Controlled Medical Device: Zirconia Blank for Dental Milling and Machining

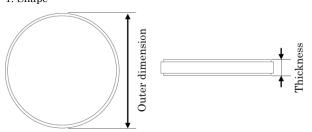
KZR-CAD Zirconia INSTRUCTIONS FOR USE

[Contraindications and Prohibitions]

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

[Shape, Composition and Principle]





Outer dimension φ : 98.5mm

Thickness: 14, 16, 18, 20, 22 and 25 mm

Shades: T, HT, A1, A2, A3, A3.5, SHT, SHT-A1, SHT-A2, SHT-A3, SHT-A3.5

[Constitution]

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

C.T.E. 10.9 ± 0.5 (50-500 degrees C) (T, HT, A1, A2, A3, A3.5) C.T.E. 10.2 ± 0.5 (50-500 degrees C) (SHT, SHT-A1, SHT-A2, SHT-A3, SHT-A3.5)

[Principle]

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

[Intended Use and Effect]

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

[Instructions for use]

- In accordance with the instruction manual of the computer-aided design and computer-aided manufacturing unit for dental laboratories (CAD/CAM system), mount a disc and input the setting values.
- (2) Milling process
- Follow the instruction manual of the CAD/CAM system to mill. (3) Sintering

After milling, place in the furnace and sinter; use the following program as a reference: <Sintering Program>

| Sintering Fregram | | | | | |
|-----------------------------|-------|-------|-------|------------|--|
| | Heat | Heat | Hold | Cool | |
| Temperature ($^{\circ}$ C) | 1,000 | 1,450 | 1,450 | Cooling | |
| Time (hour) | 2 | 4.5 | 2 | in furnace | |
| (4) Corrections to Shape | | | | | |

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

(5) Build up with porcelain for zirconium oxide in accordance with normal practice.

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

[Technical Directions and Points for Attention]

- (1) Only adequately certified personnel should handle this product.
- (2) Do not use this product outside the scope of recommended indications, effects or potency.
- (3) Do not use a CAD/CAM system whose size does not conform to this product.
- (4) Design in accordance with the magnification rate indicated for this product.
- (5) Mill this product with a dry process.
- (6) Remove refuse on the frame thoroughly after milling.
- (7) The sintering temperatures and times given are intended as a general guide.

Furnace conditions differ depending on the type and shape of furnace. Test your electrical furnace before actual use to confirm that the sintering temperature is appropriate.

- (8) When correcting the shape after forming, use diamond bur with careful attention not to cause chipping and cracking by local heating.
- (9) Use porcelain powder for Zirconia.
- (10) When placing dental restoration, conditioning is needed. Also, do not use autoclave, as Zirconia oxide is subject to low-temperature hydrothermal deterioration.
- (11) When placing dental restoration, use appropriate dental cement material.
- (12) Stop using this product immediately if any signs of allergy, such as irritation or rash, appears in patients. If symptoms persist, seek medical attention.
- (13) Do not place this product in an ultraviolet curing unit, etc.

[Precautions]

- (1) Important Basic Cautions
- During sintering, the fracture will be heated; do not touch directly.
- ② When milling and polishing sintered product, use a dust-removing device and anti-dust mask to avoid inhaling dust.
- (3) When milling and polishing sintered product, wear safety goggles to protect the eyes.

[Reference Information]

| (| 1) | Intended | Uses | of | Eε | ach | Shad | e | |
|---|----|----------|------|----|----|-----|------|---|--|
| Г | | | | | | 1 | | ~ | |

| Shade | Types & classification * | Intended Use |
|---|-----------------------------|---|
| T, HT, A1, A2, A3, A3.5 | ${ m II}~5$ | veneer, inlay, onlay, coping and crown for single to 14 unit bridge |
| SHT, SHT-A1, SHT-A2, SHT-A3, SHT-A3.5 | II 4 | veneer, inlay, onlay, coping and crown for single to 3 unit bridge |

*ISO6872: 2015

⁽²⁾ When designing frame, use the following guidelines on minimum thickness as a reference: Unit [mm]

| e int [inin] | | | | | |
|------------------|-----------|----------|------------|----------|--|
| | Anteriors | | Posteriors | | |
| Shade | Body | Incisal, | Body | Incisal, | |
| | | Occlusal | | Occlusal | |
| T, HT, | 0.5 | 0.5 | 0.5 | 0.5 | |
| A1, A2, A3, A3.5 | | | | | |
| SHT, SHT-A1, | 0.5 | 0.7 | 0.7 | 1.0 | |
| SHT-A2, | | | | | |
| SHT-A3, | | | | | |
| SHT-A3.5 | | | | | |
| | | | | | |

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(3) These are guidelines on sintering crowns for single to 8 unit bridges when using our sintering furnace "KZR Sinfer".

| | Heat | Heat | Hold | Cooling |
|-----------------------------|-------|-------|-------|---------------------|
| Temperature ($^{\circ}$ C) | 1,000 | 1,450 | 1,450 | 400 (in furnace) |
| Time (hour) | 2 | 4.5 | 2 | 1.5 |

[Storage and Expiry Date]

[Storage Method]

- Do not subject this product to strong impacts.
- $\boldsymbol{\cdot}$ Keep out of reach of personnel other than dental staff.

[Package]

• Disc: x 1



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YAMAKIN CO., LTD. 1090-3 Otani, Kamibun, Kagami-cho, Konan-shi, Kochi, 781-5451, Japan E-Mail : contact@yamakin-gold.co.jp

MT Promedt Consulting GmbH Altenhofstrasse 80, 66386 St. Ingbert, Germany Te1: +49 6894 581020 Fax: +49 6894 581021 E-Mail : info@mt-procons.com

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