ARGEN® FLEX

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Indications for Use: Argen®FLEX is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and repositioners.

Product Description: Argen®FLEX 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.

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 Argen®FLEX, 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.

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

Contraindications: Contains methacrylate 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 devices or components that are not validated or deemed acceptable by Argen. See Argen's website 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 Argen® 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. Argen recommends designating a vat that is specific for the Argen®FLEX medical device printing. DO NOT mix different batches of the same product.

9. Argen recommends against reclaiming the resin material without filtering.

Directions for Use:

1. Ensure that resin is tempered to ambient temperature (20-25°C/68-77°F) prior to printing.

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 Argen product-specific predetermined validated settings for your DLP 3D printer. The settings are provided in a downloadable file found on Argen's website. Argen®FLEX should be used with printers of a 385nm-405nm UV light source. Printers using alternative light sources require validation by Argen's technical team for optimal settings.

For a validated downloadable settings file for your printer, visit Argen's 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 device 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.

*Argen 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. In order 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 Argen®FLEX resin is compatible in cure-boxes with UV wavelengths of 250nm-390nm. Please visit Argen's website for a list of validated post-cure boxes and their settings.

Otoflash G171 Settings: Set the post-cure-box to 2000 flashes per side to complete the post-cure process.

*Allow part to cool completely before removing from the cure-box to prevent surface defects or warping. At this stage the medical device is cured and safe with respect to residual monomers.

7. Perform the final processing (i.e., polishing).

8. 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.

9. Part is ready for use. The finished medical device resulting from these directions/validated workflows 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: Argen®FLEX 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.

Manufactured for:
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ARGEN®

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