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Controlled Medical Device - Zirconia Blank for Dental Milling and Machining

KZR-CAD Zirconia Laxio

[Contraindications and Prohibitions]

Do not use this product outside the scope of recommended indications, effects or efficacy.

Do not use this product on patients who have a history of allergy, such as irritation to this product.

Do not use this product on patients who exhibit bruxism/dental parafunction.

[Product Description]

[Intended purpose]

This device is a ceramic material used for CAD/CAM processing of dental restorations or prostheses.

[Indications

Fabrication of dental restorations such as inlay, onlay, veneers, crowns and bridges (up to 14 unit), etc.

[Intended users]

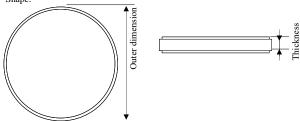
Dental professionals only: dentists and dental technicians

[Clinical benefit]

Repair a patient's teeth by replacing the damaged part of the teeth as a dental restoration.

[Shape, Composition and Principles]

Shape:



Outer dimension (φ): 98.5mm Thickness: 14, 18, 22 mm Shade: White, A1, A2, A3

Composition:

This product is a ceramic body formed by applying pressure to its main component, Zirconium Oxide, and then sintering it.

Principle

This product is a Zirconia Disc for producing dental restorations to be sintered after milling with use of computer-aided design and computer-aided manufacturing unit.

[Intended Use and Effects/Efficacy]

This product is a dental material designed for milling with use of computer-aided design and computer-aided manufacturing unit, enabling dental laboratories to produce a dental prosthesis made of ceramics.

[Instructions for Use]

(1) Preparation

Mount the disc according to the instruction manual of the computer-aided design and computer-aided manufacturing unit for dental laboratories (CAD/CAM system), and input the setting value.

(2) Milling

Mill the disc by following the instruction manual of the CAD/CAM system.

(3) Sintering

After milling, place it in a furnace and sinter according to the following program:

<Sintering Program>

	Heating	Heating	Holding	Cooling
Temperature (°C)	1,000	1,450	1,450	Cooling in
Time (hour)	2	4.5	2	furnace

(4) Shape correction

If needed, correct the shape with a diamond bur in accordance with normal practice.

(5) Build-up

Build up the zirconium oxide with porcelain in accordance with normal practice.

(6) Placement

Mount it on the restoration point in accordance with normal practice.

Technical Directions and Key Considerations

- (1) Prepare a rounded shoulder margin or a deep chamfer margin. Round the corner angles of the incisal portion and the margin to eliminate sharp angles. Aim for an axial plane angle between 5°-15°.
- (2) When preparing teeth, avoid deep shoulders, J-margins, knife edges, rough margins, non-tapered abutments, undercuts, guide grooves, the formation of retentive holes, and sharp corners.
- (3) Round the outer shape of the inlay/onlay cavity, ensuring the margins do not contact opposing teeth.
- (4) Maintain a minimum cavity isthmus of 1.5 mm for inlays/onlays.
- (5) Clean the fixing jig and fix the disc so that force is applied evenly. Excessive force may cause chipping.
- (6) Do not use a CAD/CAM system whose size does not conform to this product.
- (7) Design in accordance with the magnification rate indicated for this product.
- (8) Mill this product with a dry process.
- (9) Remove refuse on the frame thoroughly after milling.
- (10) The sintering temperatures and times given are intended as a general guide. However, Furnace conditions differ depending on the type and shape of the furnace. Test your electric furnace before actual use to confirm that the sintering temperature is appropriate.
- (11) When correcting the shape, use a diamond bur with careful attention to avoid chipping and cracking by local heating.
- (12) Use porcelain powder for zirconia.
- (13) When placing a dental restoration, conditioning is needed. Also, do not use an autoclave, as Zirconia oxide is subject to low-temperature hydrothermal deterioration.
- (14) When placing a dental restoration, use appropriate dental cement material.
- (15) Do not place this product in an ultraviolet curing unit.

(16) The minimum frame thickness should be designed based on the table below.

	Design	Anterior Region		Posterior Region	
Type		Axial surface/Margin	Incisal edge	Axial surface/Margin	Incisal edge
GR-A1	Crown Bridge	0.5 mm	0.7 mm	0.7 mm	1.0 mm
GR-A2 GR-A3	Inlay Onlay	-	=	0.7 mm	1.0 mm
GR-White	Veneer	0.5 mm	-	0.5 mm	-

(17) When creating a bridge, use the table below to guide the cross-sectional area of the connecting parts.

ì	Antorior	Anterior Region		Posterior Region	
	Allterior	Afficior Region		Posterior Region	
Type	Cross-sectional area of	Height of the	Cross-sectional area of	Height of the	
71	the connecting part	connecting part	the connecting part	connecting part	
GR-A1 GR-A2 GR-A3 GR-White	12mm ² or more	3.0 mm or more	16 mm ² or more	3.0 mm or more	

- (18) The number of pontics in a bridge should be limited to two consecutive teeth.
- (19) The number of extension pontics in a bridge should be limited to one tooth.

[Warning and Safety Instructions]

- 1) Important Precautions
- ① During the sintering process of this material, avoid direct contact with the fabricated product because of its high
- 2) When milling and polishing the sintered product, use a dust-removing device and an anti-dust mask to avoid inhaling
- ③ When milling and polishing the sintered product, wear safety goggles to protect the eyes.

(Disposal)

Dispose of this product in accordance with the law.

Storage and Expiry Date

[Storage Method]

- Store in a dry place indoors in its original packaging.
- Do not subject this product to strong impacts.
- · Keep out of reach of personnel other than dental staff.

[Package]

• Disc: x 1





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