



Instructions for Use

Rev: 2022.Feb
Version A

Instructions for use - Grand 5D ML™ – Dental Zirconia Multilayer

⚠ 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 5D ML™ Dental Zirconia Multi-Layer 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 Description

Product Name: Grand 5D ML™ Dental Zirconia Multi-Layer Blank .

2. Intended use:

Dental Zirconia Blanks and Dental Zirconia Blanks 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 cores and substructure of molar restoration for bruxism is contraindicated

3. 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.
- 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.

4. 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%
Coefficient of Thermal Expansion (CTE) - (25-500°C)	10.5±1.0×10 ⁻⁶ ·K ⁻¹

5. Instructions for use:

1. Fix the zirconia blank in the specific clamping device.
2. Start the milling process.
3. Remove milled crown or bridge from blank and pre-trim with diamond disc.
4. Remove the dust from the crown or bridge with air gun.
5. Color the crown or bridge with coloring liquid, Final-dry frame under infrared lamp (see manual for coloring liquid).
6. Load into furnace.
7. Select sintering program and start sintering (see sinter instructions).
8. Remove sintered crown or bridge from furnace after the furnace temperature drop to room temperature.
9. Check crown or bridge on working model for sitting and margin fit. Trim with grinder and polisher if required.
10. Clean with brush using water. Do not steam-clean.
11. Choose glaze to finish the restoration.
12. Now the restoration is ready for the try-in.

6. Shelf Period

5-years is an estimated replacement time. The product is not expected to degrade during this time period.

7. Storage

1. Keep container dry.
2. Store at room temperature.

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 dentist has received all of the necessary information for the correct use of the product.

8. Medical Device Adverse Event

So far there is no medical device adverse event on this product.

⚠ **Cautions:** Federal Law restricts this device to sale by or on the order of a dentist.



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9. Contradictions:

Not found.

10. Safety Instruction

1. Avoid collision with hard material, avoid squeezing or shaking.
2. Do not 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.

11. Disposal

The material is not hazardous to the environment.

12. Sinter Instructions

Once milled, all Grand 5D 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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Please make sure that the dental professional has received all of the necessary information for the use of the product.

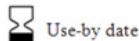
13. Questions / Comments

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

14. Manufacturer

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EC REP



Batch code

Date of manufacture

Non-Sterile