



Instructions for Use

Rev: 2020, DEC
Version A

⚠ Do not discard instructions during product use

Please read carefully before using the blank (made of zirconium dioxide) out of the package. The instructions contain important information that is essential to ensure both the accurate processing and the safety of patients and users.

Grand ML™ Dental Zirconia Multi-Layered Pre-shaded Blank product should be handled by professional dental technicians, fit and adjusted by dental specialists and follow doctor's instructions.

The instructions should be followed very carefully to avoid any loss of aesthetics, fit, durability or overall quality.

1. Product Name

Grand ML™ Dental Zirconia Multi-Layered Pre-shaded Blank

2. Indications for use:

Dental Zirconia Multilayered Pre-shaded Blanks are used for dental restoration using different CAD/CAM or manual milling machines. All Blanks are processed through dental laboratories or by dental professionals.

- ✓ intended for four units bridge with two pontics, two units cantilevered bridge with one pontic
- ✓ intended for use in implant-supported fixed restorations involving four units with two pontics
- ✓ intended for use in final restoration, cores and substructures

3. Contradictions:

- cores and substructure of molar restoration for bruxism is contraindicated
- If there is an insufficient occlusal clearance and/or vertical prep wall, making the preparation unsuitable for an all-ceramic restoration, an alternative material must be used.

4. Precautions:

⚠ Warning:

When using this product the dentist should be aware of possible interaction/reaction between this medical product and other products already in place in the patient's mouth.

⚠ General Handling:

Grand ML™ Dental Zirconia Multi-Layered Pre-shaded Blank are supplied in a pre-sintered white-fired condition. It has limited stability and strength and residual porosity. Therefore these blanks must be handled with care.

Inspect each product for damages and do not use chipped/cracked Blanks/Discs for the production of dental restorations.

Store Grand ML™ Dental Zirconia Multi-Layered Pre-shaded Blank in their original packaging in a cool and dry place, at a temperature between 10°C– 50°C. The blanks must not be subjected to impact or vibration.

Avoid contamination! Make sure restoration is only handled with dry and clean hands/gloves and it under no circumstances contaminated with liquids.

⚠ Danger

The processing of the blanks and sintered restorations produces dust, which might harm the lungs as well as irritate the eyes and skin. Therefore processing may only be done provided that the extractor system works correctly as well as wearing safety glasses and protective masks.

Please forward the above information to the dental professional as well.

Please also note the instructions for use and safety data sheets.

5. Physical Characteristics

Classification – Type II, Class 6

| | |
|---|--|
| Coefficient of Thermal Expansion (CTE) - (25-500°C) | 10.5±1.0×10 ⁻⁶ ·K ⁻¹ |
| Flexural Strength | > 1100 MPa |
| Density after Sintering | 6.08 ±0.01 g/cm ³ |
| 3-point flexural strength after sintering | >1100 (Av.) MPa |
| Accelerated aging surface monoclinic phase content | <15% |
| Chemical solubility after sintering | <100 ug/cm ² |
| Cytotoxicity test | Level 0 |
| Radioactivity after sintering | <0.1 Bq/g |
| Sintering Temperature | 1450 - 1580°C |

***Sintering oven must be collaborated to get ideal temperature

6. Chemical Composition

| | |
|--------------------------------|-------|
| Nanometer zirconia powder | >98% |
| Fe ₂ O ₃ | <0.3% |
| Pr ₂ O ₃ | <0.2% |
| Er ₂ O ₃ | <1.0% |
| Other oxide | <0.5% |



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7. Designing

Failure to observe the wall and connector thickness recommendations may result in a fracture of the final restoration. Set the required data in CAM software and make sure to reserve 2-4 mm for Incisal area (1st layer)

| Designing Guidance | | | |
|--|--|---------------------------------------|-----------------------|
| Drill Compensation | | Must be milled from a solid structure | |
| Recommended Wall and Connector Thickness | | Single Coping | Bridge |
| Anterior | Wall Thickness (substructure) | | |
| | Circular | ≥ 0.5 mm | ≥ 0.5 mm |
| | Incisal / Occlusal | ≥ 0.7 mm | ≥ 0.7 mm |
| | Connector Dimensions (substructure) | | |
| | 3-unit bridge | --- | ≥ 7.0 mm ² |
| | 4-unit & more (bridge) | --- | ≥ 9.0 mm ² |
| Posterior | Connector Dimensions (full contour) | | |
| | 3-unit bridge | --- | ≥ 7.0 mm ² |
| | 4-unit & more (bridge) | --- | ≥ 9.0 mm ² |
| | Wall Thickness (substructure) | | |
| | Circular | ≥ 0.5 mm | ≥ 0.9 mm |
| | Incisal / Occlusal | ≥ 0.7 mm | ≥ 0.9 mm |
| Posterior | Connector Dimensions (substructure & full contour) | | |
| | 3-unit bridge | --- | ≥ 9 mm ² |
| | 4-unit & more (bridge) | --- | ≥ 12 mm ² |
| | Cantilever | --- | ≥ 12 mm ² |

8. Milling

- ✓ Choose the suitable shade of Grand ML™ Dental Zirconia Multi-Layered Pre-shaded Blanks.
- ✓ Fix the zirconia blank in the specific clamping device.
- ✓ After the restorations have been digitally designed, program your milling machine and enter the enlargement factor EF (please see the blank). The mill operator should refer to the operating instructions for the applicable milling system used for the specified programming method for input of the EF. The specific EF is located on the Grand ML™ Dental Zirconia Multi-Layered Pre-shaded Blank.
- ✓ Start the milling process.

9. Sintering

Once milled, all Grand ML™ Dental Zirconia understructures and crowns must go through a final sintering cycle prior to finishing and porcelain application.

- ✓ Remove milled crown or bridge from blank and pre-trim with special tools.
- ✓ Remove any residual dust from the crown or bridge with brush and air gun.
- ✓ Use the coloring/shading technique if needed.
- ✓ Place the restorations in a sintering zirconia tray in the sintering oven.

⚠ **Please note that:** Sintering oven must be collaborated!

- ✓ Program your sintering oven in order to achieve the recommended temperatures according to the Sintering Temperature Chart below.
- ✓ For proper sintering ensure that the oven reaches 1530 °C and holds at this temperature for 2.5 hours.
- ✓ Allow the oven to cool sufficiently in order to safely remove the restorations.

⚠ Do not open the furnace before it cools down completely and it is safe to remove the restorations.

Sinter instructions:

| Units\Rate | Ramp Temp (°C / h) | T. max (°C) | Dwell Time (h) | Cooling |
|------------|--------------------|-------------|----------------|-----------------|
| Crowns | 600 | 1450-1550 | 1-2 | Natural cooling |
| Bridges | 300 | 1450-1550 | 1-3 | |



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Standard Cycle:

| Stage | Program | Rate / Minute / Temperature °C |
|-------|-----------------------|--------------------------------|
| 1 | Heat Rate(RT-500) | 2.5°C / min |
| 2 | Heat Rate (500-1200) | 8°C / min |
| 3 | Hold Time | 30 minutes |
| 4 | Heat Rate (1200-1300) | 2°C / min |
| 5 | Heat Rate (1300-FT) | 4°C / min |
| 6 | Hold Time | 2 hours |
| 7 | Final Temperature | 1530°C |
| 8 | Cooling Rate(FT-800) | 8°C / min |
| 9 | Cooling Rate(800-RT) | Natural |

10. Adjusting the Sintered Restorations

- ✓ Check crown or bridge on working model for fitting.
- ✓ If necessary to trim, use low-pressure grinding instruments/cool water with grinder and polisher is recommended.
- ✓ Carefully inspect the product to make sure that there are no cracks or chips.
- ✓ Clean with brush using water.
- ✓ Choose porcelain & glaze to finish the restoration – Send the restoration for the try-in if necessary.
(Use zirconia-compatible porcelain, follow the porcelain manufacturer's process for proper application).

11. Cementation

The dental professional should use resin-reinforced glass ionomers, resin cements or self-adhesive resin cement-to-cement Grand ML™ Dental Zirconia Multi-Layered restoration.

12. Storage and Shelf Life

Store Grand ML™ Dental Zirconia Multi-Layered Pre-shaded Blank in their original packaging in a cool and dry place, at room temperature, away from dust and contamination. The blanks must not be subjected to impact or vibration.

Shelf life of the Grand ML™ Dental Zirconia Multi-Layered Pre-shaded Blank is 5-years. The product is not expected to degrade during this time.

13. Safety Instruction

1. Avoid collision with hard material, avoid squeezing or shaking.
2. Don't apply to patient before the material is fully sintered.
3. This product should only be handled by dental specialist.
4. Wear suitable face mask to prevent fine dust inhalation.

NOTE: The product shall be used only by trained personnel. The manufacturer is not liable for any erroneous results, since we have no control if this instruction is properly followed or if the product is appropriately used. Any claims for damages therefore shall be limited exclusively to the commercial value of our products.

Please make sure that the dental professional has received all of the necessary information for the use of the product.

Medical Device Adverse Event: So far there is no medical device adverse event on this product.

Disposal: The material is not hazardous to the environment.

14. Questions / Comments

For questions and/or comments, MSDS or for further instructions regarding the use of this product, please contact **Medisco Inc.** at +1 877-922-2622 or email by Email: mediscoinc@gmail.com

15. Manufacturer

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Use-by date



Date of manufacture



Non-Sterile