Instruction for use **Zfx**[™] **Bion***X*² – **Zirconium**

Version: 4/10.2021 Compiled at 26.07.2021 Effective date: 01.10.2021 Replaces version: 3/04.2018 Page 1 of 2



Valid for Zfx™ BionX²-Zirconium and Zfx™ BionX² ML-Zirconium

Material-related characteristics

Chemical Composition [wt%]

ZrO ₂ + HfO ₂	≥ 90
Y ₂ O ₃	< 10
Al2O3	< 0.01
Other oxides	< 0.15

Physical specifications

Density (after sintering)	[g/cm³]	> 6.0
CTE (25-500°C)	[10 ⁻⁶ K ⁻¹]	10
Fracture toughness (SEVNB)	[MPa√m]	> 4.7
Fracture toughness (SEPB)	[MPa√m]	2.4
Flexural strength	[MPa]	≥ 750
E modulus	[GPa]	> 210

Explanation of symbols



Manufacturer Information: Address of legal manufacturer facility



Date of manufacture



Distributor Information: Address of legal distributor facility



Use b



LOT-Number, Symbol followed by Production Date of the lot.



Medical Device



Reference Number, Symbol followed by Manufacturer's Item Number



Store dry



Consult instructions for use www.zfx-dental.com



CE Mark for Medical Devices Class 2

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

Instruction Manual

1. Indications

 Zfx^{TM} Bion X^2 are dental mill blanks made from zirconium dioxide for the manufacture of dental prostheses. Zfx^{TM} Bion X^2 can be used for all dental constructions, bridges with up to 3 units (anterior and posterior region), inlays, onlays and veneers for dental application.

2. Contraindications

- × Parafunctional habits
- insufficient space
- × inadequate preparation
- × known intolerance to the contained components
- × insufficient oral hygiene

3. Safety information

Please pay attention to the information in the safety data sheet in its current version. Avoid the inhalation of dust particles during processing.

Wear protection gloves, safety glasses and a dust mask to prevent irritations of eyes, skin and respiratory system.

4. Handling and storage

Verify the integrity of the packaging and the blank itself before first processing. Check if packaging content corresponds to declaration given on the label. Do not use damaged material. Storage only in original containers in a cool and dry environment. Avoid vibrations, contaminations and contact with fluids.

5. Processing / Designing

Handling this medical device should only be allowed to trained staff.

 Zfx^{TM} Bion X^2 is a sensitive high performance ceramic and should be processed with caution also in pre-sintered condition.

Generally, the following construction parameters need to be considered:

Indication	Scheme	Wall thickness [mm]	connector cross section [mm²]
Single crown	х	0.5	-
Telescope	Х	0.5	-
Bridge 3 units Anterior / Posterior	e.g. XOX	0.8/0.8	≥ 10 / ≥ 13

Legend: X = abutment tooth O = pontic

Please note: Depending on the construction, the connector cross section might need to be of larger dimensions. An oval connector cross section is desirable; the height of the connector is the decisive factor. Frameworks for ceramic veneering need to be designed in a way to support the veneering ceramic in the cusp region and allow a constant layer thickness. Shoulder or chamfer preparation is recommended.

6. Milling, sintering and further processing

Machining of blanks should always be conducted in the corresponding milling system. All information given by the manufacturer of the machine shall be taken into account. Information for Amann Girrbach users: Please find code (scale factor) for utilization of 98 mm discs in Amann Girrbach milling machines on blank margin. The frameworks need to be examined for visible defects. Do not process damaged or contaminated frameworks. The white framework can be colored before final sintering with Zfx™ Color Liquid allround (pay attention to separate coloring liquid-instruction manual). Pre-colored blanks are not allowed to use with patented coloring technologies.



Instruction for use **Zfx**[™] **Bion***X*² – **Zirconium**

Version: 4/10.2021 Compiled at 26.07.2021 Effective date: 01.10.2021 Replaces version: 3/04.2018 Page 2 of 2





Please pay attention to our separate sintering instruction!

Sintering cycle for normal furnace filling without cover:

- ↑ Heating up to 900°C (1652°F) with 8°C/min (46°F/min),
- → dwell at 900°C (1652°F) for 30 minutes,
- ↑ heating up to final temp. 1450°C (2642°F) with 3°C/min (37°F/min),
- → dwell at final sintering temperature 1450°C (2642°F) for 120 min,
- \checkmark cooling to 200°C (392°F) with 10°C/min (50°F/min).

Avoid additional mechanical actions after sintering like blasting or grinding. If corrections are inevitable use water-cooled tools for the conditioning and make sure that there is no development of heat, which could lead to cracks in the material. Please work only with sharp, diamond-coated tools and very slight contact pressure. Areas that are under tension in clinical use (e.g. connectors) must not be reworked. Do not separate in interdental regions. Avoid sharp edges.

7. Ceramic veneering

Please use a veneering ceramic with a suitable WAK and pay attention to the manufacturer's recommendation. Slowing down heating and cooling rate in case of massive constructions is strongly recommended.

Weight per tooth unit [g]	<1	2	3	>4
Heating & cooling rate [°C/min]	55	45	35	25
[°F/min]	(131)	(113)	(95)	(77)

8. Mounting

For mounting we recommend conventional cementation with zinc oxide phosphates cements or glasionomer cements. Also luting composites may be used. Sufficient retentions and a stump with height of at least 3 mm are essential. A temporary mounting is not recommended!

9. Information on Manufacturer



 Dental Direkt GmbH
 T +49 (0) 5225 / 86 319 - 0

 Industriezentrum 106 - 108
 F +49 (0) 5225 / 86 319 - 99

 32139 Spenge
 info@dentaldirekt.de

 Germany
 www.dentaldirekt.de



10. Information on Distributor



 Zfx GmbH
 T +49 (0) 8131 / 33 244 - 0

 Kopernikusstraße 15
 F +49 (0) 8131 / 33 244 - 10

 85221 Dachau
 info@zfx-dental.com

 Germany
 www.zfx-dental.com

We reserve the right to make changes as a result of the continuous development of our products. Please find the current version of the instruction manual on our website: www.zfx-dental.com

Incident Reporting / Complaints

Please send to qm@zfx-dental.com

