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Zirconia Dental Ceramics
User Manual

CE 1639

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CE 1639 Zirconia Dental Ceramics User Manual

Note:

Please read this product manual before use. The product shall be processed only by professional technicians; the prepared restorations shall be installed and adjusted by professional doctors; and the patients shall wear the restorations according to the instructions and doctor's instructions.

【Product Name】 Zirconia Dental Ceramics

【Device Description】 Zirconia Dental Ceramics is composed of yttria-stabilized zirconia. It is intended to be processed into dental restorations such as crowns, bridges, inlays, onlays and veneers of fixed denture, by using computer-aided design/manufacturing (CAD/CAM) technology. The block is provided non-sterile in pre-sintered state, and the prepared restorations must be used after final-sintering.

【Model and Specification】

Table 1 Models and Specifications

Model	Translucency	Colour/Shade	Shape and Size
White	HT	White	Cylinder (diameter*height): mm 98*10, 98*12, 98*14, 98*16, 98*18, 98*20, 98*22, 98*25, 98*30, 98*35, 95*10, 95*12, 95*14, 95*16, 95*18, 95*20, 95*22, 95*25, 95*30, 95*35, 100*10, 100*12, 100*14, 100*16, 100*18, 100*20, 100*22, 100*25, 100*30, 100*35 (allowable error: ±0.5mm) Cuboid (length*width*height): mm 14×13×13, 15×13×10, 17×14×12.5, 20×15×14, 20×15×19, 40×15×14, 40×15×19, 40×20×12, 40×20×16, 40×20×20, 42×16×16, 43×25×10, 43×25×12, 43×25×14, 43×25×16, 43×25×18, 43×25×20, 55×19×15, 58×29×16, 58×29×20, 58×29×22, 60×25×14, 60×25×16, 60×25×20, 62×25×10, 62×25×12, 62×25×14, 62×25×16, 62×25×18, 62×25×20, 62×25×22, 65×20×15, 65×22×25, 65×30×16, 65×30×20, 65×40×17, 65×40×22, 65×40×25, 69×25×16, 69×29×16, 69×52×14, 70×40×12, 70×40×14, 70×40×16, 70×41×12, 70×41×14, 70×41×16, 75×25×16, 75×25×22, 85×40×22, 87×25×16, 87×25×22, 93×25×16, 93×25×22 (allowable error: ±0.5mm) U-shape (length*width*height): mm 92*75*10, 92*75*12, 92*75*14, 92*75*16, 92*75*18, 92*75*20, 92*75*22, 92*75*25, 92*75*30, 92*75*35, 89*71*10, 89*71*12, 89*71*14, 89*71*16, 89*71*18, 89*71*20, 89*71*22, 89*71*25 (allowable error: long +1.5mm~+2.5mm, width +1.5mm~+3.0mm, high ±0.5mm)
	ST	White	
	ST-II	White	
	UT	White	
Color	ST	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OM1, OM2, OM3, BL1, BL2, BL3, BL4 (23 shades)	
	SHT	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OM1, OM2, OM3, BL1, BL2, BL3, BL4 (23 shades)	
Multilayer (ML)	ST	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OM1, OM2, OM3, BL1, BL2, BL3, BL4 (23 shades)	
	SHT	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4 OM1, OM2, OM3, BL1, BL2, BL3, BL4 (23 shades)	
	UT	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OM1, OM2, OM3, BL1, BL2, BL3, BL4 (23 shades)	
	3D-plus	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OM1, OM2, OM3, BL1, BL2, BL3, BL4 (23 shades)	
	4D	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OM1, OM2, OM3, BL1, BL2, BL3, BL4 (23 shades)	

【Chemical Compositions】

Table 2 Chemical Compositions

Model	Transmittance	Composition (in wt%)		
		ZrO_2+HfO_2+Y_2O_3	Y_2O_3	Other oxides[1]
White	HT	≥99%	4.5%≤ Y_2O_3 <5.0%	<1%
	SHT	≥99%	5.0%≤ Y_2O_3 <5.5%	<1%
	ST-II	≥99%	5.0%≤ Y_2O_3 <5.5%	<1%
	UT	≥99%	5.5%≤ Y_2O_3 <6.0%	<1%
Color	ST	≥98.2%	4.5%≤ Y_2O_3 <6.5%	<1.8%
	SHT	≥98.2%	4.8%≤ Y_2O_3 <7.4%	<1.8%
Multilayer	ST	≥98.2%	4.5%≤ Y_2O_3 <6.5%	<1.8%
	SHT	≥98.2%	4.8%≤ Y_2O_3 <7.4%	<1.8%
	UT	≥98.2%	5.2%≤ Y_2O_3 <8.1%	<1.8%
	3D-plus	≥98.2%	5.4%≤ Y_2O_3 <8.4%	<1.8%
	4D	≥98.2%	5.3%≤ Y_2O_3 <8%	<1.8%

Note: 1 Other oxides mainly include Ferric oxide, Erbium oxide, etc.

【Intended Purpose】

Zirconia Dental Ceramics is a dental restorative material used for making crowns, bridges, inlays, onlays and veneers of fixed denture.

【Intended medical conditions】

The treatment of partial or total loss of anatomical crown in the anterior and posterior tooth regions due to caries, wear, trauma, periodontal disease, etc.

【Target Patient Population】

Suitable for patients of all ages and gender.

Note: The product should be used on children with primary teeth only after medical consultation from dentists. Zirconia crowns can be used on children. But more than three-unit zirconia bridges are typically not recommended for patients under 18, except in special cases (e.g., severe disease or trauma) where a dentist determines the benefits outweigh the risks. In such cases, treatment should be approached with caution, with close monitoring and regular follow-ups to adjust or replace the bridge as the child grows.

【Indications】

HT, ST, ST-II, Color-ST, Color-SHT, ML-ST, ML-SHT, ML-4D are indicated for the fabrication of
- anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers);
- anatomically reduced and fully anatomical (monolithic) multi-unit bridges with no more than two pontics between abutment crowns in the anterior and posterior tooth range;
- Cantilever bridges with maximum one free-end pontic and no further than the second premolar.

UT, ML-UT, ML-3D-plus are indicated for the fabrication of
- anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers);
- anatomically reduced and fully anatomical (monolithic) bridges (up to 3 units) in the anterior and posterior tooth range.

【Contraindication】

In the event that there is an insufficient occlusal clearance and/or vertical prep wall, making the preparation unsuitable for an all-ceramic restoration, an alternative material must be chosen. Inlay-retained bridges, endosseous implants and root posts are other contraindications. Bruxism or recalcitrant parafunctional habits are contraindications for ceramically veneered frameworks.

【Intended Users】

Zirconia Dental Ceramics shall be processed by dental technicians. And the prepared restorations shall be handled by certified dentists.

【Intended Environment】

Zirconia Dental Ceramics shall be processed in dental laboratories. And the prepared restorations shall be handled in dental departments in hospitals or dental clinic with the environment clean.

【Clinical Benefit】

- Restoration of missing tooth and masticatory apparatus portions;
- Restoration of chewing function.

【Summary of Safety and Clinical Performance (SSCP)】

The SSCP of the product (according to the requirements of Regulation (EU) 2017/745) can be downloaded from *** (EUDAMED websit).

【Undesirable Side Effects/Residual Risks】

- Mechanical failure (fracture of the restoration, chipping of the ceramic veneer or detachment of the restoration/loss of retention) with low risk of possible ingestion or reversible mucosal injuries.
- Biological incompatibility (plaque accumulation, intolerance reactions, marginal/secondary caries, loosening of the supporting teeth) resulting in possible loss of the restoration.

【Performance Characteristics】

Table 3 Performance Characteristics - Model White

Performance Item	HT	ST	ST-II	UT
Classification (per ISO 6872:2024)	Type II, Class 5	Type II, Class 5	Type II, Class 5	Type II, Class 4
Density (after sintering) (g/cm³)	≥6.0	≥6.0	≥6.0	≥6.0
Flexural strength (after sintering) (MPa)	≥800	≥800	≥800	≥600
Chemical solubility (after sintering)(μg.cm^{-2})	＜100	＜100	＜100	＜100
Radioactivity (Bq/g)	≤1.0	≤1.0	≤1.0	≤1.0
Coefficient of thermal expansion (after sintering)(×10^{-6}K^{-1})	10.5±0.5	10.5±0.5	10.5±0.5	10.5±0.5
Fracture Toughness (after sintering) (MPa*m$^{1/2}$)	≥5.0	≥5.0	≥5.0	≥3.5
Hardness (after sintering) (HV1)	≥1200	≥1200	≥1200	≥1200

Table 4 Performance Characteristics - Model Color

Performance Item	Color-ST	Color-SHT
Classification (per ISO 6872:2024)	Type II, Class 5	Type II, Class 5
Density (after sintering) (g/cm³)	≥6.0	≥6.0
Flexural strength (after sintering) (MPa)	≥800	≥800
Chemical solubility (after sintering)(μg.cm^{-2})	＜100	＜100
Radioactivity (Bq/g)	≤1.0	≤1.0
Coefficient of thermal expansion (after sintering)(×10^{-6}K^{-1})	10.5±0.5	10.5±0.5
Fracture Toughness (after sintering) (MPa*m$^{1/2}$)	≥5.0	≥5.0
Hardness (after sintering) (HV1)	≥1200	≥1200

Table 5 Performance Characteristics - Model Multilayer

Performance Item	ML-ST	ML-SHT	ML-UT	ML-3D-plus	ML-4D
Classification (per ISO 6872:2024)	Type II, Class 5	Type II, Class 5	Type II, Class 4	Type II, Class 4	Type II, Class 5
Density (after sintering) (g/cm³)	≥6.0	≥6.0	≥6.0	≥6.0	≥6.0
Flexural strength (after sintering) (MPa)	≥800	≥800	≥600	≥600	≥800
Chemical solubility (after sintering)(μg.cm^{-2})	＜100	＜100	＜100	＜100	＜100
Radioactivity (Bq/g)	≤1.0	≤1.0	≤1.0	≤1.0	≤1.0
Coefficient of thermal expansion (after sintering)(×10^{-6}K^{-1})	10.5±0.5	10.5±0.5	10.5±0.5	10.5±0.5	10.5±0.5
Fracture Toughness (after sintering) (MPa*m$^{1/2}$)	≥5.0	≥5.0	≥3.5	≥3.5	≥5.0
Hardness (after sintering) (HV1)	≥1200	≥1200	≥1200	≥1200	≥1200

【Compatible Milling System and Other Processing Equipment】

Zirconia Dental Ceramics shall only be processed using the compatible milling systems which is chosen according to the shape of the ceramic block, as shown in Table 6.

Table 6 Compatible Milling Systems

Product Shape	Compatible Milling Dystem
Cylinder of 95mm diameter	ZirkonZahn
Cylinder of 98mm diameter	Wieland
Cylinder of 100mm diameter	Zirkon
U-shape	AmannGirrbach
Cuboid	Sirona

The other equipment for processing Zirconia Dental Ceramics include:
- Sintering furnace: check it's user manual to ensure that it can provide the specified sintering schedule;
- Mechanic handpieces with different grinding heads.

Please choose and use the legally marketed equipment during processing ceramic blocks into the restorations. Before use, please read their user manuals to ensure that they can be used to process zirconia restorations.

【Compatible Devices】

The devices intended to be used in combination with Zirconia Dental Ceramics include:
1)Coloring liquid;
2)Glaze and dental porcelain: check the coefficient of thermal expansion in their labeling to confirm compatibility;
3)Cements: traditional cements such as zinc phosphate or glass ionomer cement, or conventional or self-adhesive composite resin cements.
Please choose and use the legally marketed devices. Before use, please read their instructions for use to ensure that they can be used with zirconia restorations.

【Application Method】

Take the ceramic block out of the package, and fix it in the compatible milling machine then process it into restorations as the instructions in Table 7.
After sintering and crystallization, the finished restorations will be prepared after dressing, overlaying decorative porcelain or glazing and other processes. Finally, it will be used by professional doctors for the repair, installation and wearing of human denture.

【Instructions for Use】
The detailed processing instructions of Zirconia Dental Ceramics are shown in Table 7.

Table 7 Instructions for Use

Procedure	Operating Points	Matters Need Attention
Layout	Information confirmation of the ceramic block and selection of the milling system	1.Confirm the product information of the ceramic block before layout, including the block's model, specification, shrinkage factor (i.e. scaling), and the arrow direction indicating the incisal edge for the prosthesis (only for the Multilayer blocks), etc. 2.The thickness of the block should match the height of the teeth and should be at least 0.5mm more than the height of the teeth. 3.Choose the compatible milling system with the suitable jig to fix the ceramic block according to Table 6.
	Layout method	1.The processing area should not exceed the boundary of the selected block. 2.When arranging teeth, at least 3mm of space should be reserved between teeth to facilitate the addition of connecting rods. 3.he teeth shall be arranged vertically in the ceramic block.
	Layout of connecting rods	1.The rods should be attached to the lingual side of teeth. 2.The rods should be arranged at a consistent height as possible, leaving enough distance from the edge of the teeth and parallel to the round surface of the ceramic block.
Milling	Milling method	Follow milling system's technical instructions. 1.Before processing, check the milling equipment and confirm the equipment can operate normally, the dental bur is sharp and the ceramic block is installed firmly, in order to ensure a stable cutting process. 2.During processing, do not use any liquid to cool the ceramic block. 3.After processing, check whether there are cracks, pollution and damage on the finished prosthesis. If any of the above conditions occurs, identify the cause and re-mill new prosthesis. 4.Clean the milling equipment periodically as per their user manuals to prevent too much zirconia debris from affecting the normal operation of the equipment.
Removal & Cleaning	Removal method of connecting rods	1.Remove connecting rods and trim the prosthesis using specific mechanic handpiece and grinding heads. 2.Do not mill a connecting rod at a time. Firstly mill one half, then, mill the other half. 3.In case of multiple connecting rods, symmetric milling is recommended to ensure an even stress applied to the prosthesis.
	Trimming and cleaning of prosthesis	1.Before trimming, please check and ensure the cleanliness of grinding tools to avoid contamination of zirconia prosthesis caused by foreign matters on the grinding heads. 2. During the process of removal and trim, soft material pads such as towels and foam should be placed on the desktop to prevent cracks or fragmentation of the prosthesis if falling onto the desk. 3. During operation, choose a suitable speed of the handpiece, with support points for both hands. What's more, in order to prevent hidden cracks or edge breakage, excessive trim of the prosthesis in this process is not recommended. 4. To thoroughly clean the prosthesis after removal and grinding, soft brushes of different sizes can be used to clean the residual powder on prosthesis surface and in the dental crown.

Internal Dyeing & Drying (only for Model White)	Method of internal dyeing and drying	Follow the dyeing solution's technical instructions. 1. Gently place the prosthesis in dyeing solution facing the incisal edge downward with tweezers, be aware that the prosthesis should be soaked totally into the solution in 30s, during this process, turn the prosthesis gently by tweezers to ensure the solution is absorbed evenly. 2. After soaking, wipe gently the inner and outer surface of the prosthesis with a tissue, and suck out the obvious residual liquid. After internal dyeing, the prosthesis is not allowed to contact with substances with strong water absorption for a long time. 3. Dry the prosthesis at 120℃ for 30min. For the thick prosthesis such as bridge of more than three units, implant, etc., it is recommended to extend the drying time to 60min.
Sintering	Sintering curve and placement method	Follow the furnace's technical instructions. 1. Select the appropriate sintering schedule (see Table 8 to 14). 2. Place the prosthesis in a crucible facing the incisal edge downward, avoiding stack.
	Usage of zirconium beads	1.New zirconia beads should be burned 1-2 rounds with the scraps of ceramic blocks before they can be used for sintering of the prosthesis. 2.Check zirconia beads before sintering. In case of serious discoloration and damage, zirconia beads should be replaced timely; in case of adhesion, the zirconia beads should be separated. 3.Zirconia beads should be sufficient to cover the entire bottom of the crucible (stacked 1-2 layers).
	Cleaning of sintering furnace	1. Cleaning method: Scrape off the impurities in the furnace and sinter the scraps of discarded ceramic blocks in furnace. After sintering, check whether there are traces of contamination on the ceramic scraps. If ever, repeat the above cleaning steps until the furnace is thoroughly cleaned, and please put new ceramic scraps for sintering every time. 2. Maintain the sintering furnace periodically and ensure the room where the furnace is placed is dry and free from dust pollution.
Grinding	Selection of grinding heads	1. Grinding steps are divided into rough grinding, fine grinding and rough polishing. 2. Use diamond grinding head containing rubber binder can effectively avoid edge breakage.

【Suggested Sintering Schedule】

Sintering can take place in all common dental sintering furnaces which can provide the specified sintering schedule. Since zirconia is known to be a poor thermal conductor, it is recommended that you slowly heat the restorations to the required temperature (see Table 8 to Table 14) and slowly cool them down .

Caution: Please conduct the temperature calibration of the furnaces regularly to ensure the accuracy of the sintering temperature then to provide the adequate sintering.

Table 8 Sintering Schedule - HT/ST /ST-II/Color-ST/ML-ST (1-5 Units)

Sintering step	Start Temperature (℃)	End Temperature (℃)	Time (Min)	Rate (℃/Min)
step 1	20	1000	130	7.5
step 2	1000	1530	156	3.4
step 3	1530	1530	120	0
step 4	1530	800	104	-7
step 5	800	natural cooling 20	/	/

Table 9 Sintering Schedule for - HT/ST /ST-II/Color-ST/ML-ST (6-10 Units)

Sintering step	Start Temperature (℃)	End Temperature (℃)	Time (Min)	Rate (℃/Min)
step 1	20	1000	245	4
step 2	1000	1530	177	3
step 3	1530	1530	120	0
step 4	1530	800	146	-5
step 5	800	natural cooling 20	/	/

Table 10 Sintering Schedule - HT/ST /ST-II/Color-ST/ML-ST (11-14 Units)

Sintering step	Start Temperature (℃)	End Temperature (℃)	Time (Min)	Rate (℃/Min)
step 1	20	1000	326	3
step 2	1000	1530	265	2
step 3	1530	1530	120	0
step 4	1530	800	183	-4
step 5	800	natural cooling 20	/	/

Table 11 Sintering Schedule - Color-SHT/ML-SHT/ML-4D (1-5 Units) and M-UT/ML-3D-plus (1-3 Units)

Sintering step	Start Temperature (℃)	End Temperature (℃)	Time (Min)	Rate (℃/Min)
step 1	20	1000	130	7.5
step 2	1000	1500	147	3.4
step 3	1500	1500	120	0
step 4	1500	800	100	-7
step 5	800	natural cooling 20	/	/

Table 12 Sintering Schedule - Color-SHT/ML-SHT/ML-4D (6-10 Units)

Sintering step	Start Temperature (℃)	End Temperature (℃)	Time (Min)	Rate (℃/Min)
step 1	20	1000	245	4
step 2	1000	1500	167	3
step 3	1500	1500	120	0
step 4	1500	800	140	-5
step 5	800	natural cooling 20	/	/

Table 13 Sintering Schedule - Color-SHT/ML-SHT/ML-4D (11-14 Units)

Sintering step	Start Temperature (℃)	End Temperature (℃)	Time (Min)	Rate (℃/Min)
step 1	20	1000	326	3
step 2	1000	1500	250	2
step 3	1500	1500	120	0
step 4	1500	800	175	-4
step 5	800	natural cooling 20	/	/

Table 14 Sintering Schedule - UT (1-3 Units)

Sintering step	Start Temperature (℃)	End Temperature (℃)	Time (Min)	Rate (℃/Min)
step 1	20	1000	130	7.5
step 2	1000	1450	132	3.4
step 3	1450	1450	120	0
step 4	1450	800	93	-7
step 5	800	natural cooling 20	/	/

【Service Life】 5 years.

【Storage】

Storage at indoor temperature, ventilated and dry conditions.

【Warning】

1.If the patient or the dental professional demonstrates a hypersensitivity reaction, such as rash, dermatitis etc., discontinue use of the product and seek medical attention immediately.

2.When processing the blocks of Model Multilayer, please check and confirm the arrow direction in the side tag on the ceramic block, which indicates the incisal edge of the prosthesis, as shown in the following example:

Face of zirconica blank for the Incisal edge

3.Do not use products beyond the expiration date.

【Precaution】

1.Please check the ceramic block carefully before use. Do not use the block if there is any damage in it.

2.Don't press and collide the product during storage, transit and processing.

3.When choosing the devices and equipment in combination, please strictly comply with the requirements in **【Compatible Milling System and Other Processing Equipment】** and **【Compatible Devices】**. Otherwise, the performance of restorations may be affected.

4.Restorations that aren't sintered should not be directly used in human denture or oral repair.

5.The product is a partially sintered ceramic material and shrinks during sintering, so it is vital to take into account the appropriate shrinkage factor/scaling during milling to ensure the precise fit of the restoration. The specific shrinkage factor/scaling is labeled on each block.
6.When milling the block or cutting, grinding and polishing the restorations, wear an approved dust respirator to protect your lungs from inhaling dust.
7.It is advised not to use coolant during the milling process as it may lead to color changes and/or loss of transparency.
8.In order to avoid the failure of the restorations, please make sure that the restorations after finishing shall have the following minimum thickness and connector cross section.

Table 15 Minimum Thickness and Connector Cross Section Area

Type	Anterior		Posterior	
	Thickness	Connector cross section	Thickness	Connector cross section
Single crown	≥0.9 mm	≥9 mm²	≥1.0 mm	≥12 mm²
3 unit bridges	≥0.9 mm			
Long bridges	≥0.9 mm			

9.Do not reuse the restoration.There may be cracks in the reused restorations, even invisible small cracks may bring the risk of fracture of the restoration. In addition, if a restoration is reused between different patients, there are mainly two additional risks: 1) cross-infection, 2) mismatch between the restoration prepared for one patient and the base teeth of another patient, which can badly effect the restoration.
10.Please storage the products in the conditions as specified in【Storage】, otherwise the performances of the product may be affected.

【Disposal】

1.The zirconia block itself does not cause environmental pollution. The residual blocks after processing restorations that have not been installed in the patient's mouth can be disposed of together with household waste..
2. The restorations removed from the patient's mouth, please disposed of them as medical waste according to the National and regional regulations, to avoid biological hazards and cross-infection caused by misuse or contact.

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【Symbols】

	Manufacturer		Consult instructions for use		Caution
EU REP	European representative		Date of manufacture		Use-by date
LOT	Batch code	MD	Medical device	UDI	Unique device identifier
	Keep away from sunlight		Fragile, handle with care		Keep dry
CE 1639	CE marking		Arrow direction indicates the incisal edge for the prosthesis	F**	F value
	Non-sterile				

【Release Date and VER】
Release date: Jan 6, 2026
VER: A.4

【Notice】

To users:
Please report any serious incident that has occurred in relation to the device to Shenzhen Yurucheng Dental Materials Co., Ltd. and the competent authority of the Member State of residence.