescribing professional's clinical judgement.
- Insufficient bone or periodontal support in the abutment teeth, unless prior treatment has been successful.
- Non-osteointegrated implants or implants with clinical mobility for implant-supported structures.

5. MATERIALS AND BIOCOMPATIBILITY

The materials used in the manufacture of these products are biocompatible and comply with the UNE EN ISO 10993-1 standard (Biological evaluation of medical devices). The main materials used are:

- Zirconia (ZrO_2): High purity, yttria-stabilised. Biocompatible, non-allergenic, fracture-resistant.
- Lithium disilicate: Pressed or milled glass-ceramic material. High aesthetic quality and mechanical strength.
- CrCo alloy (ISO 5832-12): Chromium-cobalt alloy for metal frameworks.
- Grade 5 Titanium (UNE-EN ISO 5832-3): Ti-6Al-4V for implant-supported structures where compatibility with the implant system is required.
- PMMA/Composite resins: For temporary restorations and composite veneers. Biocompatible in accordance with ISO 10993.

All materials used are accompanied by a supplier's certificate of conformity and are free from hazardous substances in quantities that could pose a risk to the patient.

6. INFORMATION ON SUPPLY

Supply status: NON-STERILE.
The product is supplied in a non-sterile condition. Before placing it in the mouth, the healthcare professional must clean and disinfect the product in accordance with the clinical centre's standard protocols.

No measuring function. Not intended to take or transmit quantitative measurements.

Does not contain: medicinal substances · tissues of animal or human origin · human blood derivatives · latex.

Does not emit: ionising radiation or any other type of radiation.

Power source: Not connected to any power source during clinical use.

7. INSTRUCTIONS FOR CLINICAL USE

7.1 Before placement

- Check that the product corresponds to the patient named on the label (name, reference number, UDI).
- Visually inspect the product for damage. Do not place if it shows cracks, chipping or deformation.
- Disinfect using a disinfectant certified for dental medical devices. Rinse with distilled water or sterilise in accordance with the centre's protocol if a sterile environment is required.
- Check the marginal fit and occlusal adjustment in the mouth before final cementation.

7.2 Cementation and fixation

- Follow the manufacturer's instructions for the chosen cementation material (resin cement, glass ionomer, zinc phosphate cement or other).
- For implant-supported structures: tighten to the torque values specified by the implant system manufacturer. Seal the screw access with a suitable material.
- Remove excess cement using a periodontal probe, dental floss and/or specific instruments.
- Check the occlusion in centric relation and during lateral and protrusive movements.

7.3 After placement — Instructions for the patient

- Advise the patient on the need for thorough oral hygiene: brushing at least twice a day, using dental floss or interdental brushes and, in the case of implant-supported prostheses, oral irrigators.
- Avoid biting hard objects (ice, pens, fingernails) or extremely hard foods that could fracture the restoration.
- In patients with bruxism: mandatory use of a night-time bite splint.
- Attend regular check-ups as advised by the dentist (at least once a year).

8. CLEANING, DISINFECTION AND MAINTENANCE

8.1 By the healthcare professional (prior to placement)

Clean with water and an enzymatic detergent, then rinse thoroughly with distilled water. Disinfect using a high-level disinfectant solution compatible with the product's materials. Dry with clean, dry compressed air.

8.2 By the patient (home care)

Brush the restoration with a soft-bristled toothbrush and non-abrasive toothpaste. Zirconia and ceramic products are resistant to standard cleaning agents but may be affected by highly abrasive toothpastes or products with extreme pH levels.
For implant-supported prostheses: daily use of implant-specific dental floss or interdental brushes. The use of an oral irrigator is recommended.

9. UNWANTED SIDE EFFECTS

- Temporary post-operative sensitivity to cold/heat in the days following placement (common, usually self-limiting).
- Temporary occlusal discomfort. Contact your dentist if these symptoms persist for more than 48 hours.
- In exceptional cases: hypersensitivity reaction to a component of the material. Inform your dentist immediately.
- Fracture or loosening of the product in cases of uncontrolled occlusal overload or trauma.

10. STORAGE AND ENVIRONMENTAL CONDITIONS

Store in a dry, clean place at room temperature (15–30 °C).

Protect from knocks, vibrations and harsh chemicals.

Keep in the original packaging until ready for use.

Do not expose to prolonged direct UV radiation (this may affect the colour of aesthetic restorations).

There is no expiry date for ceramic or metallic materials, provided the specified storage conditions are observed.

11. PRODUCT LABELLING

The label for each product must include the following elements, in accordance with Annex I, Section 23 of Regulation (EU) 2017/745 and ISO 15223-1 (graphical symbols):

- Name and address of the manufacturer.
- Product name and reference/model number.
- Indication: 'medical device'.
- Name of the patient for whom it is intended.
- Name of the prescribing healthcare professional.
- Non-sterile symbol

KEY TO LABEL SYMBOLS

Symbols	Description
	Manufacturer
#	Batch number
REF	Product reference
CLIENTE	Do not use if the packaging is damaged.
De	Prescriber's name
	Do not use if the packaging is damaged.
	Do not reuse
MD	Medical device
Cantidad	Packaged units

12. EU DECLARATION OF CONFORMITY

The products covered by these IFU comply with the requirements of Regulation (EU) 2017/745 on medical devices. The relevant EU Declaration of Conformity is:

Document: TD07.08.01 – Declaración de Conformidad UE
Versión / Date: v.01 – 05/06/2025
Signed By : Ignacio Mayo Fajó – Dirección General
Regulation: Reglamento (UE) 2017/745 sobre productos sanitarios
Risk Class : IIa

13. SSCP AND IMPLANT CARD

In accordance with Article 32(1) of Regulation (EU) 2017/745, the Summary of Safety and Clinical Performance (SSCP) is only required for implantable and Class III devices that are not custom-made. As these are custom-made Class IIa devices.

NEITHER THE PREPARATION OF THE SSCP NOR THE ISSUANCE OF AN IMPLANT CARD IS REQUIRED for these devices.

14. POST-MARKET SURVEILLANCE AND INCIDENT REPORTING

The manufacturer has a post-market surveillance (PMS) system in place in accordance with Article 83 and Annex III of Regulation (EU) 2017/745.
Any serious incident or field safety corrective action (FSCA) relating to these products must be reported to the manufacturer and, where applicable, to the competent authorities, in accordance with Article 87 of Regulation (EU) 2017/745.

Contact for incident reporting:

- INVESTIGACIÓN Y DESARROLLO EN MECANIZADO MÉDICO, S.L.
  Riera Montealgre 50 — 08915 Badalona — Barcelona — Spain
- SNR: ES-MF-000032558
- Regulatory contact email: calidad@element-dental.com

15. REGULATIONS AND REFERENCE STANDARDS

The products have been designed and manufactured taking into account the following main regulations (full list in the Annex of Applicable Standards of the technical dossier — REG.7.3-01-02 Rev.05):

- Regulation (EU) 2017/745 on medical devices (MDR).
- EN ISO 13485:2016 / UNE-EN ISO 13485:2018/A11:2022 — Quality Management System.
- UNE EN ISO 14971:2020 — Risk management.
- UNE EN ISO 10993-1/5/10/11/23 — Biological evaluation.
- ISO 6872:2015 — Dental ceramic materials.
- UNE-EN ISO 5832-3:2022 — Grade 5 titanium for medical devices.
- ISO 5832-12:2019 — CrCo alloy for medical devices.
- ISO 15223-1:2021 — Symbols for labelling.
- UNE-EN ISO 20417:2022 — Information to be provided by the manufacturer.

Please read the instructions set out above carefully to ensure the safe and efficient use of the products supplied by ***Investigación y desarrollo en mecanizado médico S,L. .***

The entire product range is designed to facilitate work, both in the clinic and in the dental laboratory, whilst delivering the highest quality. The product specifications and compatibility details are set out in the product catalogue; should you have any queries, please do not hesitate to contact us.

CONTROL DE MODIFICACIONES			
Versión	**Fecha / Date**	**Realizado**	**Modificación**
01	05/06/2025	F. Estebanell	**Versión Inicial**
02	19/02/2026	F. Estebanell	Se añaden puntos importantes P5-7-8-9

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Fecha: 19/02/2026	Fecha: 19/02/2026