

1. Product description

The Nacera® Pearl Natural zirconium dioxide milling blank made of yttrium-stabilized zirconium dioxide (5Y-TZP + 3Y-TZP) is a hybridlayer and is suitable for dental application of type II, class 5 in accordance with DIN EN ISO 6872, and they fulfill their material-specific requirements after specified final sintering.

2. Intended purpose

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

3. Indication

For fabrication of veneers, inlays, onlays, anatomically reduced crowns and bridges*/**, fully anatomical (monolithic) crowns and bridges*/**, hybrid abutment crowns and cantilever bridges*** 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 and contamination. Ensure that the blank and the frameworks made from it are only handled with dry and clean hands or gloves and that they are under no circumstances contaminated with fluids (such as adhesives or marker pens).

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:

			Nacera® Pearl Natural	
Indication			Minimum wall thickness [mm]	Connector cross-section [mm ²]
Single crown		incisal	0,4	–
		occlusal	0,4	
		circular	0,4	
3-unit anterior bridge		incisal	0,5	> 6*
		circular	0,5	
3-unit posterior bridge		occlusal	0,5	> 9*
		circular	0,5	
Anterior bridge with 4 or more units		incisal	0,5	> 10*
		circular	0,5	
Posterior bridge with 4 or more units		occlusal	0,5	> 16*
		circular	0,5	
Connector cross-section to cantilever unit		occlusal	0,7	> 12*
		circular	0,7	

*Do not position the connector cross-section in the incisal layer but as far as possible towards the body layer!

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 connector cross-section between two pontics should be increased to at least 20 mm² 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, the individual layer thicknesses can be taken from the following nesting table:

	Nacera® Pearl Natural			
Blank height (mm)	Layers 1 + 2: Incisal layer (mm / %)	Layer 3: Intermediate layer (mm / %)	Layer 4: Intermediate layer (mm / %)	Layer 5: Body layer cervical (mm / %)
16 mm	4/25	4/25	4/25	4/25
20 mm	4/20	4/20	4/20	8/40
25 mm	4/16	4/16	4/16	13/52

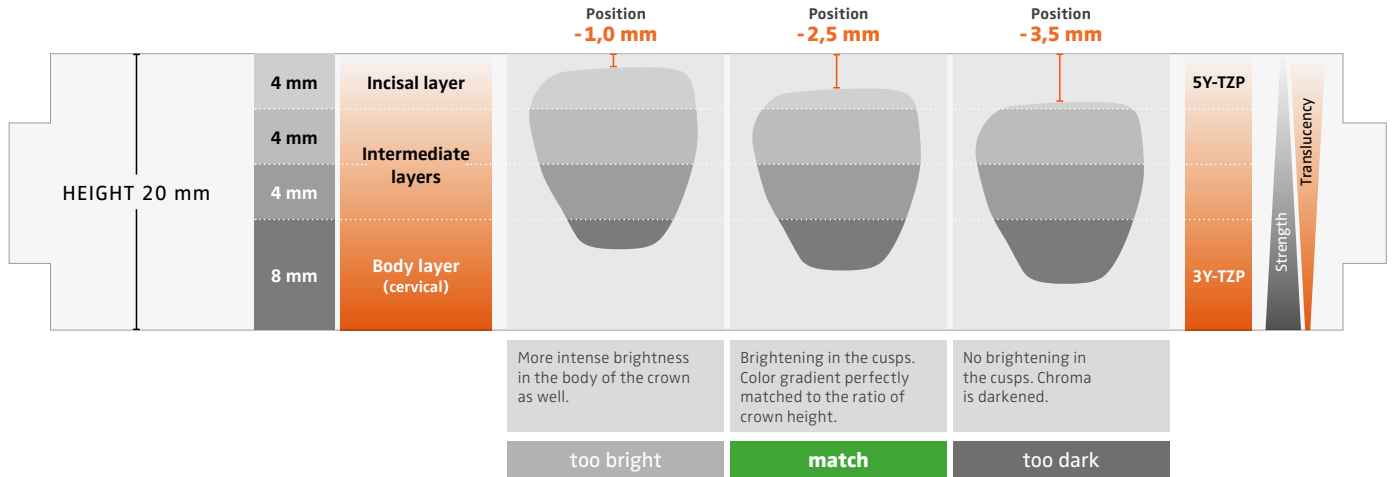
You will achieve the best color match by individually positioning the restoration in the blank (match). Depending on the height of the restoration, the positioning of the incisal, intermediate and body layer can be individually adjusted in the DD smart CAM 2.0 software to achieve the best possible color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



Please refer to our separate nesting recommendation!

Example of optimum CAM-nesting:

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.

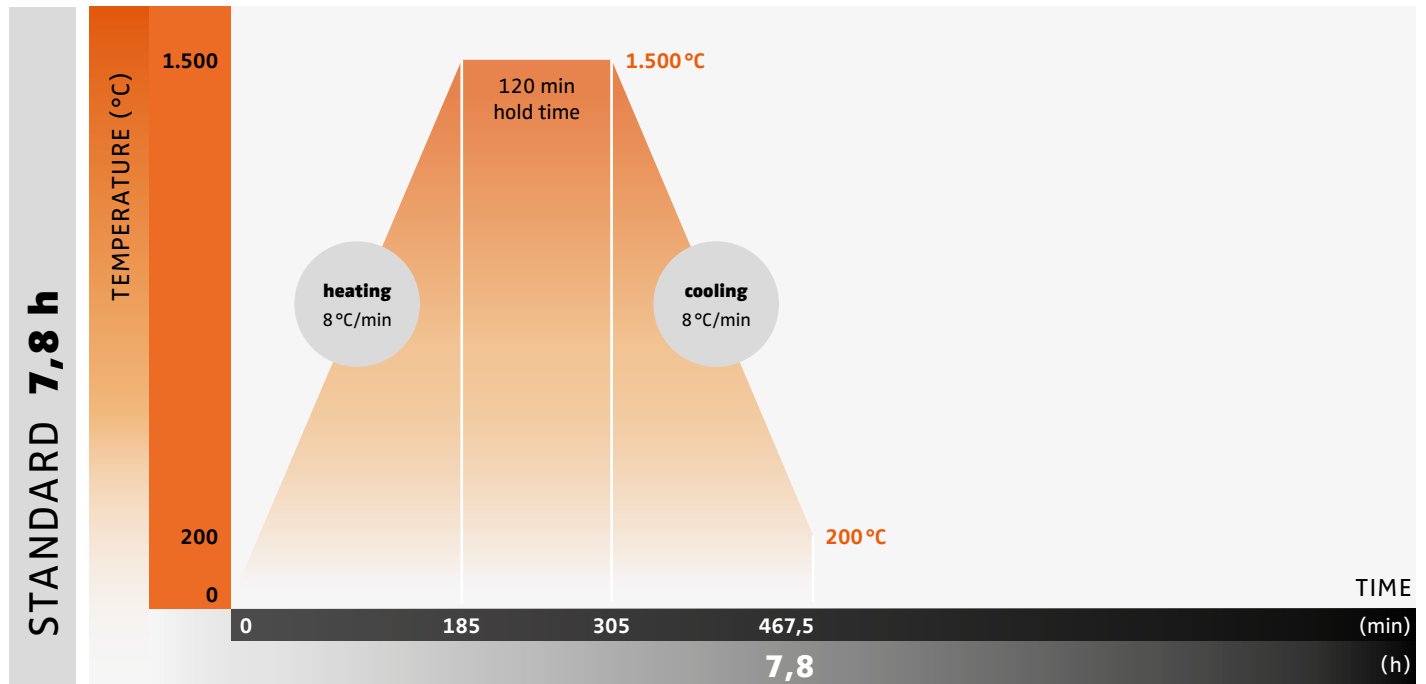
For the highest accuracy of fit, the specific magnification factor is printed on the side of the blank as the code to be used.

After the milling process, the frameworks must be checked for any visual defects (e.g. material spalling or shiny areas on the surface due to worn milling cutters). Damaged or contaminated frameworks must not be processed any further. Constructions made of pre-colored zirconium oxide can be customized with DD Art Elements (with exception: DD Art Elements „purple“) 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:



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: The processing of a blank and finally-sintered frameworks creates dust which might damage the lungs as well as irritating the eyes and skin. Therefore, 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 coefficient of thermal expansion (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

For individualising the restoration, painting techniques as well as cut-back and layering techniques, or a combination of both, are suitable.

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. %]

		Nacera® Pearl Natural
ZrO ₂ + HfO ₂ + Y ₂ O ₃		≥ 99,0
Y ₂ O ₃		< 9
Al ₂ O ₃		≤ 0,1
Other oxides		< 1

Physical properties

		Nacera® Pearl Natural
CTE (25-500°C)	[10-6 K-1]	~10,7
Chem. solubility	[µg/cm ²]	≤ 17,5
Fracture toughness* (KIC)	[MPa√m]	> 5,5
Flexural strength*	[MPa]	1.050 ± 150

* measured according to DIN EN ISO 6872 in the body layer

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.

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

This version replaces all previous versions.