keyprint®
by keystone industries

# KeyOrtho IBT™

Report any serious incident occurring with this device to the manufacturer and applicable Competent Authority of the member state in which the user/patient is established.

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Max 30°C 86°F
Min 15°C 59°F

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**Made in USA**

# KeyOrtho IBT™



**Indications for Use:** KeyPrint® KeyOrtho IBT™ is a biocompatible photopolymer resin intended for the fabrication of indirect bonding trays used during orthodontic bracket placement.

**Product Description:** KeyPrint® KeyOrtho IBT™ is a liquid photopolymer resin designed for additive manufacturing in vat Polymerization DLP printers utilizing wavelengths between 385nm–405nm. Characterized by its flexibility, elongation at break, and adhesive release from dental cement, KeyOrtho IBT™ is a material designed for 3D printing of Indirect Bonding Trays.

The user should review all applicable product labeling, including Instructions for Use, user manuals, and associated labeling for any component(s) used in conjunction with KeyOrtho IBT™. Strict adherence to all label requirements and validated printer and post cure settings, is critical in assuring a safe, biocompatible 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.

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

**Warnings & Precautions**

1. Review the product Safety Data Sheet (SDS) before use.
2. To ensure a safe and effective final device, Keystone Industries recommends using dedicated accessories for KeyOrtho IBT™, including resin tank, build platform, and washing station. For full biocompatibility, the dedicated accessories must not mix with any other resins.
3. Clean the printer build plate and vat tray before using a different batch of KeyOrtho IBT™. DO NOT mix different batches of the same product.
4. Do not use any devices or components that are not validated in collaboration with Keystone Industries.
5. As per the SDS, wear proper personal protective equipment when handling KeyPrint® resins and uncured printed parts.
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. Cap the bottle when not in use.
8. Keystone recommends against reclaiming the resin material without filtering. In the unlikely event of print failure, filter the liquid resin through a mesh screen with pore sizing <200 microns. It is a good practice to filter the resin vat periodically to prevent print failures.
9. To achieve proper consistency of the resin and prevent bubbles, thoroughly mix 1 hour before use.
10. Allow the resin to reach ambient temperature (20-25°C/68-77°F) before printing.
11. Limit the total wash time with Isopropanol (IPA) to no more than 5 minutes to prevent adverse effects on final physical properties.

**Compatible Equipment:** To ensure the biocompatibility of the final device, Keystone Industries collaborates with printer manufacturers to provide validated printer and post-cure settings. Visit Keystone Industries' website for a list of completed and in-process validations.

KeyOrtho IBT™ is compatible with DLP Printers utilizing UV wavelengths between 385nm-405nm and post-cure units using UV wavelengths of 250nm-390nm.

**Processing Printed Parts**

1. Pour the liquid material in the reservoir of the printer. Follow the Printers' instructions for use.
2. Print the part according to your printers' Instructions for Use. Keystone Industries recommends nesting the print files on the build plate in a flat orientation, aligning the trays' non-intaglio surface to be in contact with the build plate.
3. Remove printed parts from the build plate.

**Directions for cleaning/ post-cure of printed part(s)**

1. **Stage 1 Cleaning:** Place printed part(s) in an Isopropanol (IPA) bath with at least 97% IPA. Use this bath as the first wash of any part coming from the printer. Remove excess liquid resin from the printed part(s). Run fingers over the surface, using swishing or vibrating motions with the part submerged in the IPA bath.
2. **Stage 2 Cleaning:** Transfer the part(s) into a Stage 2 IPA bath. To achieve optimal final print quality, use fresh IPA with a lower concentration of contaminants. A soft bristle brush or cotton swab dipped in IPA can help remove excess resin.
3. **Dry Part(s):** Use compressed air to dry part(s), looking for glossy spots of residual liquid resin. If residual resin remains, repeat steps 1-3 as needed.
4. **Post Cure:** KeyOrtho IBT™ requires post-cure to reach optimal physical properties and biocompatibility. After cleaning, place the part(s) in a validated post-cure box, ensuring the part is placed flat to prevent warping. Cure time will depend on the wavelength and intensity of light used.

   One validated method of post-curing is:
   *Otoflash G171:* Set the post-cure box to 1000 flashes per side without nitrogen
   See Keystone's website for validated post-cure box settings.

   Allow part to cool completely before removing from the cure-box to prevent surface defects or warping.

The finished medical device resulting from following these directions/validated workflows is safe, biocompatible, and effective for its intended use.

**Clinical Use Instructions:** An Indirect Bonding Tray fabricated with KeyPrint® KeyOrtho IBT™ is a customized single-patient, single-use oral appliance that should be disposed of after it is used to place orthodontic brackets.

**Disposal Considerations:** KeyPrint® KeyOrtho IBT™ is not 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.