Instruction for Use

CE 0197

[Product name]: Zirconia Dental Ceramics
[Types]: CMW, CMC.
[Materials]: Zirconia
[Shade of product]:

Basic UDI-DI	Types	Shades
697420858DECMWKE	CMW	White
697420858DECMCJ6	CMC	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4

[Type of product (ISO 6872)]: Type II;
[Class of product (ISO 6872)]: Class 5.
[Working principle]:
Zirconia Dental Ceramics is made of all-ceramic denture material, usually using CAD / CAM (computer aided design / computer aided manufacturing) method of making all-ceramic denture crown, sintered inner crown with high strength, hardness, good resistance to fracture toughness and wear resistance, its has chemical stability and good biocompatibility and other excellent features, used to replace some or all of the human teeth to achieve its function.
[Intended purpose]:
The Zirconia Dental Ceramics is used for fabrication of dental fixed denture crowns and bridges in the anterior and posterior region.
[Indication]:
Denture restorations of dental fixed denture crown,bridge,and for permanent dentition with defect or missing.
[Contraindications]:

- The use of the product is contraindicated if the patient is known to be allergic to any of its ingredients.

Limitations of use：
Do not use the product in the following cases:

- Untreated bruxism(the use of a splint is indicated after seating)
- Hybrid abutments and hybrid abutment crowns
- Temporary seating

[Medical conditions]:
The device is intended used for clinical patients with dentition defect or missing. Dentition defects or missing teeth can result from various causes, including congenital factors, diseases, injuries, or nutritional deficiencies.
[Intended users]:
-Dentists;
-Trained professional denture fabrication operators.
[Intended patient population]:
Patients with permanent teeth(defect or missing),adults.

[Intended use environment]:
This product is expected to be used in legal denture manufacturing institutions.
[Clinical benefit]:
The Zirconia Dental Ceramics is used for fabrication of dental fixed denture crown, bridge. It has good fabrication performance and forming performance, its fabricated crown and bridge can increase survival of teeth, protect residual teeth.
The clinical benefit associated with the device is define as direct, can be used for patients with permanent teeth.
[Complications]:
- Fracture
- Chipping

[Shelf life]: 5 years.
[Single use]: Yes.
[Chemical Composite]:
The main chemical composite content consists of:

ITEM	Composition	Content
White zirconia	ZrO_2+HfO_2+Y_2O_3	≥99%
	Y_2O_3	4.5～6.0%
	HfO_2	≤5%
	Al_2O_3	≤0.5%
	Other oxide (TiO_2,CaO,MgO,SiO_2,Na_2O)	≤0.5%
Color zirconia	ZrO_2+HfO_2+Y_2O_3	>98%
	Fe_2O_3	<0.3%
	Pr_2O_3	<0.2%
	Er_2O_3	<1%
	Other oxide (CeO_2,Na_2O_3,CoO,MnO_2,SiO_2)	<0.5%

[Use method]:
Open the package to remove the green block, placed in a dedicated dental processing equipment for processing high temperature (1400-1600 ℃);
After sintering, sem-product trimmed into finished products, for final product process recommended the use of thermal expansion coefficient of 10.5 $x10^{-6}$-11.5$x10^{-6}$ /K and applied by a professional doctor for human denture Or dental restoration.
[Combination devices]:
1) The combination devices for model CMW includes:
- CAD/CAM;
- Coloring solution;
- Sintering furnace;
- Separating and finishing equipment;
- Furnace for Glaze;
- Dental adhesives;
- Fixture.

The combination devices shall comply with following functions or technical

performance requirements:

Combination device	Requirements for combination devices' function or technical performance
CAD	The CAD software shall be EXO CAD, 3SHAPE CAD, and UP CAD, its generated dental data shall be STL format;
CAM	The typesetting software generated machining data shall include NC format; The CAM can present zirconia typesetting, different from glass ceramics and resin materials, including function of setting the amplification factor for zirconium blocks; The CAM shall be Four axis X/Y/Z/A, or, five axis equipment X/Y/Z/A/B (for example, A-axis:+ 135°, -30°; B-axis: 360°); The speed of machining spindle (usually 20000-30000r/min) and the feed rate (usually 0.5-2mm/min); CAM shall include three processes of rough machining, precision machining, and tooth pattern machining; The cutting tools' diameters shall be 2mm/1mm/0.6mm.
Separating and finishing equipment	Professional zirconia grinding needles, generally made of tungsten steel, with a speed not exceeding 10000r/min; The diameter of working end of the needle shall cover diameter ≦1mm
Coloring solution (only for CMW)	Three types: cutting fulid (TO), diluent, coloring solution with VITA-classical and VITA-3D Master Standard color card; The volume shall be ≥50ml.
Sintering furnace	The sintering temperature can reach 1600℃, with a heating rate of 5-20 ℃/min and a holding time of at least 2 hours; The furnace constant temperature accuracy of less than ±1℃.
Furnace for Glaze	The vacuum degree of the equipment is ≥ 90Kpa, temperature can reach 730-900 ℃, heating rate can be 40-80 ℃/min; maintained for at least 45-60 minutes.
Dental adhesives	Dual-cure resin The Dual-cure resin used to bond zirconia restorations must meet ISO 4049:2019.
Fixture	discs shape block：Spring chuck fixture: uses the elastic deformation of the spring to clamp the cylindrical ceramic block, and the spring chuck is contracted or expanded by rotating the nut, thereby clamping and loosening the ceramic block. It has high clamping accuracy and rigidity, can adapt to high-speed rotation processing environment, and is often used in high-precision turning, grinding and other processing processes. Horseshoe shape blocks：Profiling fixture: usually composed of two blocks, with a first assembly slot and a second assembly slot respectively provided on the fixed block and the movable block to match the shape and size of the horseshoe-shaped zirconium block.

	When in use, the horseshoe-shaped zirconium block is placed between the two slots, and the movable block is driven close to or away from the fixed block by a vise or other device to clamp and release the zirconium block, which can ensure the stable clamping of the horseshoe-shaped zirconium block and ensure the processing accuracy. Rectangular shape blocks：Magnetic fixture: For square zirconia ceramic blocks that can conduct magnetism (or ceramic blocks with magnetic components installed on them), magnetic fixtures can be used. The ceramic blocks are fixed on the workbench through magnetic adsorption, which is convenient and fast to clamp, and can effectively improve processing efficiency. At the same time, the magnetic fixture can provide uniform adsorption force to ensure the stability of the ceramic blocks during processing.

2) The combination devices for model CMC includes:

- CAD/CAM;
- Sintering furnace;
- Separating and finishing equipment;
- Furnace for Glaze;
- Dental adhesives;
- Fixture.

The combination devices shall comply with following functions or technical performance requirements:

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CAD	The CAD software shall be EXO CAD, 3SHAPE CAD, and UP CAD, its generated dental data shall be STL format;
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Furnace for Glaze	The vacuum degree of the equipment is ≥ 90Kpa, temperature can reach 730-900 ℃, heating rate can be 40-80 ℃/min; maintained for at least 45-60 minutes.
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[Use of combination device]

1, CAD design

Design according to the actual situation of the patient and the requirements of the doctor.As an all ceramic restoration, the following requirements must be met:

(1) The thickness of the restoration should not be less than 0.6mm.

(2) Due to the critical role of the geometric structure of zirconia dental bridge in crack resistance, the cross-sectional area of the anterior dental connector should be at least 9mm², and the cross-sectional area of the posterior dental connector should be at least 12mm².

(3)The continuous missing of a bridge body shall not exceed two units.

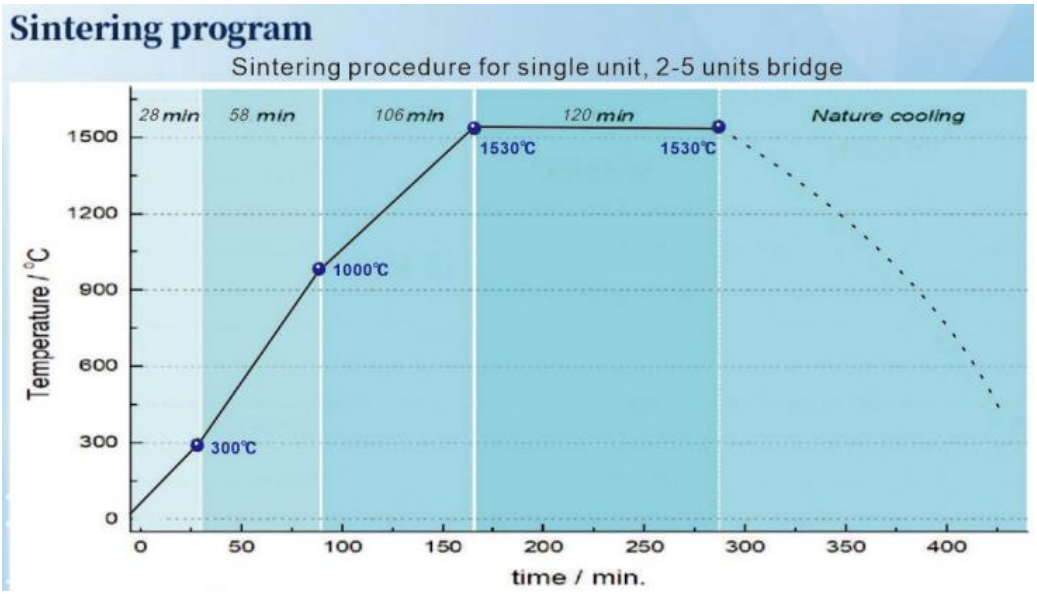
(4) Avoid free absence.

2, Typesetting
Operation points:
(1) Before typesetting, determine the material model, size, shrinkage ratio, and other parameters.
(2) Choose the appropriate fixture.
(3) Choose the appropriate shade zirconia dental ceramics(for CMC) .
(4) The thickness of a selected porcelain block should be greater than the height of the teeth.
(5) The processing area of a row of teeth cannot exceed the boundary of the selected material.
(6) If cutting on a used ceramic block, determine the orientation of the processed area of the ceramic block in the fixture and reserve sufficient space When multiple teeth or bridges need to be processed in one piece of processing material, a certain amount of clearance should be left between the teeth to facilitate the addition of connecting rods to fix the teeth.
Placement of connecting rods:
(1) Attach the connecting rod to the protruding part of the teeth
(2) Keep the height of the connecting rod as consistent as possible
(3) Do not add it near/far
(4) Maintain sufficient distance from the neck line
(5) The connecting rod should be parallel to the plate, without too much angle.
3, Milling
Place the ceramic block in a specialized zirconia processing equipment for cutting processing.
matters needing attention:
(1) Before processing, check whether the needle used is sharp enough to ensure the stability of the cutting equipment.
(2) For manual entry the specific shrinkage factor can be found on the disc. Detailed information can be found in the Instructions for Use
of the CAM software.
(3) When securing the disc in the holder, care must be taken to ensure that the circumferential notch and the disc holder are absolutely
clean and that the screws are tightened evenly crosswise
(4) During the processing, liquid cooling of zirconia blanks is not allowed.
(5) After the processing is completed, check whether the repaired body after cutting has cracks, contamination, or damage. If any of the above situations occur, the cause must be investigated and re-cut.
4, Separating and finishing
(1) Use a technician's specialized mobile phone and a dedicated grinding head for separation and repair.
(2) The correct method for dividing the connecting rod is to divide the connecting rod in stages in the same direction (clockwise or counterclockwise), First, polish off half of the connecting rod, and then perform secondary segmentation until the restoration falls off. (Note: Do not completely separate a connecting rod at once).

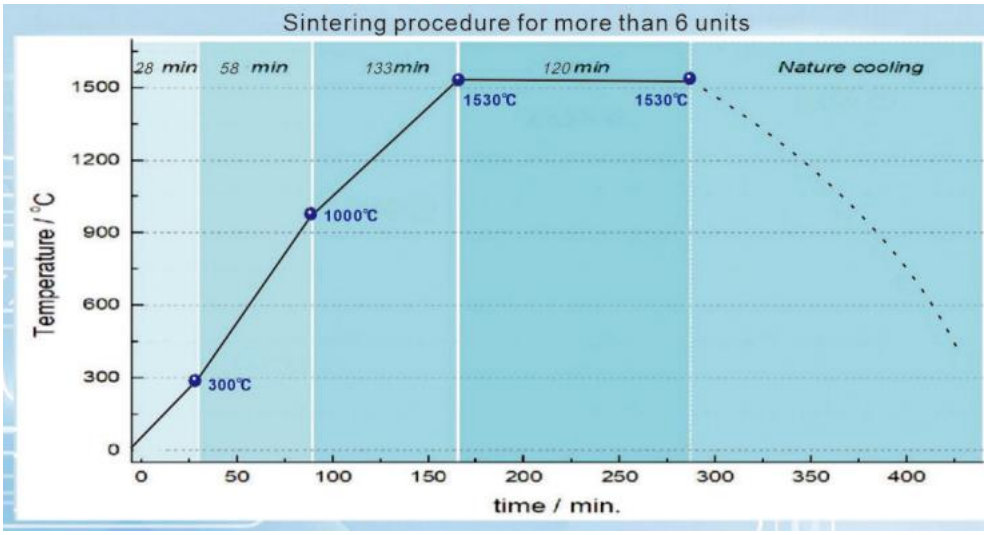
Matters needing attention:
(1) Grinding tools should not be mixed with tools used for grinding metal to avoid contamination of zirconia restorations by metal debris. Before polishing, a towel can be placed on the tabletop to prevent the repaired object from falling onto the tabletop and causing cracks or fractures.
(2) Use a tungsten steel grinding head to remove the connecting rod.
--It is not recommended to make excessive adjustments to the shape of the restoration when it is soft, in order to avoid problems such as hidden cracks or broken edges.
(3) Use a brush or porcelain brush to thoroughly clean the powder on the surface of the restoration and inside the crown.
(4) If the cleaning is not thorough, the powder will adhere to the surface and crown of the restoration after high-temperature sintering, forming white spots that affect the appearance and placement of the restoration; At the same time, soaking can contaminate the dyeing solution and affect the accuracy of color.
(5) In the non-sintered state, any contact with unsuitable liquids and liquids not approved for zirconium oxide (e.g. unpurified water and/or lubricant coolant) and/or contact media (e.g. occlusion spray) must be prevented.
5, Coloring infiltration(only for CMW)
The following aspects should be taken into consideration when applying the coloring infiltration technique:
(1) Choose the appropriate shade of colouring liquids；
(2) The restoration must be free from dust and grinding residue.
(3) Restorations must be completely dry before infiltration.
(4) The colouring liquids must not be contaminated.
(5) The colouring liquids have to be sealed when not in use.
(6) If there is cloudiness or precipitation (e.g. sediments), the colouring liquids should no longer be used.
Cloudiness or precipitation of the colouring liquids is promoted by contamination.
(7) Do not decant and/or store the colouring liquids in metal containers.
(8) Infiltrated restorations must be completely dried before sintering.
(9) It is advisable to wear protective gloves during the infiltration process. They help prevent skin irritation caused by the colouring liquids and the formation of a grease film on the restoration, which may compromise the infiltration of the colouring liquids.
6, Sintering
In general, the following notes should be taken into consideration when sintering:
-Only fully dried restorations may be sintered in order to prevent damage to the furnace and/or the object.
– Sufficient atmospheric exchange in the sintering sagger must be ensured.
– The restorations must not come into contact with each other during sintering.
– The correct program selection must be observed.
– Sintering temperatures that are too low or too high and/or sintering times that are too short or to too long will have a negative effect
on the above mentioned final properties.

– Always keep the sintering accessories clean and free of dust so that the sintered restorations are not contaminated.
Place the teeth face down onto the zirconium beads in the bowl and sinter them according to the following sintering curve.

Sintering procedure for single unit, 2-5 units bridge					
Steps	Starting temperature(℃)	Maximum temperature(℃)	Time(m**in**)	Heating rate(℃/min)	Heating rate(℃/h)
1	20	300	28	10.00	600
2	300	1000	58	12.00	720
3	1000	1530	106	5.00	300
4	1530	1530	120	0.00	0.00
5	1530	20	189	-8.00	-480



Sintering procedure for more than 6 units					
Steps	Starting temperature(℃)	Maximum temperature(℃)	Time(m**in**)	Heating rate (℃/min)	Heating rate(℃/h)
1	20	300	28	10.00	600
2	300	1000	58	12.00	720
3	1000	1530	133	4.00	240
4	1530	1530	120	0.00	0.00
5	1530	20	189	-8.00	-480



Precautions for using zirconium beads:

--Zirconium beads should be replaced in a timely manner if any of the following situations occur:

1) Severe discoloration

2) The shape is incomplete or damaged

3) Color is dead and opaque

-Before sintering, check whether the zirconium beads are adhered. If the zirconium beads are adhered, they should be separated to ensure good fluidity.

--The quantity of zirconium beads should ensure that they can completely cover the entire bottom of the bowl (1-2 layers).

--When replacing new zirconium beads, first burn the zirconium beads together with waste material 1-2 times before using them for sintering the restoration.

Cleaning and maintenance of sintering furnace:

- Cleaning method: Scrape off the impurities in the furnace, and then put the discarded zirconia scraps into the furnace for air burning. The sintering furnace should be cleaned once a week.

Before sintering, check the heating elements of the sintering furnace. If there is peeling on the surface of the heating rod (silicon molybdenum rod), place it in the corner material for air burning treatment.

When the equipment is not in use, the furnace should be closed to ensure a dry environment inside the furnace.

Please keep the operating room of the sintering equipment clean and tidy, and avoid using it in production environments with dust, metal shavings, or a lot of dust to avoid adverse effects on the heating elements Reasonable drying of the restoration before sintering can reduce pollution to the sintering furnace.

7, Processing after sintering

The following aspects should be taken into consideration when processing restorations after sintering:

– Processing of sintered restorations should be kept to a minimum.

– The restoration should only be mechanically processed if it is absolutely necessary.

– Use only light pressure and low speed to adjust the restoration.

– Prevent sharp edges when finishing frameworks.
– Bridge connectors must not be post-separated with a separating disc.
– We recommend using a rubber polisher to smooth the basal side of the bridge connectors.
– The material-specific minimum wall thicknesses and connector dimensions must not be undermined during processing.
– Use only immaculate grinding instruments
– Remove zirconium oxide dust sintered to the restoration with suitable grinding instruments. As an alternative, zirconium oxide dust sintered to the restoration may be removed by blasting with Al2O3, 25 – 70 µm at a pressure of 1 bar (15 psi) or 70–110 µm at a pressure of 1.5 bar (22 psi).– Rinse the restoration under running water or use the steam jet to remove any adhering residue and dry.
– Finish the restoration in accordance with the desired processing technique (staining, cut-back or layering).

[Cautions]:

- When using this product for processing, be sure to take appropriate dust protection device (wear dust masks, use goggles, etc.); Improper operation during transport / storage may cause damage to the ceramic block and the internal structure. Damage to the block may result in a decrease in the performance of the denture. Please check whether the ceramic block is intact before use;
- During use of the product, please wear masks so as to avoid inhalation of ceramic dust;
- Avoid severe squeeze, force and vibration and hit with hard object;
- It shall strictly follows the operation procedure defined in this IFU, otherwise, fracture may happen to fabricated dental fixed denture crown, bridge.
- Not sintered product can not be directly used for human denture or oral repair;
- This product is required by professional technicians, professional doctors use;
- If any serious incident happened, the users shall report it to the manufacturer and the competent authority.

[Physical and chemical properties]:

Density: ≥ 3.0 g / cm^3;
Sintered density: ≥ 6.02 g / cm^3;
Sintered flexural strength: > 800MPa;
Chemical solubility: <100 µg.cm^{-2}
Radioactive: uranium-238 active concentration ≤ 1.0 Bq/g.

[MRI compatibility]: since zirconia does not contain metal, it will not cause magnetic interference, so it will not produce artifacts or image distortion in MRI scanning.
[Net weight]: see product label.
[Net volume]: see the product label.
[Side effects]: There are no unexpected side effects to date.
[Notice]： A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is

establishe.

[Storage and transportation]:

Should be stored in a dry, non-corrosive gas and well ventilated room.

[Packing]: carton or plastic bag.

[DISPOSAL]: Dispose the device in accordance with local regulations.

[Production date]: see product label.

[Symbols]

CE 0197	CE mark	MD	Medical device
	Single use		Date of manufacture
LOT	Lot number		Manufacturer
	Notice	EU REP	European union representative
	Reference instruction for use	REF	Category number
	To be sold by or on the order of a licensed dentist	UDI	UDI
	Importer		Made in China
#	Model number	MR	MR safe
	Avoid getting wet by the rain		valid until

[Contact information]:

Manufacturer:

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