VeriSPLINT™ 3D Print Resin Instruction for Use (IFU)



Indication of Use

Whip Mix VeriSPLINT™ is a light-cured resin and sold as Rx only. It is a base polymer used to create removable structures for therapeutic restorations i.e., bite guards/splints and occlusal night guards/splints using the Additive Manufacturing process. The resin in combination with a scanner, printer, and curing unit make up the system.

Storage and Transportation

- 1. VeriSPLINT™ must be stored in the original packaging at room temperature in a dry area.
- 2. Always keep the container tightly sealed and close the container immediately after each use.
- 3. Do not expose VeriSPLINT™ to any light source. Minimum amount of light can induce polymerization (solidification).
- 4. Resin that is stored in a tray must be stirred before each print using a plastic or paper card (similar to a business card), to ensure a homogenous mixture.
- 5. Do not use the product past the expiration date.
- 6. The lot number and expiration date are indicated on VeriSPLINT™ packaging. In case of questions or concerns, please refer to the lot number.
- 7. Packages are ideally transported at room temperature and away from light in a tightly sealed container to prevent leakage.

Validated Equipment

For all validated printers, curing units, and their setting, please scan the QR code



Design Recommendation

Minimum sidewall thickness	1.5 mm
Minimum occlusal surface thickness	2.2 mm*
Internal offset	≥ 0.1 mm
Block out angle	0°
Retention amount	0 mm

^{*} If splint needs to be adjusted, do not grind occlusal surface to less than 2 mm

Processing

- 1. When printing with VeriSPLINT™ 3D Print Resin, make sure resin is at a temperature between 20°C and 30°C. Extreme high or low temperatures could potentially affect the accuracy of the printed models or cause failure of the printed objects.
- 2. VeriSPLINT™ OS bottle must be shaken thoroughly before use.
- 3. Don't add supports to the intaglio surface.
- 4. Don't print with the end of the splint arch attached to the build plate with any print orientation because failure could happen at the tip of the arch.
- 5. After the build process is finished, post processing is required. If this cannot be immediately completed, leave the printed objects in the printer until ready to post process

Post Processing:

- 1. When the print job is complete, remove the build platform from the printer, then carefully remove the printed objects from the platform.
- 2. The printed object must be rinsed with Isopropyl alcohol using an ultrasonic bath/washing unit for 5 minutes to eliminate any excess resin.
- 3. Printed objects must be rinsed with Isopropyl alcohol in a second fresh ultrasonic bath/washing unit for an additional 5 minutes.

NOTE: Do not immerse the printed parts in alcohol for more than 10 minutes, as prolonged exposure may cause the material to deteriorate.

- 4. To remove excess alcohol, leave prints to dry at room temperature (or compressed air can also be used).
- 5. Carefully remove all support structures from the printed object.
- 6. Place the printed objects in the light curing unit, such as Otoflash G171 for 6,000 flashes.
- 7. Look for cured debris in the tray after each print job. A paint strainer can be used to filter out any debris. Printing with cured debris could potentially cause damage to the tray or the printed objects.

Finishing

- 1. Use cross-cut carbide bur at a slow speed to remove the remaining printed support pins.
- 2. Use a rag wheel at low speed and medium grit pumice to smooth the outside surfaces of the printed splint.
- 3. Do not polish the intaglio surface of the printed splint as this can alter the fit.
- 4. To achieve a glass like surface, use a dry rag wheel and a high shine acrylic polish.

Patient care instructions

- 1. Wash the device daily after use with warm water and soap to remove any debris . Once dried, store it in a dry case
- 2. Remove the device before eating, drinking, or smoking

Warning





Contains Methacrylate oligomers and monomers, Acrylate oligomers and monomers, and Phosphine Oxide.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

H412 Harmful to aquatic life with long lasting effects.

Precautionary Phrases:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P261 Avoid breathing mists, vapors or spray.

P264 Wash thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing must not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves and eye protection.

P308 + P313 IF exposed or concerned: Get medical attention.

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P312 Call a POISON CENTER or doctor if you feel unwell.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor.

P337 + P313 If eye irritation persists: Get medical attention.

P391 Collect spillage.

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

P501 Dispose of contents and container in accordance with local and national regulations.

Symbols and their Descriptions

Symbol	Description
Ţ.	See Instructions for use
***	Manufacture by
	Use-by-date
类	Keep away from sunlight
1	Temperature limit
O;	Shake well before use
LOT	Batch number
UDI	Unique Device Identifier
REF	Reference number
Rx	Prescription-only



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