

INDICATIONS OF USE

Whip Mix VeriFIT™ Splint is a thermo-adaptive light-cured 3D printable resin for the fabrication of orthodontic and dental appliances such as splints, mouth guards, night guards, repositioners and retainers. The resin in combination with a scanner, printer, and curing unit make up the system.

STORAGE AND TRANSPORTATION

1. Whip Mix VeriFIT™ Splint Resin must be stored in the original packaging at room temperature in a dry area away from sunlight.
2. Always keep container tightly sealed and close the container immediately after each use.
3. Do not expose Whip Mix VeriFIT™ Splint Resin to any light source to avoid unwanted polymerization (solidification).
4. Resin 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 Whip Mix VeriFIT™ Splint Resin packaging. Packages are ideally transported at room temperature and away from light in a tightly sealed containers to prevent leakage.

VALIDATED EQUIPMENT

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



CAUTION: Only use the validated equipment (3D printers and post-curing units) specified on the Whip Mix website. Substitutions or modifications may result in a device that does not meet safety and performance standards and could pose risk to patients.

DESIGN RECOMMENDATION

Minimum sidewall thickness	1.5 mm
Minimum occlusal surface thickness	1.5 mm
Internal offset	≥ 0.05 mm
Block out angle	0°
Retention amount	0 mm

PROCESSING

1. When printing with Whip Mix VeriFIT™ Splint 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 splints or cause failure of the printed objects.
2. Wear proper PPEs when handling uncured resin.
3. Whip Mix VeriFIT™ Splint Resin bottle must be shaken thoroughly for approximately five minutes before use.
4. Splints can be printed at slice thicknesses of 50, 75 or 100 microns.
5. Don't add supports to the intaglio surface.
6. Vertical nesting is recommended to avoid supports on critical surfaces. Please scan the QR code for an example. VeriFIT can also be nested 20-60 degrees for shorter print times.
7. After the build process is finished, post-processing is required.

POST PROCESSING

1. When the print job is complete, remove the build platform from the printer, and then carefully remove the printed objects from the platform.
2. The printed object must be rinsed using a ≥ 95% isopropyl alcohol bath for 5 – 10 minutes to eliminate any excess resin.
3. Printed objects should then be rinsed in a second fresh ultrasonic isopropyl alcohol bath for an additional 5 – 10 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 use compressed air).
5. Place the printed objects in the light curing unit e.g. Otoflash G171 for 10,000 flashes (5000 flashes on one side, cool for 2 minutes, flip and 5000 flashes on the other side). For the complete list of recommended curing units, please scan the QR code.
6. Allow the part to cool completely before removing from the curing unit to prevent surface defects or warping.
7. Carefully remove all support structures from the printed object.
8. Look for cured debris in the tray after each print job. A mesh 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.

INSTRUCTIONS FOR HEATING UP THE PRINTED SPLINT USING A WATER BATH*

1. Set the water bath to 160°F (71.12°C). Allow 10 - 20 minutes for the water to heat up.
2. Once the water has reached 160 °F (71 °C), immerse the splint in the water bath for 30-60 seconds. Remove the splint and gently squeeze the sides together. If the material feels soft and pliable, it is ready for molding. If it remains firm, return it to the hot water for an additional 15 seconds. Proceed when the splint is soft and pliable.
3. Immediately insert the warm splint into the patient's mouth and instruct the patient to bite gently and close fully to seat the splint completely.
4. Instruct the patient to remove and reinsert the splint several times while it is still warm to ensure optimal adaptation. Then, immerse the splint in cold water for 30-60 seconds to fully cool and harden the material, locking the adapted fit in place.
5. Confirm with the patient that the splint fits passively, with no localized pressure or discomfort on any teeth or soft tissue areas.
6. Verify occlusion.

Note: Although the splint is designed to fit as delivered, use of the water-bath adaptation method described is **strongly recommended for optimal fit and patient comfort.*

PATIENT CARE INSTRUCTIONS

1. Wash the device daily after use with cold water and soap to remove any debris. Do not wash in hot water. Once dried, store in a dry case.
2. Do not soak the device in any solutions.
3. Do not use if you have bleeding gums or injury in mouth.
4. Remove device prior to any eating, drinking, or smoking.

WARNING

Label Elements:

DANGER!



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.

H360 May damage fertility or the unborn child.

H361d Suspected of damaging the unborn child.

H411 Toxic to aquatic life with long lasting effects.

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.

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.

VeriFIT™ Splint Thermo-Adaptive 3D Print Resin

Instructions for Use (IFU) – For Professional Use Only



Symbols and their Descriptions

SYMBOL	DESCRIPTION
	See Instructions for use
	Manufacture by
	Use-by-date
	Keep away from sunlight
	Temperature limit
	Shake well before use
	Batch number
	Unique Device Identifier
	Reference number
Rx	Prescription-only



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