

# DD medical zirconia



**DE** Gebrauchsanweisung, **EN** Instructions for Use, **FR** Notice d'utilisation, **IT** Istruzioni per l'uso, **ES** Instrucciones de uso, **NL** Gebruiksaanwijzing, **EL** Οδηγίες χρήσης για το, **PT** Instruções de utilização, **TR** Kullanım talimatı, **RU** Инструкция по применению, **SV** Bruksanvisning, **ET** Kasutusjuhend, **DA** Brugsanvisning, **NO** Bruksanvisning, **FI** Käyttöohje, **IS** Notkunarleiðbeiningar, **PL** Instrukcja używania, **CS** Návod k použití skenovacího tělíska, **HU** Használati útmutató, **RO** Instrucțiuni de utilizare, **SK** Návod na použitie, **BG** Инструкция за употреба, **SR** Упутство за употребу, **FA** راهنمای استفاده از, **AR** دليل استخدام, **ZH** 使用说明书, **KO** 사용 설명서, **HR** Upute za uporabu, **GA** Treoracha úsáide, **LV** lietošanas pamācība, **LT** Naudojimo instrukcija, **SL** Navodila za uporabo, **MT** Struzzjonijiet għall-użu, **JA** 取扱説明書, **BS** Uputstvo za upotrebu

## 1. Product description

Dental Direkt zirconium dioxide milling blanks are made of yttrium-stabilized zirconium dioxide (Y-TZP) for dental application of type II, class 4 (DD cubeX<sup>2</sup>®) or class 5 (DD cube ONE® / DD Bio ZX<sup>2</sup> / DD Bio Z) in accordance with DIN EN ISO 6872, and they fulfill their material-specific requirements after specified final sintering.

Depending on material group, Dental Direkt zirconium dioxide exhibits different levels of translucency. To enable the dentist to provide each patient with customized and aesthetic restorations, Dental Direkt zirconium dioxide milling blanks are available uncolored and precolored.

## 2. Intended purpose

Dental Direkt zirconium dioxide milling blanks are intended for the fabrication of fixed restorations for long-term use.

## 3. Indication

### DD Bio Z (color)

*DD Bio ZW iso (color); DD Bio ZS*

For fabrication of reduced crowns, reduced bridges<sup>\*/\*\*</sup>, hybrid abutments, bars and cantilever bridges<sup>\*\*\*</sup> as anterior and posterior restorations.

### DD Bio ZX<sup>2</sup> (color)

For fabrication of monolithic crowns and bridges<sup>\*/\*\*</sup> in the posterior region, reduced crowns and bridges<sup>\*/\*\*</sup> hybrid abutments, hybrid abutment crowns, bars and cantilever bridges<sup>\*\*\*</sup> as anterior and posterior restorations.

### DD cube ONE® (ML)

For fabrication of veneers, inlays, onlays, reduced crowns, monolithic crowns, hybrid abutment crowns, monolithic and reduced bridges<sup>\*/\*\*</sup> and cantilever bridges<sup>\*\*\*</sup> as anterior and posterior restorations.

### DD cubeX<sup>2</sup>® (ML)

For fabrication of veneers, inlays, onlays, reduced crowns, monolithic crowns, hybrid abutment crowns, monolithic and reduced bridges (up to 3-unit) as anterior and posterior restorations.

\* Up to two adjacent pontics.

\*\* In Canada the indication for bridges is limited to a maximum of six units with up to two pontics.

\*\*\* Cantilever pontics must not be dimensioned longer than 2/3 of the load-bearing abutment crown from mesial to distal.

## 4. Contraindications

Parafunction, insufficient space, unsuitable preparation, insufficient dental hard tissue, intolerance to components and inadequate oral hygiene.

## 5. Intended users

Dental Direkt zirconium dioxide milling blanks must only be used by dentists and dental technicians in compliance with the procedures in the Instructions for Use.

## 6. Intended patient group

Fixed restorations using Dental Direkt zirconium dioxide milling blanks are suitable for the permanent dentition in adult patients of any gender and nationality.

## 7. Handling and storage








Before using the material for the first time, check that the packaging and the blank itself are intact. Check whether the contents of the packaging correspond to the declaration on the label. Never use damaged material. Store the blanks only in the original packaging and in a cool, dry place. Avoid vibration, contamination and all contact with fluids.

## 8. Instructions for Use in the laboratory

### 8.1 Processing / construction

Dental Direkt zirconium dioxide is a sensitive, high-performance ceramic and should be processed with special care, including in the partially sintered state!

The following construction parameters must always be considered when fabricating zirconium dioxide constructions:

			DD Bio Z (color), DD Bio ZX <sup>2</sup> (color), DD cube ONE® (ML)		DD cubeX <sup>2</sup> ® (ML)	
Indication			Minimum wall thickness [mm]	Connector cross-section [mm <sup>2</sup> ]	Minimum wall thickness [mm]	Connector cross-section [mm <sup>2</sup> ]
Single crown		incisal	0.5	–	0.5	–
		occlusal	0.5		0.5	
		circular	0.5		0.5	
Telescopic		incisal	0.7	–	0.7	–
		occlusal	0.7		0.7	
		circular	0.5		0.5	
3-unit anterior bridge		incisal	0.5	> 7	0.8	> 10
		circular	0.5		0.8	
3-unit posterior bridge		occlusal	0.7	> 9	0.8	> 12
		circular	0.5		0.8	
Anterior bridge with 4 or more units		incisal	0.7	> 9		
		circular	0.6			
Posterior bridge with 4 or more units		occlusal	0.8	> 12		
		circular	0.7			
Cantilever bridge		occlusal	0.8	> 12		
		circular	0.7			

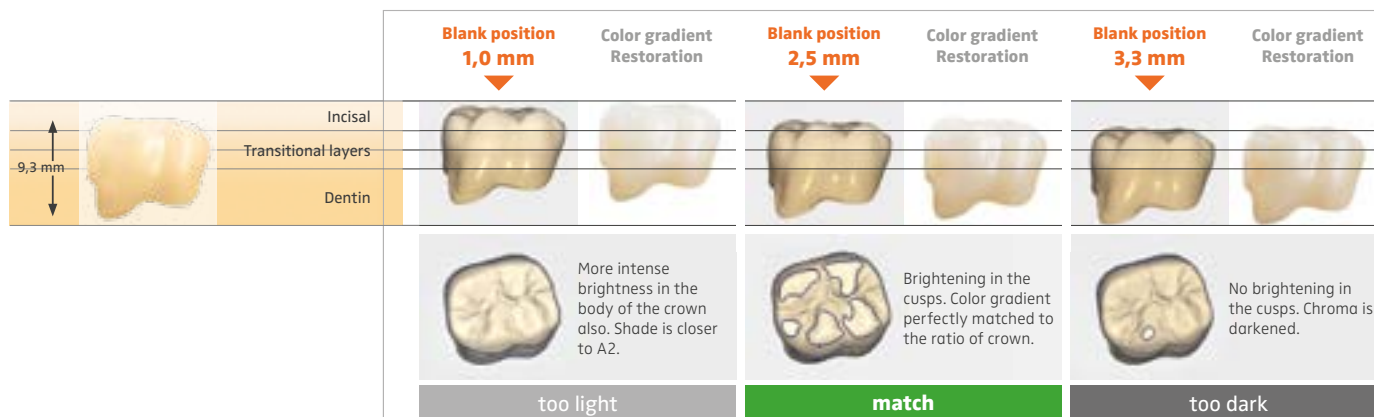
Please note that the connector cross-section may have to be of larger dimensions, depending on the construction. For example, in the case of long-span posterior bridges (made of DD Bio Z, DD Bio ZX<sup>2</sup> or DD cube ONE®), the connector cross-section between two pontics should be increased to at least 20 mm<sup>2</sup> if possible. The aim is to achieve an oval connector cross-section; the height of the connector is decisive for stability. The design should avoid sharp edges and acute angles. Frameworks for ceramic veneering should be designed in such a way that they support the veneering ceramic in the area of the cusps and enable an even layer thickness. Chamfer or shoulder preparation is recommended.

#### Nesting recommendation:

For the design and positioning of the construction in the multilayer blank (DD cubeX<sup>2</sup>® ML and DD cube ONE® ML), the individual layer thicknesses can be taken from the following nesting table:

Blank height (mm)	DD cube ONE® ML				DD cubeX <sup>2</sup> ® ML			
	Layers 1+2: Incisal (mm / %)	Layer 3: Intermediate layer (mm / %)	Layer 4: Intermediate layer (mm / %)	Layer 5: Dentin (mm / %)	Layers 1+2: Incisal (mm / %)	Layer 3: Intermediate layer (mm / %)	Layer 4: Intermediate layer (mm / %)	Layer 5: Dentin (mm / %)
14 mm	3.5 / 24.9	2.1 / 15	2.1 / 15	6.3 / 45.1	3.5 / 24.9	2.1 / 15	2.1 / 15	6.3 / 45.1
18 mm	3.5 / 19.4	2.1 / 11.7	2.1 / 11.7	10.3 / 57.2	3.5 / 19.4	2.1 / 11.7	2.1 / 11.7	10.3 / 57.2
22 mm	3.5 / 15.9	2.1 / 9.6	2.1 / 9.6	14.3 / 64.9	3.5 / 15.9	2.1 / 9.6	2.1 / 9.6	14.3 / 64.9
25 mm	3.5 / 14	2.1 / 8.4	3.3 / 13.2	16.1 / 64.4				

You will achieve the best color match by individually positioning the restoration in the blank (match). Depending on the height of the restoration, the positioning of the incisal, intermediate layer and dentin can be individually adjusted in the DD smart CAM 2.0 software to achieve the best possible color gradient.

**Example of optimum nesting:****Indication:** Crown, tooth 46 (lower right first molar), shade A3**Blank:** DD cube ONE® ML, height 14 mm, color A3**CAM Software:** DD smart CAM 2.0**8.2 Milling, sintering and finishing**

The blanks must only be processed with the milling systems intended for this purpose. The specifications of the machine manufacturer must be observed.

For the highest accuracy of fit, the specific magnification factor is printed on the side of the blank (disc) or on the surface of the blank (block) as the code to be used.

After the milling process, the frameworks must be checked for any visual defects. Damaged or contaminated frameworks must not be processed any further. The white frameworks can be colored with DD Basic Shade, DD Pro Shade C, DD Pro Shade Z and DD Art Elements effect colors, and constructions made of pre-colored zirconium oxide can be customized with DD Art Elements before sintering to full density (observe separate Instructions for Use).



**Please refer to our separate sintering instructions!**

**Sintering cycle with normal furnace filling without cover:**

- ↑ Heating to 900°C (8°C / min.),
- 30 mins hold time at 900°C,
- ↑ Heating to final temp. 1450°C (3°C / min.),
- 120 mins hold time at 1450 °C,
- ↓ Cooling to at least 200°C (10°C / min.)

During finishing, avoid additional mechanical effects on the outer surface, such as blasting or grinding. If adjustments to the framework are necessary, they must only be carried out using a water-cooled tool. Avoid heat build-up at all times, as this can cause cracks in the material. Work with very low pressure and with sharp, diamond grinding wheels. Areas that are under tensile load in clinical use (e.g. connectors) must not be finished. Do not separate at interdental connection sites. Always avoid sharp edges.

**Caution:** Avoid inhalation of milling dust during processing. Wear gloves, protective goggles and a face mask to avoid skin irritation.

### 8.3 Ceramic veneering

Please use a veneering ceramic with a suitable CTE and observe the manufacturer's recommendation. Slowing down the rate of heating and cooling for heavier constructions is strongly recommended.

Weight per unit [g]	< 1	2	3	> 4
Heating and cooling rate [°C/min]	55	45	35	25

### 9. Instructions for Use in the dental practice

For luting, we recommend conventional cementing with zinc oxide phosphate cements or glass ionomer cements. Luting composites can also be used. Ensure sufficient retention and a minimum stump height of 3 mm. For additional cleaning, the inner surface being bonded may be blasted with aluminum oxide (50 µm at 1-2 bar).

Ensure that the surface is free of grease. Temporary luting is not recommended!

### 10. Material

#### Chemical composition [Weight %]

	DD Bio Z (color)	DD Bio ZX <sup>2</sup> (color)	DD cube ONE® (ML)	DD cubeX <sup>2</sup> ® (ML)
ZrO <sub>2</sub> + HfO <sub>2</sub> + Y <sub>2</sub> O <sub>3</sub>	≥ 99.0	≥ 99.0	≥ 99.0	≥ 99.0
Y <sub>2</sub> O <sub>3</sub>	< 6	< 6	< 8	≤ 10
Al <sub>2</sub> O <sub>3</sub>	< 0.5	≤ 0.15	< 0.15	≤ 0.01
Other oxides	< 1	< 1	< 1	< 1

#### Physical properties

		DD Bio Z (color)	DD Bio ZX <sup>2</sup> (color)	DD cube ONE® (ML)	DD cubeX <sup>2</sup> ® (ML)
CTE (25-500°C)	[10 <sup>-6</sup> K <sup>-1</sup> ]	~ 10.8	~ 10.6	~ 10.8	~ 10.2
Chem. solubility	[µm/cm <sup>2</sup> ]	≤ 9.1	≤ 11	≤ 15.3	≤ 2.9
Fracture toughness (KIC)	[MPa√m]	> 9.5	> 8	> 10	4.0
Flexural strength*	[MPa]	1150 ± 200	1150 ± 150	1200 ± 150	700 ± 100

\* measured according to DIN EN ISO 6872

### 11. Possible side effects and interactions

No known side effects or interactions.

### 12. Disposal

In compliance with local regulations. Non-contaminated and completely emptied packaging can be recycled.

**Please note:** Observe the information in the latest version of the safety data sheet.

### 13. Reporting incidents

Any serious incident that occurs in connection with the product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is located.

**Please note:** The safety and clinical performance summary report can be requested at [info@dentaldirekt.de](mailto:info@dentaldirekt.de).

We are continuously developing and enhancing our devices, and therefore reserve the right to make changes. The latest version of the Instructions for Use can be found on our website at:

[www.dentaldirekt.de/en/IFU](http://www.dentaldirekt.de/en/IFU)

This version replaces all previous versions.

**Explanation of symbols:**

Manufacturer



Date of manufacture



Use before



Batch code



Catalog number



Keep dry



Height



Content (Quantity)

Consult electronic Instructions for Use  
[www.dentaldirekt.de/en/IFU](http://www.dentaldirekt.de/en/IFU)Caution: Under U.S. federal law, the device may only  
be sold by or on behalf of a dentist.

Medical device



Unique device identification