

LayZir

Layered Zirconia

All Indication Zirconia Disc

en Instructions for use

1.0:2020-03
GBCT000197

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en

READ CAREFULLY BEFORE USE

Safety notes

Please read the instructions for use carefully before taking the disc (made of zirconium dioxide) out of its packaging. They contain important information that is essential to ensure both the correct processing and the safety of patients and users. LayZir discs are manufactured and tested according to the highest quality standards. In order to guarantee this level of quality during subsequent processing, the procedures described in the following must be absolutely adhered to.

General handling notes

LayZir discs are supplied in a pre-sintered white-fired condition. They have limited stability and strength and a residual porosity. Therefore, they must be handled with care and stored in their original packaging. They must not be subjected to impact or vibration. Contamination must absolutely be avoided. Make sure restorations are only handled with dry and clean hands or gloves, and under no circumstances should they be contaminated with liquids (such as adhesives or marker pens). Coolants will reduce the material's translucency.

Storage:

Avoid high humidity and high temperatures. Keep away from direct sunlight. This product must be kept out of the reach of infants and children as well as stored and managed in an appropriate way so it does not come into contact with anybody except dental professionals.

Indication:

LayZir Disc is a zirconium dioxide 3Y-TZP and 5Y-PSZ used for manufacturing fixed dental prostheses. The material is suitable for prostheses involving partially or fully covered substructure for four or more units and fully covered substructure for prostheses involving four or more units.

Contraindications:

In the event that there is an insufficient occlusal clearance and/or vertical prep wall, thereby making the preparation contraindicated for an all-ceramic restoration, an alternative material must be chosen. Inlay bridges, endosseous implants and root posts are other contraindications. This product is contraindicated for patients with a medical history of hypersensitivity (e.g., rash or skin inflammation) to this product, with poor oral hygiene, with bruxism, with insufficient dentin, and with hypoplasia or inappropriate preparation of the tooth to be crowned with a restoration.

Warning:

Known cross-reactions or interactions of this medical device with other medical products or material already present in the oral environment must be taken into consideration by the dentist when selecting this product.

Type/class of dental ceramic:

Type II/Class 5 (EN ISO 6872:2015)

Physical properties:

Coefficient of thermal expansion (25 - 500 °C): $10.5 \times 10^{-6} \text{K}^{-1}$

Precautions:


Processing the material will result in the release of dust that may cause irritation of the eyes, skin or respiratory passages. Keep product dust away from eyes and avoid any contact with mucosa. After use, wash your hands. When using, do not eat or drink, do not ingest, and do not inhale dust particles. Use local suction and suitable mouth/ face protection during grinding. Safety Data Sheets (SDS) may be obtained from <https://www.smartdentistrysolutions.com/>, or by calling 1.949.446.9383.

Adverse Effects:

We are not aware of any risks or adverse effects related to LayZir Disc. If properly processed and used, it is highly unlikely that this medical product will have any adverse effects. However, when using zirconia, there is a potential for reactions of the immune system (such as allergies) or localized paresthesia (such as an irritating taste or irritation of the oral mucosa). If you experience any adverse effect or reaction, please contact your dentist or physician immediately.

Operation Instructions:

Caution:

The LayZir Disc is to be placed in direction of the arrowhead (upside = occlusal side .

Make sure that following criteria are secured for any restoration.

➤ Thickness


Anterior region	Crown or bridge	$\geq 0.8 \text{ mm}$
	Veneer	$\geq 0.4 \text{ mm}$
Posterior region	Crown or bridge	$\geq 1.0 \text{ mm}$
	Inlay or onlay	$\geq 1.0 \text{ mm}$

➤ Connector cross-section area

Anterior region	$\geq 12 \text{ mm}^2$
Posterior region	$\geq 16 \text{ mm}^2$

- Do not use this product for fabrication of bridge restorations including 3- or more connecting pontics.
- When building up porcelain on a frame, build up and shape individually.
- Do not use ordinary cementation to connect restorations made of this product.
- Prepare a deep chamfer margin or a rounded shoulder margin. Round the corner angles of the incisal portion and the margin to eliminate sharp angles. In addition, be sure to achieve an axial plane angle of 5° – 15° .
- Do not process this product with any apparatus except computer-aided design/manufacturing units intended to be installed in dental laboratories.

- Do not apply a blast of alumina particles, glass beads or other materials to a workpiece that has not been subjected to final sintering.
- Do not prepare pits and fissures of molar teeth or bridge connections into an extremely sharp wedge shape.
- Include an annealing process of five minutes or longer in the pre-stain-firing heat treatment and the stain-firing cooling.
- Do not use significantly discolored working models.
- Dry milling is recommended.

Fix a disc according to operating instructions of the CAD/CAM system and enter the set value (look ). Start the system to cut and machine the disc.

Neither coolant nor compressed air should be used during processing. Please observe the instructions for the use of your milling machine, as well as the parameters of the CAD/CAM software. Please carefully separate the finished milled parts from the blanks using suitable tools. Then, thin the edges that have been thickened by the machine and remove the tapping.

Visual inspection:

Before the milled mounts are processed further, they must be inspected for the following faults: - Shiny areas on the surface (indicating a worn milling cutter) - Discoloration - Material spalling (due to the milling strategy and milling cutter) - Cracks - Faulty restorations must not be processed further.

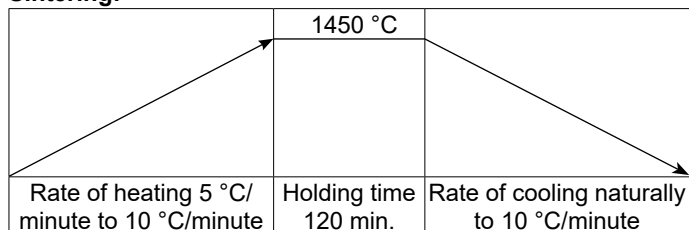
Final Sintering:

Sintering can take place in all common dental sintering furnaces that are approved for the sintering of restorations made of zirconium dioxide. Since zirconium dioxide is known to be a poor thermal conductor, it is recommended that you slowly heat the mounts to the required temperature (see sintering graph) and cool them down equally slowly.

Recommended Sinter-Program:

Increase temperature by 5 °C /minute to 10 °C /minute from room temperature to 1450 °C. Keep at 1450 °C for 120 minutes, and then cool from 1450 °C to room temperature decreasing the temperature by naturally to 10 °C /minute.

Sintering:



Further processing of the finally-sintered restorations:

IMPORTANT: The sintered units will only achieve their final color after the glaze firing. If possible, the sintered units should not be milled by hand. However, if this is unavoidable, only water-cooled diamond-fitted tools in correct working order may be used. Ideally, the interdental connection points should not be polished. In principle, the basal polishing of these points must always be avoided for stability reasons (predetermined breaking points). For abutments, sharp edges should be avoided and rounded, if possible.

When performing abutment preparation, avoid the following configurations; a deep shoulder, a jumping margin, a knife edge, a saw blade, a non-tapered abutment, an undercut, a guide groove, the formation of a retention hole, and the formation of a sharp corner angle.

Grinding:










In order to protect the antagonists (abrasion) and for material engineering reasons, ground occlusal contact points and surfaces must be either high-gloss polished after the try-in and/ or glaze-fired. Do not apply excessive force when performing grinding (do not apply an excessive load when grinding sintered restorations).

Cementation:

The interior surfaces of the restoration should obtain mechanical retention by means of blasting with 29.0–43.5 psi (0.2–0.3 MPa) -Particle size of Al₂O₃ 50–100 µm. Before the cement is applied internally, the blasted interior surface should be cleaned with alcohol. It is preferable to use self-adhesive and adhesive cementation with state-of-the-art dental technologies.

Material: ZrO₂ 3Y-TZP and 5Y-PSZ

Symbols glossary:

Symbol	Meaning	Symbol	Meaning
	Catalogue number		Batch code/number
	Use-by date		Caution
	Keep dry		Keep away from sunlight
	Consult instructions for use		
	Direction of a disc		Enlargement/ Shrinkage factor