

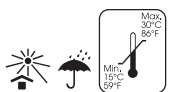
keyprint®
by keystone Industries

BLEACHING TRAYS
KeySplint Soft™

For professional use only

keystone®
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The following instructions for use are for dental professionals who use KeyPrint® KeySplint Soft® for the fabrication of cosmetic tooth whitening/bleaching trays. KeyPrint® KeySplint Soft® is intended exclusively for professional dental work. This instruction for use also provides information about safety and environmental aspects, a safety datasheet is available on www.keystoneind.com. When using the bleaching tray as a cosmetic appliance, follow the instructions for use provided by the manufacture of the tooth whitening gel or other materials used as tooth whitening agents. Wear your tray as indicated by a dental professional.

Indications for Use: KeyPrint® KeySplint Soft® is a monomer-based resin that can be used for the individual manufacturing of 3D-printed cosmetic tooth whitening/bleaching trays.

Product Description: KeyPrint® KeySplint Soft® is a light-curing resin for the 3D printing of flexible biocompatible bleaching trays in DLP 3D printers utilizing wavelengths between 385nm –405nm. For any components that are used in conjunction with the KeySplint Soft resin, the user should review all applicable product labeling including Instructions for Use pamphlets, user manuals and other associated labeling. Strict adherence to all labeling is critical in assuring a safe and effective printed appliance.

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

Warnings & Precautions:

1. Follow all recommended validated settings for safe and effective print results.
2. Do not use any components that are not validated or deemed acceptable by Keystone Industries. See Keystone Industries' website (dental.keystoneindustries.com) for additional information on validated workflow options.
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. When pouring the resin, be careful not to splash.
6. Store in a cool, dry place 15°C-30°C (59°F-86°F) and away from light. Ensure that the bottle is capped while not in use.
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 vat periodically to prevent print failures.
8. Clean out the printer platform and vat tray prior to using a different batch of resin. Keystone recommends designating a vat that is specific for the KeySplint Soft® material. DO NOT mix different batches of the same product.
9. Keystone recommends against reclaiming the resin material without filtering.

Compatible Equipment:

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

Directions for Use of KeySplint Soft® material:

1. Ensure that resin is tempered to ambient temperature (20-25°C/68-77°F) for 24 hours prior to printing.
2. 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 KeySplint Soft® product-specific predetermined validated settings for your DLP 3D printer. The settings are provided in a downloadable file found on Keystone Industries' website. KeySplint Soft® should be used with printers of a 385nm - 405nm UV light source. Printers using alternative light sources require validation by Keystone's technical team for optimal settings. For a validated downloadable settings file for your printer, visit Keystone Industries' website.
4. Once design is completed per CAD software manufacturer's directions for use, import into the CAM software unique to the printer manufacturer.
5. Nesting of the printed tray in the CAM software at a 35°-50° angle using supports on the non-intaglio surface is recommended to achieve optimal results (using printer manufacturer's directions for use).
6. Resin coated parts should be cleaned with Isopropanol (at least 97% purity) within approximately 8 hours from the completion of the print. Do not allow the parts to sit in Isopropanol for longer than 5 minutes as the properties may begin to deteriorate.

*Keystone discourages the use of denatured alcohol or ethanol for cleaning as they may diminish or degrade the quality of the finished parts.

Directions for post-cure treatment of printed part(s):

1. Remove part from printer and build platform.
2. Remove support structures from the part if applicable.
3. Place in Stage 1 Isopropanol (IPA) bath. This bath is used for the first wash of any part coming from the printer.
4. 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.
5. Transfer the part(s) into a Stage 2 IPA bath. To achieve optimal final print quality, use fresh IPA with lower concentration of contaminants. Using a soft scrub brush, toothbrush or cotton swab dipped in IPA can help remove excess resin.
6. 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 5 and 6 as needed.

Place the part in the post-cure cure-box being sure to place the part flat to prevent warping. The KeySplint Soft® resin is compatible in cure-boxes with UV wavelengths of 250nm-390nm. Please visit Keystone Industries' website for a list of validated post-cure boxes and their settings.

7. Perform the final processing (i.e., polishing).
8. Prior to use or delivery to the patient, clean the cosmetic tooth whitening/bleaching trays with soap and water to ensure the tray is free of any debris from the polishing process.
9. **Important:** Allow the tray to sit for at least 24 hours after the prior steps are completed and before being used as a cosmetic tooth whitening/bleaching tray.
10. After waiting at least 24 hours, the device will be ready for use as a cosmetic tooth whitening/bleaching tray. The finished bleaching tray resulting from these directions/validated workflows is safe, biocompatible, and effective for use as instructed.
11. The cosmetic tooth whitening/bleaching tray resulting from the process described herein as approved for use with bleaching materials containing up to 35% Carbamide Peroxide or 15% hydrogen peroxide. When using the bleaching tray as a cosmetic appliance, follow the instructions for use provided by the manufacture of the tooth whitening gel or other materials used as tooth whitening agents. Wear your tray as indicated by a dental professional.
12. It is recommended that a cosmetic tooth whitening/bleaching tray resulting from the process described herein be replaced after 14 treatment sessions of an approximate duration of 30 minutes each.

Patient Care and Cleaning Instructions:

A cosmetic tooth whitening/bleaching tray resulting from the process described herein should be cleaned between uses.

- Clean whitening trays with a toothbrush or Q-tip and cold water. Soap, or any over-the-counter mild cleaning agents indicated for oral devices, also can be used.
- Do not soak the oral appliance for a long period of time, no more than 3 hours.
- Dry the tray before storage
- Store trays in a separate case or holder in a dry, cool place. Keep the whitening trays away from heat to avoid risk of distortion

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.