

Indications for Use: KeyPrint® KeySplint Soft™ is indicated for the fabrication of orthodontic and dental appliances such as bite planes, mouthguards, nightguards, snoring appliances, splints and repositioners.

Product Description: KeyPrint® KeySplint Soft™ is a light-curing resin for the 3D printing of flexible biocompatible dental devices for use in DLP 3D printers utilizing wavelengths between 385nm –405nm.

Contraindications: Contains methacrylate monomers and oligomers which, although rare, may cause an allergic reaction in individuals sensitive to acrylic containing products.

Warnings & Precautions:

1. Deviation from the described manufacturing process may compromise biocompatibility, user safety, and lead to unwanted material properties of the finished printed product.
2. Follow all recommended validated settings for your printer and post curebox located on the Keystone website to achieve biocompatible and effective print results.
3. Review the product Safety Data Sheet (SDS) prior to use.
4. As per the SDS, wear proper personal protective equipment when handling KeyPrint® resins and uncured printed parts.
5. Avoid contact with skin and eyes when handling this resin and uncured printed parts. In case of accidental contact, follow the "First-aid measures" listed in Section 4 of the SDS and seek medical attention if necessary.
6. When pouring the resin, be careful not to splash.
7. Store in a cool, dry place 15°C-30°C (59°F-86°F) and away from light.

CAUTION: Federal law restricts this device to sale by, or on the order of a dental professional.

Directions for Use:

1. Ensure that resin is tempered to ambient temperature (20-25°C/68-77°F) prior to printing.
Note: While handling KeyPrint® KeySplint Soft™, we recommend wearing personal protective equipment (i.e. safety glasses, lab coat, closed-toe shoes, gloves, etc).
2. In order to achieve consistency of the resin and to prevent bubbles, agitate the bottle 1 hour prior to use. If bubbles are present, remove with a clean instrument/spatula.
3. Only use KeyPrint® KeySplint Soft™ predetermined settings for your DLP 3D printer and post curebox provided on Keystone's website. KeySplint Soft™ should be used with a 385nm - 405nm UV light source. Printers using alternative light sources require validation by Keystone's technical team for optimal settings.
4. Resin coated printed parts should be cleaned of any residual liquid resin with Isopropyl Alcohol (IPA) (at least 97%) within approximately 8 hours from the completion of the print.

Note: Do not allow the parts to sit in IPA for longer than 5 minutes, as the properties may begin to deteriorate. Keystone discourages the use of denatured alcohol or ethanol for cleaning as it may diminish or degrade the quality of the finished parts.

Directions for Post-Processing Treatment of Printed Part(s):

1. Remove part from printer and build platform. If applicable, remove support structures from the part.
2. Place in Stage 1 Isopropanol (IPA) bath. This bath is used for the first wash of any part coming from the printer.
3. Remove excess liquid resin from the printed part. This can be done by running fingers over the surface, swishing or vibrating with the part submerged in the IPA bath.
4. Transfer the part(s) into a Stage 2 IPA bath. In order to achieve optimal final print quality, use fresh IPA with lower concentration of contaminants. Using a soft scrub brush, tooth brush or cotton swab dipped in IPA, can help remove excess resin.
5. Use compressed air to dry part, looking for residual liquid resin, which will be visible as it remains glossy. If residual resin remains, repeat steps 4 & 5 as needed.
6. Place the part in the validated post-processing curebox. Be sure to place the part flat side down to prevent warping.
Note: The resins are compatible in cureboxes with UV wavelengths of 250nm-390nm. Check Keystone's website for a list of validated cureboxes and printer settings.
7. Allow part to cool completely before removing from the curebox to prevent surface defects or warping. At this stage the medical device is cured and safe with respect to residual monomers and can be handled without gloves.
8. Perform final processing (i.e., polishing).
9. Prior to delivery to the patient, clean the dental oral appliance with soap and water to ensure the device is free of any debris from the polishing process.
10. Part is ready for use. The finished medical device resulting from these instructions for use is safe, biocompatible and effective.

Patient Cleaning Instructions:

This medical device is a single-patient, customized, multi-use oral appliance that should be cleaned between usages. The patient should clean the appliance with soap and warm water, or any over-the-counter mild cleaning agents for oral devices.

Disposal Considerations: KeyPrint® KeySplint Soft™ is not considered an environmental hazard in its final, fully cured state. Dispose of unused and non-recyclable liquid resin materials in accordance with federal, state and local regulations.