

※※ CAUTION ※※

U.S. Federal law restricts this device to sale by or on the order of a physician

1. Material Properties

Property	Value
CTE (100-550°C / 212 - 1022°F)	10.7 ± 0.5 (10 <sup>-6</sup> K <sup>-1</sup> )
Flexural strength <sup>1)</sup>	≥ 800 MPa <sup>2)</sup>
Chemical Solubility	< 100 µg/cm <sup>2</sup>
Chemical composition	ZrO <sub>2</sub> with others
Type / Class	Type II / Class 5

1) According to ISO 6872:2015

2) typical values for flexural strength are 1200±200Mpa

2. Indication for Use:

ARUM DENTISTRY Zirconia Blocks are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

3. Precautions

- This product is intended to be used only as specifically outlined in these Instructions for Use. Any use of this product inconsistent with the Instructions for Use is at the discretion and is the sole responsibility of the practitioner
- ARUM DENTISTRY Zirconia Blocks are delivered in a pre-sintered state. In this state, the material can be processed very well, but does not yet have the properties it has after sintering. Careful handling in this state is necessary for this reason.
- Please check the packaging and the material immediately upon receipt for an intact condition with regard to:
  - integrity of the packaging
  - integrity of the product (no disruptions, cracks or shade irregularities must be noticeable).
- Wear suitable protective eyewear, clothing and gloves. Protective eyewear is recommended for patients.
- Contamination of the preparation or margin area with saliva, blood, water, or hemostatic agents during adhesive cementation may lead to an adhesive failure.
- Devices marked "single use" on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
- ARUM DENTISTRY Zirconia Block restorations require adequate preparation reduction and restoration thickness. Insufficient wall thickness may lead to premature failure.
- ARUM DENTISTRY Zirconia Block restorations must be sintered and must be polished, or polished and glazed before insertion.
- Use only in well ventilated areas.

4. Storage Conditions

- Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product. Store in a dry place and protect from moisture.
- Store the Zirconia blocks in the original packaging and in a dry place.
  - The Milled restorations are disposable and do not reuse single-use products.
  - Keep out of reach of children.
  - Take care when handling these, that the Zirconia blocks are not exposed to any blows or vibrations.
  - Take care that the materials are not allowed to be touched with wet hands. Handle with dry gloves only.
  - The materials must not be contaminated with foreign substances (e.g., glass-ceramic or metal grinding dust).

5. Instructions for dentists

In order to guarantee a top-quality restoration which will deliver long-term satisfaction for the patient, a high-quality material must be prepared and processed in a professional manner. You can ensure maximum safety and satisfaction for your pa-

tient by following the following recommendations:

- No preparations with corners or sharp edges Shoulder-type preparation with a rounded inner edge or a chamfer-type preparation
  - Depth of cut at least 1 mm at the preparation margin Remove 1.5 – 2 mm of occlusal / incisal tooth substance Edge radius: 0.7 mm
  - Preparation angles: 6 – 8° for conventional cementation, > 6° when using an adhesive
  - No more than two pontics may be placed between any two abutment teeth
- The work can be cemented conventionally with phosphate or glass ionomer cement. Furthermore, you should be sure to observe the following:

6. Contraindications

- More than two adjacent pontics
- Very deep subgingival preparations
- Patients with inadequate natural dentition
- Patients with parafunctions in particular for bruxism
- Two or more adjacent cantilever units
- All other applications which are not included in the indications
- Insertion as a provisional restoration

7. Interactions

ARUM DENTISTRY Zirconia Blocks using non-compatible CAD/CAM systems may lead to inadequate or unacceptable restorations. ARUM DENTISTRY Zirconia Blocks are designed to be dry milled only. Do not mill in a wet-milling CAD/CAM system. Pre-sintered blocks and restorations absorb moisture. If restorations are milled wet or otherwise become wet in pre-sintered state, prolonged drying is required prior to sintering. Re-milling dry is recommended.

8. Instruction for dental laboratories

Design parameter ARUM DENTISTRY Zirconia Blocks

Anteriors	Minimum wall thickness in mm	Connector cross-section in mm <sup>2</sup>	Design type
Crowns	0.4	-	Should support tooth shape / gingiva (incisal, occlusal or basal)
Splinted crowns	0.6	7	
3-unit bridges	0.6	7	
Bridges with 4 or more units and 2 pontics	0.6	9	
Bridges with one cantilever unit	0.7	12	
Posteriors	Minimum wall thickness in mm	Connector cross-section in mm <sup>2</sup>	Design type
Crowns	0.6	-	Should support tooth shape / gingiva (incisal, occlusal or basal)
Splinted crowns	0.6	9	
3-unit bridges	0.6	9	
Bridges with 4 or more units and 2 pontics	0.7	12	
Bridges with one Cantilever unit	0.7	12	

In addition, the following points should be observed:

- Frameworks to be veneered must be designed in such a way as to provide support

for the veneering ceramic in the area of the cusps so that the veneer can be applied in a layer of fairly uniform thickness.

- If the framework design criteria, e.g. minimum wall thickness and minimum cross-section of connectors, are not met, this can result in clinical failure (e.g. the restoration may fracture).
- When designing pontics, the type of subsequent finishing must be taken into account.
- When designing connectors, it is not only necessary to ensure that the surface area of the cross-section is adequate but also to pay attention to the ratio of the width to the height: height ≥ width.

9. Milling the blocks

- For detailed processing, please consult the Instructions for Use and technical manuals of the appropriate CAD/CAM systems. Make sure to follow the manufacturers' recommendations.
- Make sure that the chamber of the milling unit is clean and dry.
- To reduce the risk of moisture contamination ARUM DENTISTRY Zirconia Blocks can be dry milled only.
- After the milling process and prior to sintering, remove the sprue. Do not thin walls beyond the minimum wall thickness.
- Please ensure that frameworks are clean and free of milling dust before sintering. Remove any dust with a soft brush.

10. Sintering the restorations

- After the milling process (and prior to sintering) a tungsten carbide tool shall be used to separate the restoration from the blank.
  - Remove the sprue prior sintering.
  - If further adjustments are needed, it is recommended to do the adjustments before sintering.
  - Do not group restorations of different shades/sintering times into one sintering cycle.
  - Before sintering the restoration, it is recommended to free the restorations from dust using compressed air or a ceramic brush.
  - Do not inhale abrasive dusts. Use a vacuum system and wear a mask.
- Recommended Sintering condition:

From ~ To		Time (min)	Rate
Room Temp	~ 900°C (1652°F)	115	↑ (7.8°C/min, 46.04°F/min.)
900°C (1652°F)	~ 1250°C (2282°F)	117	↑ (3°C/min, 37.4°F/min.)
1250°C (2282°F)	~	30	Holding
1250°C (2282°F)	~ 1530°C (2786°F)	93	↑ (3.2°C/min, 37.76°F/min.)
1530°C (2786°F)	~	120	Holding
1530°C (2786°F)	~ 100°C (212°F)	230	↓ (6°C/min, 42.8°F/min.)

General principle:

Ideally, sintering should be carried out in the Program sintering furnace from sintering machine for used dental. The sintering programs recommended by ARUM DENTISTRY are given in the detailed instructions for use.

11. Finishing the restorations

- Crack caution – When removing the sintered restorations from the sinter tray after sintering, should check the temperature of the sintering furnace to be 100°C or less. If it is removed at a temperature higher than 100°C, cracks may occur inside the sintered restorations due to thermal shock.





Surface Condition – To reduce risk of compromised flexural strength  
The surface condition of ceramic materials is critical for their flexural strength. Adjustment of the sintered restorations with milling tools, especially in the connector area, must be avoided.

However, if adjustment is necessary, then follow these basic rules:

- Adjustment in the sintered state should be performed with fine diamonds in a highspeed handpiece with water cooling and with low pressure. Adjustments made with diamonds instruments must be followed by polishing.
- As an alternative it is possible to do adjustments with soft diamond rubber polishers and a handpiece at low speed and low pressure. The tool must be applied flat to minimize the chatter.
- Areas that are under tension in clinical use, i.e. primarily the connectors in bridge structures, should not be adjusted.
- This may negatively affect the color/translucency and the bonding area towards the glazing material.

#### MR Statement



The Non-Sterile Zirconia Block has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Non-Sterile Zirconia Block in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

#### 12. Label Symbols

Symbol	Description	Symbol	Description
	Catalogue(Model) Number		Consult instructions for use
	Batch code		Do not re-use
	Date of manufactured		Keep away from sunlight
	Legal Manufacturer		Use by Prescription Only
	Caution		Don't use if package is damaged
	Keep the temperature (0 ~ 30 C)		Non-sterile
	Keep dry		Medical Device
	Fragile, handle with care		

#### 13. Manufacturer



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