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## TECHNICAL DOCUMENTATION

Product name	Zirconia Dental Ceramics
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Document Name:

### Instructions for use

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Chengdu Besmile Medical Technology Co., Ltd.

## Revision history

Version	Revision date	Revisor	Revised Content
A00	2025.01.23	Youming Luo	First compiled
A01	2025.10.10	Huan Xue	Update the symbol and content

# Instructions for use

**Product name:** Zirconia Dental Ceramics

**Model:** See label.

**Intended purpose:** It is suitable for all types of denture processing system to make full-mouth base crown and partial denture base crown.

## Indications:

Types of restoration:

- Single crowns,
- Inlays,
- Veneers,
- Bridges.

**Intended users:** Dental professionals only: dentist and dental technician.

**Intended patient population:** Adults patients with permanent teeth, not for pregnant or breast feeding women.

## Contraindication:

- Patients with severely reduced residual dentition;
- Patients in provisional insertion/trial wear period;
- Any other uses not listed in the indications;
- If the patient is known to be allergic to any of the components of the device, the product should not be used to fabricate restorations.

## Residual risks and undesirable side effects:

Endodontic treatment, fractures, bleeding on probing, chips, delaminations, secondary caries, debonding, periapical periodontitis.

## Clinical benefit:

The device is used to fabricate single crowns, inlays, veneers and bridges. It can replace missing or damaged natural teeth, restore normal chewing function for patients, and effectively mimic the shape and color of natural teeth to provide a natural appearance and improve the patient's facial contour.

The clinical benefits associated with the device are defined as direct, and adult

patients can achieve these benefits. The device is not intended for use in pregnant or breastfeeding women.

The restorations of single crowns, inlays, veneers and bridges are implantable and designed for long-term use. Some patients may require repeated procedures during their lifetime.

**Composition:** This product is composed of  $\text{ZrO}_2$ ,  $\text{HfO}_2$ ,  $\text{Y}_2\text{O}_3$ ,  $\text{Al}_2\text{O}_3$ , and other oxides.

Composition	Ratio	Composition	Ratio	Composition	Ratio
$\text{ZrO}_2+\text{HfO}_2+\text{Y}_2\text{O}_3$	$\geq 99\%$	$\text{Y}_2\text{O}_3$	$4.5\% \sim 10.0\%$	$\text{HfO}_2$	$\leq 5\%$
$\text{Al}_2\text{O}_3$	$\leq 0.5\%$	Other oxide	$\leq 0.5\%$	/	/

#### **Materials patients can be exposed:**

All the compositions of the device can be exposed to patients during long-term use.

#### **Product performance:**

Physical and chemical properties	Sintered Density	$> 6.02 \text{ g/cm}^3$
	CTE	$(10.5 \pm 0.5) \times 10^{-6} \text{ K}^{-1}$
	Veneering porcelain bond strength	$> 25 \text{ MPa}$

#### **Precautions:**

- Before use, please read the instructions carefully.
- During use, it is recommended to wear dust masks and goggles, so as to protect against dust.
- Without sintering ceramic can not be applied directly to the body or oral denture repair.
- This product is inlaid, adjusted and worn according to the requirements of professional dentist and professional dental technician.
- Equipment or materials of the same linear expansion coefficient as our department when used with other materials or instruments.
- When there are any serious incidents related to the device, users report to the manufacturer, European representative or the competent authority of the member state.

#### **Methods of use:**

Zirconia Dental Ceramics usually use CAD/CAM (computer aided design / computer aided manufacturing) method of making porcelain dentures, production process is as follows:

- 1)Scanning the teeth or dental digital , access to dental three-dimensional data.
- 2)In accordance with the dental data CAD design, design of porcelain block processing model.
- 3)The use of CNC machine tools in accordance with the porcelain block processing model for CAM manufacturing to make all-ceramic crowns denture.
- 4)Porcelain denture crown by sintering in air or vacuum sintering, to meet the use requirements of strength and appearance.
- 5)With porcelain powder in all-ceramic crowns of denture surface glazing, forming porcelain porcelain bonding, to create a full porcelain denture.

**Storage Condition:** This product should be stored in a room free of corrosive gases, well ventilated, avoiding strong sunlight.

**Shipping Condition:** Prevent severe extrusion and vibration, prevent snow and rain from soaking, and must not be mixed with corrosive substances during shipping.

**Date of manufacture:** See label.

**Shelf life:** 20 years.

**Disposal of waste:**

Discarded devices shall be disposed of by the user as medical device waste.

**Link to SSCP:** The SSCP (CE-CK-026) for the device can be found in the Eudamed website.

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

**Description of label symbols:**

	Date of manufacture		Batch code		Consult instructions for use or consult electronic instructions for use
	Caution		Do not re-use		Manufacturer
	Medical device		CE mark		Authorized representative in the European Community/ European Union

	Importer	<b>UDI</b>	Unique device identifier		Use-by date
<b>REF</b>	Catalogue number				

**Manufacturer's name:**Chengdu Besmile Medical Technology Co., Ltd.

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