

Controlled Medical Device: Zirconia Blank for Dental Milling and Machining

KZR-CAD NANOZR
INSTRUCTIONS FOR USE

【Contraindications and Prohibitions】

- Bruxism.
- Insufficient amount of hard tooth structure.
- Insufficient preparation results.
- Insufficient oral hygiene.
- More than two connected pontics in the area of the posterior teeth.
- Known intolerance to the constituents
- Caution when handled by children or pregnant women.

【Product Description】

1. Common name: Zirconia dental ceramics
2. Material type: Ce-TZP/Al₂O₃ nanocomposite ceramics
3. Dental ceramic type:
Type II, Class 5 according to EN ISO 6872: 2015

【Description of Device】

KZR-CAD NANOZR is zirconium oxide pre-sintered blocks for open CAD/CAM systems or manually operated systems. The blank is constructed mainly from zirconium oxide, cerium oxide and aluminum oxide. They are ideal for indications that require high strength and high toughness, such as posterior bridges.

KZR-CAD NANOZR is milled into the required frame shapes by typical milling systems used by dental technician. The milling frame must add approximately 17% to the original size, so as to compensate for shrinkage during the final sintering process. The exact shrinkage ratio or expansion factor is given according to the milling system used.

【Intended Purpose】

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

【Indication】

Fabrication of substructure ceramic for dental restoration or prosthetics.

【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.

【Technical Data】

1. Composition of the device
Zirconium oxide (ZrO₂) + Hafnium oxide (HfO₂) 67.9 wt%
Hafnium oxide (HfO₂) < 4.0 wt%
Cerium oxide (CeO₂) 10.6 wt%
Aluminum oxide (Al₂O₃) 21.5 wt%
2. Identified specifications (after sintered)
Biaxial flexural strength 1290 MPa
Fracture toughness K_{IC} (SEVNB) 8.62MPa√m
Density 5.52 g/cm³
Coefficient of expansion (25-500°C) 10.0±0.5x10⁻⁶/K

【Instructions for Use】

(1) Framework model and tooth preparation

Fabricate a working model with removable segments as usual. The directions of the different CAD/CAM systems regarding the plaster to be used must be observed.

*Important for die preparation:

- Check the radius of the incisal/occlusal edge on the prepared die (maxilla and mandible).
- The prepared incisal edge should be at least as thick as the diameter of the bur used in the cavity during the CAD/CAM process.

- If the incisal edge of the prepared die is thinner than the diameter of the bur, the incisal edge has to be blocked out accordingly.
- Also observe the information provided by the manufacturer of the CAD/CAM system regarding the die geometry.





(2) Material specific framework parameters

The restoration design is key to the success of durable all-ceramic restoration. The more attention is given to the design, the better the final results and clinical success will turn out to be. The following basic guidelines have to be observed.

- The KZR-CAD NANOZR material is the high-strength component of your restoration and must always be given a design that supports the overall shape and cusps.
- In large preparations and for veneered or partially veneered restorations, the excess available space must be compensated by the corresponding dimensions of the high strength and high toughness KZR-CAD NANOZR component and not by the pressed-on or layered-on materials.
- The design of the restoration generated by the software has to be individually adjusted, if necessary, in accordance with the clinical situation using the design tools.
- If possible, the connector design should be extended in the vertical direction, rather than in the horizontal direction.

The following minimum thickness has to be observed for the framework design with KZR-CAD NANOZR (after full-sintered): Please note: The minimum dimensions of the KZR-CAD NANOZR framework before full sintering must be larger by the shrinkage factor.

Minimum dimensions KZR-CAD NANOZR (full-sintered)

Anterior Region	Crowns	Splinted crowns	3-unit bridges	4-7-unit bridges with 2pontics	8-12-unit bridges with 2pontics	Cantilever bridges with 1pontic
Minimum framework dimensions	0.3 mm	0.3 mm	0.3 mm	0.3 mm	0.7 mm	0.7 mm
Connector Dimensions	—	≥3.0 mm 		≥6 mm ²	9 mm ²	12 mm ²
Posterior Region	Crowns	Splinted crowns	3-unit bridges	4-7-unit bridges with 2pontics	8-12-unit bridges with 2pontics	Cantilever bridges with 1pontic
Minimum framework dimensions	0.3 mm	0.3 mm	0.3 mm	0.3 mm	0.7 mm	0.7 mm
Connector dimensions	—	≥3.0 mm 		≥8 mm ²	12 mm ²	12 mm ²
		≥3.2 mm 		≥9 mm ²		
		≥2.5 mm 		≥9 mm ²		

(3) CAD/CAM manufacturing of framework

Since the KZR-CAD NANOZR framework shrink by approximately 17% during full-sintering, the shrinkage ratio of the respective batch, which is inscribed on the package label. The “Expansion” which is inscribed on the package label and product label is a magnification of when machining with CAM.

The shrinkage factor then ensures that the milled KZR-CAD NANOZR restorations demonstrate optimum accuracy of fit after full sintering. The milling tool should be use of with carbide milling cutters. Do not exceed the maximum amount of abrasive agent. The milling should be cleaned to avoid cross-contamination (e.g. milling dust, acid).

Contamination may result in deterioration of the frameworks during sintering.

***Magnification factor**

Magnification factor inscribed on the disc label.

(4) Finishing of framework

It is of critical importance to use the correct grinding instruments for finishing and adjusting KZR-CAD NANOZR. The following notice have to be observed.

- Non full sintered blanks are susceptible to damage and fracture. This fact has to be kept in mind during the entire working procedure.
- All adjustments by grinding should always be carried out while the framework is still in its non-full sintered stage, if possible, do not use water/oil cooling or contact media (e.g. occlusion spray)
- The non-full sintered framework must not be cleaned with ultrasonic on water bath or with a steam jet.
- Do not blast the framework with Al₂O₃ or glass polishing beads.

(5) Final sintering

Once the framework is completely dry, the sintering procedure can be carried out. During the sintering process, the framework will shrink to its final size.

The full sintering of the framework takes place according to the following:

- Room temperature to final temperature 1450°C
- Hold time at final temperature 2 hours
- Cooling down phase up to room temperature: approx. 5°C/min.

The following points should be observed.

- Always keep the sintering auxiliaries clean and free of dust so that no contamination may be sintered to the framework.
- Do not sintering in vacuum condition.

(6) Framework finishing after full sintering

After checking fitting accuracy such as contact points and occlusion, interior surfaces of the crown should be cleaned by corundum jets or other applicable means such as subsequent evaporation.

(7) Veneering ceramic

KZR-CAD NANOZR is suitable for veneering with conventional zirconium oxide veneering ceramics. The thermal expansion coefficient of KZR-CAD NANOZR can be gathered from the technical data.

[Technical Directions and Points for Attention]

- 1) Round the corner angles of the incisal portion and the margin using a rounded shoulder margin or a deep chamfer margin to eliminate sharp angles. In addition, be sure to achieve an axial plane angle of 5°-15°.
- 2) When preparing teeth, avoid the following shape margin: deep shoulders, J-margins, knife edges, rough margins, non-tapered abutments, undercuts, guide grooves, the formation of retentive holes, and sharp corners.
- 3) Clean the fixing jig and fix the disc so that force is applied evenly. If too much force is applied when fixing, the disc may chip.
- 4) Do not use with dental CAD/CAM machines whose size is not compatible with this material.
- 5) Dry milling is recommended.
- 6) The sintering temperature and hold time are only guidelines, and the sintering condition varies depending on the type and shape of the furnace. Therefore, perform a test firing in the electric furnace used to confirm that the sintering temperature is appropriate before using it.
- 7) When morphological modification of the post-formed restoration is carried out, care should be taken to avoid fracture/breakage due to excessive local heating, and a diamond bar or similar tool

should be used.

- 8) Do not place the product in a UV irradiator
- 9) Limit the number of pontics in the bridge to two in a row.
- 10) This product shall not be used for bridges containing extended pontics.

[Warning and Safety Instruction]

When processing, please use personal protective clothing (dust mask, protective goggles, protective glove, etc.)

Users with a history of hypersensitivity such as rashes or dermatitis to this or similar products should avoid direct contact. Patients or surgeons who experience hypersensitivity symptoms such as rashes or dermatitis as a result of using this product should discontinue use and seek medical attention immediately.

[Guarantee/Disclaimer Clause]

Recommendations regarding the application technique, whether they are given orally, in writing or in the course of practical instruction, should be regarded as guidelines. Our products are subject to ongoing development.

We therefore reserve the right to make changes in handling and composition.

Do not use KZR-CAD NANOZR excluding the dental intended indications.

[Disposal]

When discarding, please follow the laws.

[Storage and Expiry Date]

[Storage Method]

- Store in a dry indoor place in its original packaging.

[Package]

- Disc x 1

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