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INSTRUCTIONS FOR USE

Dental Lithium Disilicate Glass-Ceramic

CAD/CAM and press blocks



Read these instructions carefully before use and keep them for future reference.

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MD

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01 Product description

Dental Lithium Disilicate Glass-Ceramic is a lithium disilicate ceramic supplied in block form. It can be processed by CAD/CAM milling or by hot pressing.

The ceramic is composed of SiO_2, Li_2O, K_2O, Al_2O_3, P_2O_5, ZrO_2 and other oxides. It contains inorganic pigments which, after crystallization in the dental laboratory, give the restoration a colour matching the natural teeth of the patient.

The product complies with ISO 6872:2015 Dentistry – Ceramic materials. It is a single-use device, supplied non-sterile.

02 Intended use

Dental Lithium Disilicate Glass-Ceramic is a CAD/CAM or hot-pressing machinable glass-ceramic based on lithium disilicate for the fabrication of inlays, onlays, veneers, anterior and posterior single crowns, three-unit prostheses not involving molar restoration, adhesively or non-adhesively cemented, and partially or fully covered substructures for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration, adhesively or non-adhesively cemented.

03 Indications

Clinical indications

- Missing tooth structure in anterior and posterior teeth
- Partial edentulism in the anterior and posterior region

Types of restoration

- Inlays
- Onlays
- Veneers
- Crowns
- Three-unit prostheses not involving molar restoration

The product must not be used for

- Posterior bridges reaching into the molar region
- Bridges of 4 units or more
- Inlay-retained bridges
- Very deep subgingival preparations
- Patients with substantially reduced residual dentition
- Bruxism
- Cantilever bridges / extension units
- Maryland bridges
- Any other use not listed in the indications

04 Models and formats

Models are named after the translucency and the shade of the 20-shade guide (A1–D4 and bleach shades BL1–BL4). Translucency decreases from HT to HO: HT is chosen when the colour of the underlying tooth should show through; HO when it should be masked.

HT	High translucency	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4
MT	Medium translucency	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4
LT	Low translucency	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4

Opaque models (one model covers several clinical shades)

MODEL	OPACITY	CORRESPONDING CLINICAL SHADES
MO0	Medium opacity (MO)	BL1, BL2, BL3, BL4
MO1	Medium opacity (MO)	A1, A2, B1, B2, C1
MO2	Medium opacity (MO)	A3, A3.5
MO3	Medium opacity (MO)	B3, B4
MO4	Medium opacity (MO)	A4, C2, C3, C4, D2, D3, D4
HO0	High opacity (HO)	BL1, BL2, BL3, BL4
HO1	High opacity (HO)	A1, A2, B1, B2, B3, B4, C1
HO2	High opacity (HO)	A3, A3.5, A4, C2, C3, C4, D2, D3, D4

Formats

Format codes: L-length-width-height (cuboid block, mm) · D-diameter-height (cylinder, mm).

Cuboid blocks (CAD/CAM)

L-18-15-13, L-40-15-14, L-40-15-19, L-55-15-19, L-65-25-22, L-85-40-22, L-92-75-12, L-92-75-14, L-92-75-16, L-92-75-18, L-92-75-20, L-72-40-25, L-60-25-20, L-50-25-20, L-43-25-16, L-58-29-16, L-75-36-16, L-87-56-16, L-93-75-16, L-72-42-12, L-72-42-14, L-72-42-16, L-72-42-18, L-72-42-20, L-72-42-22, L-32-15-15, L-15.5-11-13, L-18-14-12, L-14-12-10, L-15-8-8, L-18.5-15-12.5, L-15-10-8, L-18-14-14, L-20-19-15.5, L-22-18-13, L-22-15-13, L-24-15-13

Cylinders (CAD/CAM)

D-06-15, D-11-08, D-13-10, D-13-20, D-12-18, D-16-16, D-20-20, D-98-10, D-98-14, D-98-16, D-98-18, D-98-20, D-98-22, D-98-25, D-95-10, D-95-14, D-95-18, D-95-22, D-100-10, D-100-12, D-100-14, D-100-16, D-100-18, D-100-20, D-100-22, D-100-25

Cuboid formats are for CAD/CAM processing only. All cylinder formats can be milled; formats D-06-15, D-11-08, D-13-10, D-13-20 and D-12-18 can also be used for hot pressing. The formats available depend on your distributor.

05 Technical specifications

Product name	**Dental Lithium Disilicate Glass-Ceramic**
Type and class (ISO 6872)	**Type II, Class 3**
Medical device class (MDR)	**Class IIa**
Composition	**SiO_2, Li_2O, K_2O, Al_2O_3, P_2O_5, ZrO_2 and other oxides**
State as supplied	**Partially crystallized; final crystallization in the dental laboratory**
Flexural strength	**≥ 300 MPa**
Glass transition temperature	**495 ± 20 °C**
Coefficient of thermal expansion	**$(9.8 \pm 0.5) \times 10^{-6}\ K^{-1}$**
Chemical solubility	**≤ 100 µg/cm²**
Radioactivity	**U^{238} ≤ 1.0 Bq/g**
Biocompatibility	**Compliant with ISO 7405:2018**
Shelf life	**10 years**

06 Contraindications

Do not use the product if the patient is known to be allergic to any of its ingredients.

07 Warnings

- The product must be handled by professional dental technicians.
- Never use a non-crystallized (unfired) restoration in the mouth.
- Do not inhale ceramic dust during grinding and finishing: use extraction and wear a mask and other protective equipment.
- Keep your hands away from the milling tools.
- Make sure the block holder is correctly positioned in the milling machine.
- Do not drop the product or subject it to strong force: it may be damaged.
- Keep out of reach of children.
- Do not use a broken or cracked product.

08 Side effects and complications

Possible complications include chipping or fracture of the restoration material.

09 Target patients and users

Target patients

Patients aged 15 years and older with permanent teeth, regardless of gender.

Intended users

Restorations must be fabricated by professional dental technicians and placed by dentists.

10 Disinfection

The finished restoration must be disinfected before it is used on the patient: soak it in 75 % alcohol for 30 minutes, scrubbing the surface grooves during immersion, then remove and dry it before try-in.

11 Performance and safety

Performance

A machinable glass-ceramic block for veneers, inlays, onlays, anterior and posterior single crowns and three-unit prostheses. Available in several shades and translucency levels to meet high aesthetic requirements, with a flexural strength above 300 MPa and good biocompatibility.

Safety

Thanks to its mechanical properties the material shows a low fracture rate and a high survival rate. Its good biocompatibility has practically no adverse effect on gingival health in patients with adequate oral hygiene. Because ceramics are brittle, chipping or fracture may occur; fracture resistance depends on the tooth structure, the cementation technique and the occlusion, and survival also depends on the clinician's skills and the patient's habits.

MRI and X-ray

The material is compatible with MRI and X-ray environments and meets the relevant safety requirements for medical devices.

12 Potential and residual risks

Potential risks

- Without protective measures during grinding and polishing, ceramic dust may irritate the respiratory tract or the eyes.
- A restoration that is not disinfected before use may cause infection.
- Improper polishing may lead to fracture.
- Excessive biting forces or lack of protection by the patient may cause the restoration to break.

Residual risk

RESIDUAL RISK / COMPLICATION	PROBABILITY
Chipping / fracture of the restoration material	**Fracture rate ≤ 6 % after 8 years of clinical use**

13 Processing

Product selection

The dentist selects the shade and translucency closest to the patient's teeth or to the desired result. The technician selects the format according to the equipment used (CAD/CAM or press furnace) and the number of restorations to be made at once.

CAD/CAM: crystallization (program 1)

Mill the L or D format, then crystallize the restoration in a ceramic furnace with program 1. Finish (e.g. glaze) before placement by the dentist.

PARAMETER	VALUE
Start temperature	**Room temperature**
Heating rate 1	**90 °C/min**
Holding temperature 1	**830 °C**
Holding time 1	**10 s**
Heating rate 2	**30 °C/min**
Holding temperature 2	**827–850 °C**
Holding time 2	**4–7 min**
Cooling rate	**50 °C/min**

Hot pressing (program 2)

Press the suitable D formats in a press furnace with program 2, then finish (e.g. glaze).

PARAMETER	VALUE
Start temperature	**700 °C**
Heating rate	**60 °C/min**
Pressing temperature	**900–930 °C**
Holding time	**15–25 min**

If required, characterize the restoration with stains and glazes intended for lithium disilicate glass-ceramics that are registered as medical devices, following their manufacturer's instructions.

14 Storage, transport and disposal

Storage

Store at room temperature in a dry place.

Transport

Avoid impacts with hard objects, strong pressure and vibration during handling.

Disposal

Single-use device, do not reuse. Dispose of remaining stock and removed restorations in accordance with national regulations.

15 Incident reporting

Report any incident involving injury or malfunction to the manufacturer, to your distributor, or to the competent authority of your country.

16 Manufacturer and regulatory information

Manufacturer	**Fuzhou Rick Brown Biomaterials Co., Ltd.** The first and second floors of R&D Building, Jiecheng Industrial Park, No. 36 Houshan Zhaishan, Nanyu Town, High-Tech District, Fuzhou, Fujian Province, China Tel. +86 591 23507151 · Fax +86 591 23507152 · SRN CN-MF-000033940
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Basic UDI-DI	**697614641DLDGC01NX**
EMDN code	**Q010699**
Distribution	Distributed under the Sunnyzir brand. Date of manufacture, batch and expiry date: see label.

17 Symbols

SYMBOL	MEANING	SYMBOL	MEANING
	Batch code		Manufacturer
	Date of manufacture		Authorized representative in the EU
	Medical device		Unique device identifier
	Do not re-use		CE marking with notified body number
	Non-sterile		Fragile, handle with care
	Dispose of safely		Keep dry
	Catalogue number		This way up
	Consult instructions for use		Use-by date