Instruction for use Zfx[™] PMMA splint

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Zfx

1. Material-related characteristics

Composition [wt.%]

Polymethylmethacrylat (PMMA) 100

Physical specifications

Flexural strength	[ISO 178]	[MPa]	92
Charpy impact strength +23°C	[ISO 179/1eU]	[kJ/m²]	45
Density	[ISO 1183]	[g/cm ³]	1.17
Water sorption	[ISO 20795-1]	[µg/mm³]	0.02
Solubility	[ISO 20795-1]	[µg/mm³]	0.0
Residual monomer content	[ISO 20795-1]	[%]	< 0.7

Date of manufacture

Use by

Medical Device

(E 0482

CE Mark for Medical

Devices Class 2

Protect from

direct sunlight

2. Explanation of symbols



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Manufacturer Information: Address of legal manufacturer facility



Distributor Information: Address of legal distributor facility



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



Reference Number, Symbol followed by Manufacturer's Item Number



Store dry



Consult instructions for use www.zfx-dental.com

3. Instruction Manual

3.1. Indications

Zfx[™] PMMA splint are transparent dental milling blanks out of PMMA for the manufacture of splints, therapeutic splints, bite regulators and drilling templates 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



Please pay attention to the information in the material 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.

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. Milling and further processing



Only use one-edged milliing 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.

3.6. 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

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

3.8. Information on Manufacturer

Dental Direkt GmbH Industriezentrum 106 - 108 32139 Spenge Germany T +49 (0) 5225 / 86 319 - 0 F +49 (0) 5225 / 86 319 - 99 info@dentaldirekt.de www.dentaldirekt.de



3.7. Disposal

3.9. Information on Distributor

Zfx GmbH Kopernikusstraße 15 85221 Dachau Germany T +49 (0) 8131 / 33 244 - 0 F +49 (0) 8131 / 33 244 - 10 info@zfx-dental.com www.zfx-dental.com

We reserve the right to make changes because 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

