

1. Material-related characteristics

Composition [wt.%]

| | |
|------------------------------|-------|
| Polymethylmethacrylat (PMMA) | 100 |
| Coloring pigments | ≤ 0.2 |

Physical specifications

| | | |
|--------------------------|----------|---------|
| Flexural strength | [MPa] | ~ 78 |
| Flexural modulus | [MPa] | ~ 2988 |
| Water absorption | [µg/mm³] | 19 - 25 |
| Residual monomer content | [%] | 0.02 |

2. Explanation of symbols



Manufacturer Information: Address of legal manufacturer facility



Date of manufacture



Distributor Information: Address of legal distributor facility



Use by



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



Medical Device



Reference Number, Symbol followed by Manufacturer's Item Number



CE Mark for Medical Devices Class 2



Store dry



Protect from direct sunlight



Consult instructions for use www.zfx-dental.com

3. Instruction Manual

3.1. Indications

Zfx™ PMMA temp are pre-colored dental milling blanks out of PMMA for the manufacture of temporary crowns and bridges for long-term application in the oral cavity up to 12 months.

3.2. Contraindications

- × intolerance to the contained components
- × bridges with two molar pontics
- × too little connector cross section
- × model casting with clasps, bars, narrow sublingual bars and transversal connectors

3.3. Safety information

Please pay attention to the information in the instruction manual 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.

3.4. Handling and storage

Only use clean, defect-free material out of undamaged packaging and make sure that the blanks are always stored in their original container in a dry and cool place, protected from light. Avoid contact with fluids.

3.5. Designing

Handling this medical device should only be allowed to trained staff. Following construction parameters need to be considered:

| | | Single crown | 3-unit bridge | 4-unit bridge |
|-----------|-------------------------------|--------------|---------------|---------------|
| Anterior | Wall thickness [mm] | 0.6 | 0.8 | 1.0 |
| | Occlusal thickness [mm] | 1.0 - 1.2 | 1.0 - 1.2 | 1.2 - 1.5 |
| | Connector cross section [mm²] | - | 10 | 16 - 18 |
| | Maximum of span [mm] | - | - | 20 - 25 |
| Posterior | Wall thickness [mm] | 0.6 - 0.8 | 0.8 | 1.5 |
| | Occlusal thickness [mm] | 1.2 - 1.4 | 1.2 - 1.4 | 1.5 |
| | Connector cross section [mm²] | - | 16 - 20 | 22 - 25 |
| | Maximum of span [mm] | - | - | 20 |

The given requirements for thickness and span need to be observed.

In general all constructions should be designed in a way to enable the compensation and the transfer of the mastication forces to the abutment teeth.

Design for vestibular veneering:

- × wraparound technique is required
- × where applicable produce retentions
- × where applicable construct thin, labial / circularly shoulder margins

3.6. Milling and further processing



Only use one-edged milling tools in the milling machine or wet grinding procedures!

Further processing:

Tungsten carbide burs like the one you use for soft reline materials are suitable for rough adaption. For the finalization common cross-toothed millers can be used. Polishing should be carried out with regard to a low contact pressure, otherwise the resulting heat might lead to smearing or melting.

3.7. Cleaning

- × ultrasonic bath (max. 40 °C) with mild cleaning agent

Do not use the following methods for cleaning:

- × steam blasting
- × autoclave method
- × organic solvents and acids (e.g. acetone, hydrochloric acid)
- × highly concentrated alcohols
- × chemical denture cleaners
- × abrasive cleaning agents

3.8. Mounting

Bonding extra-orally:

Choose primers suitable for the adhesive. Only use special adhesives, adapted to the material you want to combine with the PMMA. Pay attention to the instructions of the adhesive manufacturer.

Cementation:

For temporary cementations temporary cements and for permanent cementations self-adhesive glass ionomer cements are recommended.

3.9. Disposal

Remains of PMMA blanks can be disposed of in the regular household garbage.

3.10. Information on Manufacturer



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3.11. Information on Distributor



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We reserve the right to make changes due to 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