3D **Freeprint®** Material

splintmaster

EN

Caution statement
Caution: Federal Law restricts this device to sale by or on the order of a dentist.

Indications for use
The Freeprint® splintmaster is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. The Freeprint® splintmaster is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as mouthguards, nightguards, splints, retainers and bleaching trays.

Patient target group
Persons being treated in the context of a dental procedure.

Intended users
Dentist, dental technician

Special manufacturing requirements
The printing machine and post-curing unit should be set-up, validated and maintained according to their labelling and instructions for use. Freeprint® splintmaster is only intended to be used with the identified compatible equipment in Annex 1.

Environmental conditions
Processing temperature 23 °C ± 2 °C / 73 °F ± 4 °F

Cleaning supplies
Rinse bathtubs, flush cutter, paper towel, squeeze bottle for isopropyl alcohol, scraper.

Processing
- The use of Freeprint® splintmaster is only approved when applied with the compatible devices mentioned in this instruction for use as outlined in Annex 1.
- Generate the object (STL-file) using a commercial CAD software, which is intended for dental applications.
- The properties of the final product depend, among other things, on post-processing. Correct post-exposure is important for biocompatibility. Therefore it must be ensured that the exposure device is in an orderly condition and that the moulds are completely cured (observe manufacturing process).
- After storage, the material in the bottle should be shaken and homogenized with a bottle roller before use.
- Do not use heat-based methods for disinfection or sterilisation. This could possibly deform the workpiece.
- Minimum wall thickness for the design is flex: 1.0 mm; taff: 0.8 mm. Layer thickness for printing is 100 µm.

Safety information
- Avoid direct contact with the liquid material and the components before post-curing, in particular in pregnant / breastfeeding women. Irritating to eyes and skin (sensitization possible).
- Wear personal protective equipment (protective gloves, goggles) when handling the uncured material.
- Wear suitable personal protective equipment (protective gloves, goggles, face mask) when finishing the cured material.
- After contact with eyes rinse thoroughly with water immediately and consult a doctor.
- After contact with skin wash immediately with water and soap.
- Biocompatibility is only guaranteed with complete polymerisation.

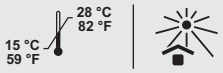
Technical Data

ISO 20795-2-Type 2
Does not contain MMA monomer.
Does not contain phthalates.

Processing

at 23 °C ± 2 °C / 73 °F ± 4 °F

Storage



Ordering information

Freeprint® splintmaster	1000 g
splintmaster flex	04441
splintmaster taff	04442

detax GmbH
Carl-Zeiss-Str. 4 • 76275 Ettlingen • Germany
+49 7243 510 0 • post@detax.com • detax.com

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Notes
- Detax does not accept liability for any damage caused by misuse.
- Always keep container tightly sealed, immediately close the container carefully after each use.
- Read and understand the safety data sheet!

MRI Safety Information
Freeprint® splintmaster is MR Safe as it is composed of materials that are electrically nonconductive, nonmetallic and nonmagnetic.

Storage
Freeprint® splintmaster is to be stored dry at 15 °C - 28 °C / 59 °F - 82 °F and protected from light. Minimal influence of light can already induce polymerisation. Please cover the material vat with its lid or a glass plate to protect material from contamination.

Contraindications
Contains (meth)acrylics and phosphine oxide.
Some ingredients of Freeprint® splintmaster may cause allergic reactions in predisposed persons. In such cases refrain from using the product. Freeprint® splintmaster only insert intraorally in completely polymerised state.

Adverse effects
Product may cause allergic reactions.

Disposal
Disposal of the contents/container must be carried out in accordance with the local/regional/national and international regulations.

Material properties

Freeprint® splintmaster flex	
Color*	clear-transparent
Viscosity*	1500-2500 mPas
Flexural strength**,***	≥ 2 MPa
Bending modulus**,***	≥ 100 MPa
Water sorption**	< 32 µg/mm³
Water solubility**	< 5 µg/mm³

Freeprint® splintmaster taff	
Color*	clear-transparent
Viscosity*	800-1600 mPas
Flexural strength**,***	≥ 2 MPa
Bending modulus**,***	≥ 100 MPa
Water sorption**	< 32 µg/mm³
Water solubility**	< 5 µg/mm³

* applies to liquid resin; **applies to cured objects ;***according to internal design and requirements specifications

Technical Data
ISO 20795-2-Type 2
Does not contain MMA monomer.
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Processing
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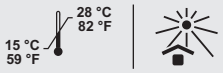
Storage


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Manufacturing process

① Mixing

Before filling resin into the reservoir, the material must be mixed. Use a bottle roller or mix/shake it by hand. Inadequate mixing could cause deviations of colour and print failures.

② Filling of printer

Fill 3D printing resin in the reservoir of the printer. It is not allowed to pour 3D printing resin from the reservoir of the printer back into the resin bottle.

③ Construction process

After storage, the material in the bottle should be shaken intensively and homogenized with a bottle roller before use. Generate a print job complying with printer and material parameters. For setting up the printer follow the instructions for use of the printer. Data preparation and fabrication of the support structure according to the instructions of the CAD software manufacturer. Remaining print resin material after printing is not allowed to be poured back into the resin bottle.

④ Post-processing

If possible, post-processing should commence immediately following with this construction process. After raising the platform, a drip time of approx. 10 minutes is recommended. Remove the platform from the printer and remove the construction components using appropriate device (e.g., knife or spatula). Carefully remove excess resin using a light flow of compressed air.

⑤ Cleaning

1. Clean the construction components with a suitable cleaning unit (see Annex 1, item "Cleaning Equipment")
Then carefully remove the construction components from the support structure.
2. Further cleaning is performed with a suitable cleaning unit (see Annex 1, item "Cleaning Equipment"). Prior to post-exposure, check the construction components for residues. Then blow off with compressed air. After cleaning the surface of the construction components must no longer be sticky (dry) and not shiny (matt).

⑥ Post-exposure

Post-exposure is performed with a suitable curing unit (See Annex 1, item „Light curing Equipment")

Caution
The use of Freeprint® splintmaster is only approved when applied with the compatible devices mentioned in this instruction for use. Any unauthorized changes to the process equipment, parameters, or software may result in a device that is out of specification.

Finishing
Finish the construction components by using conventional dental methods and instruments.

Symbol explanation

Graphic	Reference number	Title	Description	Reference
	**5.1.1**	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	**5.1.4**	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	**5.1.5**	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	**5.1.6**	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	**5.3.2**	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	**5.3.7**	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	**5.4.3**	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
		Prescription only	Requires a prescription in the United States of America Caution: In the United States of America, federal law restricts this device to sale or use by, or on the order of, a dentist.	USA Code of Federal Regulations 21CFR Part 801 § 801.109 (b)(1)
		Magnetic resonance	The Freeprint® splintmaster is MR Safe.	FDA Guidance document: Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment dated May 20, 2021.
		Warning	The uncured material is considered as hazardous substance.	29 CFR 1910.1200 Occupational Safety and Health Standards
		This way up	This is the correct upright position of the distribution packages for transport and/or storage.	ISO 780:2015(E) Packaging-Distribution packaging- Graphical symbols for handling and storage of packages