

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

Product Description: KeyPrint® KeySplint Soft™ Clear for Carbon® Printers is a light-curing resin for the 3D printing of flexible biocompatible dental devices for use with Carbon® M-series printers.

This system integrates multiple components of the digital dentistry workflow: scan files from intra-oral scanners, CAD/CAM software, resins, printers, post cure devices and associated tools and accessories. For any components that are used in conjunction with the KeyPrint® KeySplint Soft™ Clear for Carbon® Printers resin, the user should review all applicable product labeling including Instructions for Use pamphlets, user manuals, online training, and other associated labeling. Strict adherence to all labeling is critical in assuring a safe and effective printed appliance.

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. Review the product Safety Data Sheet (SDS) prior to use.
3. As per the SDS, wear proper personal protective equipment when handling KeyPrint® KeySplint Soft™ Clear for Carbon® Printers resin and uncured printed parts.
4. 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.
5. When pouring the resin, be careful not to splash.
6. Store in a dry place at ambient temperatures (15 - 30°C /59 - 86°F), away from light.
7. In the unlikely event of a print failure during printing, filter the liquid resin through a mesh screen with pore sizing <200 microns. It is a good practice to filter the resin in a cassette periodically to prevent print failures.
8. Clean out the printer platform and cassette tray prior to using a different batch of resin. Keystone recommends designating a cassette that is specific for the KeyPrint® KeySplint Soft™ Clear for Carbon® Printers medical device printing. DO NOT mix different batches of the same product.
9. Keystone recommends against reclaiming the resin material without filtering.

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

Compatible Equipment:

The KeyPrint® KeySplint Soft™ Clear for Carbon® Printers resin is compatible with the following:

1. 3Shape Ortho System Software
2. Carbon M-series Printers
3. Dreve PCULED/Dreve PCU9D/OtoFlash G171

Note: For alternative compatible workflow options, see Keystone Industries' website.

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™ Clear for Carbon® Printers resin, 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.
3. KeyPrint® KeySplint Soft™ Clear for Carbon® Printers resin should only be used with your Carbon® printer, by selecting the "Keystone KeySplint™ Soft Clear" resin on the drop-down menu.
4. Follow KeyPrint® KeySplint Soft™ Clear for Carbon® Printers directions for importing the sliced STL design file.

Note: Nesting of the printed device in the CAM software at 35°-50° angle using supports on the non-intaglio surface is recommended to achieve optimal results.

5. 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 fresh IPA bath and wash for 3 minutes at ~140 RPM in a sealed, labeled container placed in an orbital shaker. Use a dedicated IPA bath for washing.

Note: Fill container with IPA until ¾ of the tallest parts are covered. Dispose of soiled IPA in accordance with local regulations and refill container with fresh IPA.

3. Place parts in a second bath of fresh IPA and continue washing for another 2 minutes at ~140RPM.

Note: Dispose of soiled IPA in accordance with local regulations.

4. Transfer parts onto a paper towel on a tray lined with aluminum foil.
5. Using a cleaning foam swab dipped in IPA, wipe the entire intaglio surface of each part.
6. Allow parts to air dry on the paper towel for 25-30 minutes. Compressed air can be used to shorten the wait time.
7. Use compressed air to inspect parts for glossy areas, which indicate residual liquid resin. If present, repeat step 5 and step 6 and allow parts to fully dry.
8. Place objects in one of the adequate UV curing units below, using the instructions provided.

Post-cure unit	Procedure
Dreve PCU LED (with nitrogen)	Place parts in the Dreve PCU LED N2 unit on the removable glass platform, and rotate the control knob to select the "Splint" program. Press the control knob again to initiate the post-cure cycle (90% LED intensity, 32 minutes).
Dreve PCU 90 (with nitrogen)	Place parts in the Dreve PCU 90 unit on the reflective surface of the foam block for 15 minutes per side. Start the cycle by closing the door, rotating the control knob to display "15:00", and pressing the knob.
Otoflash G171 (with nitrogen)	Place parts flat in the unit for 2000 flashes per side. Allow parts to cool completely before removing from the cure-box to prevent surface defects or warping.

9. Parts are now safe to handle without gloves. Perform final polishing/finishing steps as needed.
10. Prior to delivery to the patient, clean the medical oral appliance with soap and water to ensure the device is free of any debris from the polishing process.
11. Part is ready for use. The finished medical device resulting from these directions 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 indicated for oral devices.

Disposal Considerations:

KeyPrint® KeySplint Soft™ Clear for Carbon® Printers 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.