Instruction for Use

Dental Ceramic

Model: Zirconia Ceramic

Instruction for Use

【Device Name】Dental Ceramic

【Model and Specifications】Zirconia Ceramic (ZCG) (Refer to appendix 1 for details)

【Chemical Composition】SiO_2(52-62%), Al_2O_3(14-16%), K_2O(7-10%), Na_2O(7-10%), CaO(1-4%), BaO < 3%, SrO < 2%, B_2O_3< 1.5%, Others < 2%.

【Intended Use】Dental ceramic (metal ceramic and zirconia ceramic) is used for the fabrication of dental restorations (inlays/onlays, veneers, touch-ups, etc.). Dental ceramic is coated on the surface of the metal crown or zirconia crown, made into the shape of the tooth crown, and then sintered into the form of a restoration in which the inner crown and this dental ceramic are sintered as one, for the restoration of damaged or missing teeth.

【Clinical Indications】Indicated for tooth damage (decayed tooth, damaged tooth, etc.), fixed-bridge restorations for tooth absence, aesthetic restoration for tooth discoloration.

Zirconia Ceramic is a special veneering ceramic featuring a fine structure for partially yttrium-stabilized ZrO_2 substructures with a CTE range(25~500℃): 10.0~10.6 ($\times 10^{-6}K^{-1}$).

【Clinical Benefit】As effective materials with good biocompatibility and wear resistance, Dental Ceramic in dental restorations are aimed at repairing damaged / missing tooth such as damaged natural crown, absence of tooth or deformed teeth, and at recovering their masticatory function, remaining healthy tooth structure.

【Applicable Population】People who need dental prosthesis restoration. Human above 18 years old.

【The Intended user】All Dental Ceramics (Metal Ceramic, Zirconia Ceramic) are processed through dental laboratories or by dental professionals.

【Intended use environment】Dental Ceramics (Metal Ceramic, Zirconia Ceramic) are processed in dental laboratories or dental institutes, and intended used in human intraoral.

【Contraindication】Bruxism and allergic reactions to dental materials / ingredients in this product.

【Precautions & Warnings】

- For dental use only.
- If accidental contact with eyes or prolonged contact with inhalation of oral tissues occurs, flush immediately with large amounts of water.
- Consulting with a doctor in case of toothache, allergy and crack on prosthesis are strongly recommended.
- the operator must undergo special training and be skilled in the operation of the product.
- When working with the products, wear suitable safety goggles/face protection, gloves and safety clothing.
- Our products must be used in accordance with the actual version of the instructions for use.
- Any misuse may cause damage, resulting from incorrect handling or usage.
- The user is furthermore obliged to check the product before use with regard to its suitability for the intended area of applications.
- All apparatus for mixing shall be clean and dry.
- Spatula, made from material that is not readily abraded by the dental ceramic powder (glass is recommended). Instruments used for the mixing procedure shall be made of materials that do not contaminate the ceramic material.
- We cannot accept any liability if the product is used in conjunction with materials and equipment from other manufacturers that are not compatible or not authorized for use with our product.
- If serious incidents have occurred in connection with the product, they must be reported to BAOT Biological Technology Co., Ltd., and the competent authority of the Member State in

which the user and/or patient is established.

【Handling】In the case of dust formation use an extractor unit or the dust mask (or grind when wet). Protective goggles should be worn when grinding the fired ceramic.

【Instructions】The product is a veneering material used with inner zirconia crown to make into all-ceramic porcelain restorations. Mix the ceramic powder with the corresponding liquid until paste and then following the work instruction and firing parameters to operate. Formative Liquids(CFS, OF, and GY) are produced by the manufacturer is recommended used for Dental Ceramic.

- Modeling the Bond (Wash opaque), Opaque with the Opaque liquid (OF).
- Modeling the Opacious Dentine, Dentine, Semi-transparent, Transparent with the Modeling liquid (CFS).
- Modeling the Glaze, Corrective, Stain with the Glaze & Stain liquid (GY).
- Combine the formative liquid and the ceramic powder according to categories and specifications in the proportions recommended as reference below:

Model	Porcelain Powder	Formative Liquid	Recommended Powder and Liquid mixing proportion
Zirconia Ceramic	Opacious Dentine, Dentine, Semi-transparent, Transparent	Modeling Liquid (CFS)	1g : 0.39g
	Glaze, Corrective, Stain	Glaze & Stain Liquid (GY)	1g : 0.67g

- Avoid vigorous mixing which will tend to incorporate air bubbles with the paste and, both during and after mixing, examine for compliance with Uniformity and be free from extraneous materials by visual inspection.
- Detailed Operation Steps and Attentions are given in the Appendix 2.
- Troubleshooting Guide are given in the Appendix 3.

【Coefficient of Thermal Expansion】8.7~9.7 ($\times 10^{-6}K^{-1}$).

【Glass Transition Temperature】600 (±20)℃

【Transportation】The product is not regulated for transport of dangerous goods. Examine whether the package of the containers are integrate and tighten closed before transport. No divulgence, no collapse, no precipitation or no damage during the course of transportation. Don't put the goods together with strong base, water and so on. During transport should prevent exposure, rain and high temperature.

【Storage】Do store at proper temperature or keep out of intense light. Keep the product out of the reach of the children. Package tight closed.

【Dispose】This product is not regarded as hazardous waste. When dispose the product or its container can be refer to national or local regulations.

【Date of Manufacturing】See the labelling.

【Shelf life】Zirconia Ceramic (Powder): 5 years, limited time of use after opening packaging: 6 months. Zirconia Ceramic (Paste): 1 year, limited time of use after opening packaging: 3 months, just suggest use it as soon as possible.

【Country of Origin】Made in China

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【Symbol】

Symbol	Instruction	Symbol	Instruction
	Fragile, handle with care.		Temperature limitation: - 18 °C ~ 50℃
	Consult instructions for use, or consult electronic instructions for use(eIFU)		Humidity limitation: 30% ~ 80%
	Keep dry		Do not use when the packing is damaged
	Attention(See user's manual)		Stacking limit by 5 layers
	Date of manufacturing		Prevent from heat
	Date of expiry		Prescription Use (Rx)
LOT	Lot number		Manufacturer and address
CE 1639	Conformity to the requirements of the applicable EC directives	EC REP	Authorized Representative in the European Community/European Union
MD	Medical device, indicates the item is a medical device		Importer

Suggested profile and training of users

BAOT Dental Ceramic are designed for use by professional users. This specification is made clear by the labeling of BATO products with the symbol "Rx only". The specialist users are dentists and dental technicians who have excellent prior knowledge in the use of our products due to their many years professional training and/or university education. Follow-up training is the responsibility of the expert users and is offered by BAOT specifically for BAOT products. This guarantees safe handling of BAOT products at every point in the application process.

Product reliability

Information on reporting serious incidents in connection with medical devices, general risks associated with dental treatments, residual risks and Summary of Safety and Clinical Performance (SSCP) is available in EUDAMED database (URL: https://ec.europa.eu/tools/eudamed) under the product Basic UDI-DI: 697313331CE01BG.

Safety data sheets can be downloaded at https://www.baotdent.com or requested by fax at (+86) (0)760-87893825 or by Email: baotw@baot.biz.

Disclaimer

Please note: Our products must be used in accordance with the instructions for use. We do not accept any liability for damage resulting from incorrect handling or usage. The user is furthermore obligated to check the product before use with regard to its suitability for the intended area of applications. We cannot accept any liability if the product is used in conjunction with materials or equipment from other manufacturers that are not compatible or not authorized for use with our product and this results in damage.

Date of issue of these Instructions for Use: 2024-10. After the publication of these instructions for use, any previous versions become obsolete. The current version can be found at https://www.baotdent.com

Appendix 1: Product introduction of Zirconia Ceramic (ZCG) series

Category			Shades	State	Spec. (g)
Dentine	Opacious Dentine	16 color series	A1 A2 A3 A3.5 A4 B1 B2 B3 B4 C1 C2 C3 C4 D2 D3 D4	Powder	2, 5, 7, 10, 15, 50, 100, 200
		30 color series	B1M1 BL1 B1M1 BL2 B1M1 BL3 B1M1 BL4 B1M1 B1M2 B2L1.5 B2L2.5 B2M1 B2M2 B2M3 B2R1.5 B2R2.5 B3L1.5 B3L2.5 B3M1 B3M2 B3M3 B3R1.5 B3R2.5 B4L1.5 B4L2.5 B4M1 B4M2 B4M3 B4R1.5 B4R2.5 B5M1 B5M2 B5M3	Powder	2, 5, 7, 10, 15, 50, 100, 200
	Dentine	16 color series	A1 A2 A3 A3.5 A4 B1 B2 B3 B4 C1 C2 C3 C4 D2 D3 D4	Powder	2, 5, 7, 10, 15, 50, 100, 200
		30 color series	B1M1 BL1 B1M1 BL2 B1M1 BL3 B1M1 BL4 B1M1 B1M2 B2L1.5 B2L2.5 B2M1 B2M2 B2M3 B2R1.5 B2R2.5 B3L1.5 B3L2.5 B3M1 B3M2 B3M3 B3R1.5 B3R2.5 B4L1.5 B4L2.5 B4M1 B4M2 B4M3 B4R1.5 B4R2.5 B5M1 B5M2 B5M3	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Dentine Modifier	DM-2A DM-2B DM-2C DM-2D DM-2E DM-2F DM-2G DM-2H	Powder	2, 5, 7, 10, 15, 50, 100, 200
Enamel	Semi-transparent	Semi-transparent	E-2A E-2B E-2C E-2A 201	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Semi-transparent Effect	EE-2A EE-2B EE-2C EE-2D EE-2E EE-2F EE-2G EE-2H	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Cervical	C-2A C-2B C-2C C-2D C-2C 203	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Cervical Effect	CE-2A CE-2B CE-2C	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Opal Translucent	OT-2A OT-2B OT-2C OT-2D OT-2E	Powder	2, 5, 7, 10, 15, 50, 100, 200

		Pearl Translucent	PL-2A PL-2B PL-2C	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Luminary	LM-2A LM-2B LM-2C LM-2D LM-2E LM-2F LM-2G LM-2H	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Mamelon	MM-2A MM-2B	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Margin	M-2A M-2B M-2C M-2D	Powder	2, 5, 7, 10, 15, 50, 100, 200
	Transparent	Transparent	T-2 T-2A T-2B T-2C T-2 261 T-2 262 T-2 263 T-2 264 T-2 265 T-2 268 T-2 271 T-2 275	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Window	WIN-2	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Gingiva	GIN-2A GIN-2B GIN-2B 273	Powder	2, 5, 7, 10, 15, 50, 100, 200
	Glaze	Glaze	G-2 G-2A	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
		Corrective	COR-2A COR-2B COR-2C COR-2D	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
		Stain	S-2A S-2B S-2C S-2D S-2A 211 S-2A 212 S-2A 213 S-2A 214 S-2B 221 S-2B 222 S-2B 223 S-2B 224 S-2B 225 S-2B 226 S-2B 227 S-2B 228 S-2C 231 S-2C 232 S-2C 233 S-2C 234 S-2C 235 S-2D 241 S-2D 242 S-2D 243 S-2D 244 S-2D 245 S-2D 246 S-2D 247 S-2D 248 S-2D 249	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
Formative Liquid	Opaque Liquid		OF	Liquid	15, 50, 240
	Modeling Liquid		CFS	Liquid	15, 50, 240
	Glaze & Stain Liquid		GY	Liquid	5, 15, 50, 240

【Firing Parameters】

Process \ Model/Type	Zirconia Ceramic			
	Margin	Body*	Add on	Glaze & Stain
Initial Temp (℃)	500	500	500	500
Drying Time (min)	2	3	2	2
Heating Time (min)	2	3	2	2
Heating Rate (℃/min)	50	50	50	50
Firing Temp. (℃)	960	920	910	890
Holding Time (min)	1	1	1	1
Cooling Time (min)	4	4	4	4
Cooling Temp. (℃)	550	550	550	550
Vacuum Start (℃)	550	550	550	-
Vacuum End (℃)	960	920	910	-

Note:

Please kindly note, as the manufacturer recommended, the inner zirconia crown should be a CTE range (25~500℃): 10.0~10.6 ($\times 10^{-6}K^{-1}$).

(1) *Body: including Cervical, Opacious Dentine, Dentine, Enamel, Transparent, Gingiva.

(2) Add on: the second add-on porcelain material.

(3) According to the characteristics of different porcelain ovens, the firing parameters can be adjusted appropriately, and attention should be paid to test and confirm the firing situation before production.

Appendix 2: Operating instructions

Basic Process

1. Bonding Layer Application

Inspection

Inspect the size, length, and thickness of the inner crown on the model to ensure they are appropriate. If not, adjust by grinding or redesigning.

Bonding Layer Application

During the heat treatment of the inner crown, apply a thin layer of body porcelain on its surface as a bonding layer. Roughen the surface of the inner crown to enhance the bonding strength between the inner crown and the body porcelain.

Bonding Layer Firing

Refer to the sintering parameters in the firing parameter table for heat treatment.

2. Body Porcelain Application

Preparation

1) Use a plastic stick to take an appropriate amount of body porcelain and place it on a glass plate. Add a suitable amount of special body porcelain liquid beside it. (See Figure 1)
2) Use the plastic stick to push the porcelain powder onto the liquid and wait briefly for the powder to naturally absorb the moisture. (See Figures 2 & 3)

* Add a small amount of liquid until the porcelain powder is fully moistened. Avoid excessive stirring, and ensure it is neither too dry nor too wet.

Figure 1

Figure 2

Figure 3

Layering Porcelain

Determine the size, thickness, and length of the porcelain tooth based on the adjacent space and occlusion. Since the porcelain tooth will shrink after sintering, the layered porcelain tooth should generally be about 10% larger than the final completed tooth.

* During the layering process, pay attention to moisture absorption as needed. Moisture absorption helps to consolidate the porcelain paste, preventing issues such as collapse, cracking, bubbles, or inconsistent colors due to the flow of porcelain powder.
Ensure the porcelain powder is compact and connected at the tooth gaps to avoid cracks caused by shrinkage during sintering. The porcelain paste at the edges should be adequately covered with a certain thickness to prevent incomplete coverage after shrinkage.

3. Applying Translucent and Transparent Porcelain

Applying Translucent Porcelain

Layer the translucent porcelain up to one-third of the incisal edge.

* Use a slightly moistened brush to gently push and pull, ensuring the porcelain layers are tightly bonded.

Applying Transparent Porcelain

Layer the transparent porcelain up to two-thirds of the incisal edge, covering the translucent porcelain.

Firing

Refer to the temperature in the firing parameter chart for sintering.

* Before starting sintering, if the porcelain powder is too wet, extend the drying time.

Porcelain Addition

Use the tip of a porcelain layering brush to gently tap the hemostatic clamp, absorbing any excess moisture to consolidate the porcelain powder. Repeat several times until it becomes difficult to extract more moisture.

* Be cautious not to apply too much force to avoid collapsing the porcelain layers or causing inconsistent colors.

Sintering

The sintering temperature for porcelain addition is slightly lower than the initial sintering temperature. Please refer to the firing parameter table.

4. Contouring and Glazing

Contouring

Refine the shape of the porcelain tooth and confirm whether additional porcelain is needed.
If additional porcelain is required, the sintering temperature should be 5-10℃ lower than the porcelain layering temperature.

* Avoid excessive additions, as this may result in color dullness.

Preparation

Mix the glaze powder with the glaze liquid into a paste-like consistency, as shown in the image to the right.

* Stir thoroughly to ensure the glaze powder and liquid are fully blended. If too dry or too thin, the final glaze will lack sufficient luster.

Application and Color Matching

* Apply evenly without making the layer too thick.
* Compare the glazed porcelain tooth with the corresponding shade guide. If the color is insufficient, use a staining agent for uniform coloring. After staining, continue comparing until the desired color is achieved.

Sintering

After glazing, refer to the firing parameter chart for sintering. Vacuum is generally not required.

* Excessively high sintering temperatures may result in overly rounded crown shapes, overly bright glaze surfaces, and unnatural colors.
* Insufficient sintering temperatures may result in a dry, dull surface of the porcelain tooth, without gloss.

Appendix 3: Troubleshooting Guide

Step 1: Perform heat treatment for the inner crown.			
Inner Crown Processing	Steps	Requirements	Reasons
	Polishing	Remove sharp edges and uneven surfaces.	Sharp surfaces easily cause porcelain cracking, and depressions may lead to bubbles.
	Cleaning	Use ultrasonic cleaning to remove polishing residues	Removes impurities, prevents bubbles and porcelain detachment.
	Heat Treatment	Degrease and apply a thin layer of body porcelain as a bonding layer	Prevents porcelain cracking, bubbles, and improves bonding strength.
Step 2: Ensure the porcelain powder remains uncontaminated. Take out an appropriate amount of porcelain powder each time. Once removed, it is not recommended to return the powder to the bottle.			
Applying Body Porcelain	Issues	Cause	Solutions
	Bubbles	Insufficient porcelain powder compaction.	Avoid leaving gaps when layering porcelain and ensure proper vibration to absorb water.
		Excessively high sintering temperature.	First follow the recommended temperature; if too high, reduce by 5°C.
	Detachment	Inner crown is contaminated	Avoid contaminating the inner crown with oil or dirt; do not handle with bare hands, use tweezers instead.
		No bonding layer applied	Apply a thin bonding layer with porcelain powder.
	Fractures	Insufficient drying time or overly rapid temperature increase.	Extend the drying time or reduce the heating rate.
	Shrinkage Cracks	Porcelain layers or developmental grooves are not connected during layering	Use a brush to gently connect them and lightly vibrate to consolidate.
	Crazing	Excessive drying time causing cracks	Shorten drying time.
	Edge Cracking	Porcelain layering is too thick, or cooling time is too short	Avoid layering porcelain too thickly, and extend cooling time
		Inner crown design is too short, resulting in thick porcelain layering	Improve the inner crown design.
	Contouring Cracks, Soft Feeling	Low sintering temperature resulting in incomplete crystallization, leading to weak bonding between crystals and cracking during grinding; or over-sintering, causing increased glass phase, surface brittleness, and ease of grinding and cracking, giving a false impression of softness.	Control the sintering temperature properly. The recommended sintering temperature for Baot porcelain powder is around 925°C, with adjustments based on the number of teeth. Also, consider the temperature deviation of the porcelain furnace.

	Color issues	Contamination of the furnace chamber by volatile sources.	Raise the temperature from 550°C to 960°C under vacuum and fire for 10 minutes to volatilize and remove contaminants.
		Show-through, uneven thickness of body porcelain and transparent porcelain	Control the thickness of body porcelain and transparent porcelain
		Bluish color due to low sintering temperature or short firing time.	Increase firing temperature and duration
	Murky color.	Disordered layering of porcelain during application	Avoid excessive vibration while layering.
		Low or abnormal vacuum level in the furnace.	Ensure proper vacuum settings in the porcelain furnace.
Applying Glaze	Insufficient Gloss	Firing temperature too low	Refer to the firing temperature chart and increase the sintering temperature.
		Surface not cleaned properly after adjustments	Clean the porcelain tooth surface before glazing.
		Uneven mixing of glaze powder or mixture too thick	Mix glaze powder evenly and avoid overly thick consistency.
	Excessive Roundness and Shine	Firing temperature too high or multiple firings	Reduce firing temperature and the number of firings.

Note: Information on troubleshooting can be found on our website, at https://www.baotdent.com, search keyword: ‘troubleshooting guide’.