Dentsply Sirona

Lucitone Digital Print Denture™ System for SprintRay Printers

3D Printing Materials

Instructions for Use Supplement

Indications for Use

- Lucitone Digital Print™ 3D Denture Base is a light-cured resin indicated for the fabrication of denture bases in dental laboratories, including full and partial dentures [1] and implant overdentures.
- Lucitone Digital IPN™ 3D Premium Tooth is a light-cured resin intended for printing denture teeth.
- Lucitone Digital Value™ 3D Economy Tooth & Trial Placement is used as a try-in material for evaluation prior to fabrication of the final restoration and is intended for printing full arch and tooth segments. [3]
- Lucitone Digital Fuse™ Step 1 – 3D Tooth Conditioning Agent is indicated for use in enhancing the bond of denture teeth to denture base and denture base to denture base.
- Lucitone Digital Fuse™ Step 2 – 3D Denture Bonding Resin is utilized as an aid in bonding denture teeth to denture base as well as repair using traditional techniques.
- Lucitone Digital Fuse™ Step 3 – 3D Sealer is a light-cured sealant that produces a smooth, glossy surface finish on the denture.
- Lucitone Digital Fuse™ Step 3 – Total 3D Sealer is a light-cured sealant that produces a smooth, glossy surface finish on the denture.

[1] Partial and full dentures are replacement for patients with missing teeth. [2] Statement added for EU MDR alignment.
[3] Indicated only as a try-in appliance for SprintRay printers.

Intended Purpose and Benefit

- Device is intended for fabrication of removable dental prostheses to restore function and aesthetics.
- Patient Target group(s) - Patients with missing teeth.

Contraindications

- Lucitone Digital Print Denture System components are contraindicated for patients with known hypersensitivity or severe allergic reactions to any of the components.

Warnings

- Lucitone Digital Print Denture System materials contain components that may cause skin dryness or irritation, sensitization (allergic contact dermatitis), or other allergic reactions in susceptible persons.
  - Skin Contact: Wash thoroughly with soap and water. If skin sensitization occurs, discontinue use. If dermatitis or other symptoms persist, seek medical assistance.
  - Eye Contact: Flush eyes promptly with copious amounts of water for 15 minutes and consult a physician. Wash skin with soap and water.
- Lucitone Digital Print Denture System materials: Avoid inhalation or ingestion. High vapor concentration might induce headache, nausea, and irritation of the eyes and respiratory system. Work in a well-ventilated area. Avoid contact with eyes. Wear eye protection. Excessive long-term exposure may be associated with other more serious health effects.
  - Inhalation: Move subject to fresh air. Give oxygen or artificial respiration as required.
  - Ingestion: Contact your regional Poison Control Center immediately.
- Lucitone Digital Print 3D Denture Base and Lucitone Digital Value 3D Economy Tooth & Trial Placement are suspected of damaging fertility or the unborn child.

- Lucitone Digital Fuse Step 1 - 3D Tooth Conditioning Agent liquid is highly flammable. Keep container tightly closed and use/store away from sources of ignition. Allergic contact dermatitis and other allergic reaction may occur in susceptible individuals. Product may cause skin dryness, sensitization, or other allergic reactions.
- Lucitone Digital Fuse Step 2 – 3D Denture Bonding Resin is suspected of damaging fertility or the unborn child.
- Lucitone Digital Fuse Step 3 - 3D Sealer (liquid/vapor) is highly flammable. Keep containers tightly closed and use/store away from heat or sources of ignition. Suspected of damaging fertility or the unborn child. Toxic to aquatic life with long-lasting effects. Avoid release into the environment.
- Lucitone Digital Fuse Step 3 - Total 3D Sealer (liquid/vapor) is highly flammable. Keep containers tightly closed and use/store away from heat or sources of ignition. May damage fertility or the unborn child. Harmful to aquatic life with long-lasting effects. Avoid release into the environment.
- Dispose of contents and containers in accordance with local and national regulations.

Precautions

- These products are intended to be used only as specifically outlined in the Instructions for Use (IFU). Any use of these products inconsistent with the IFU is at the discretion and sole responsibility of the practitioner.
- Store resins and system components at room temperature 60°F - 80°F (16°C – 27°C) and avoid direct sunlight. Keep containers closed when not in use. Do not use products after expiration dates. Dispose of contents and containers in accordance with local and national regulations.
- Lucitone Digital Print 3D Denture Base, Lucitone Digital IPN 3D Premium Tooth, Lucitone Digital Print 3D Economy Tooth & Trial Placement, and Lucitone Digital Fuse Step 2 - 3D Denture Bonding Resin: When washing a 3D printed appliance with a solvent or polishing the appliance, use in a properly ventilated environment with proper protective masks and gloves. Dispose of unused resins in accordance with local and national regulations.
- Lucitone Digital Fuse Step 1 – 3D Tooth Conditioning Agent: Use in a ventilated workspace. Handle teeth with solvent-resistant gloves and tweezers. The product is sensitive to light - minimize exposure to light and keep the lid on the container to maintain its effective use. The product is very volatile and flammable. Keep away from heat, sparks, and flame. Do not add Lucitone Digital Fuse Step 1 to a warm metal container or while the container is on the electric hotplate.
- Lucitone Digital Fuse Step 3 – 3D Sealer and Lucitone Digital Fuse Step 3 - Total 3D Sealer: Use in a ventilated workspace. Keep bottle tightly closed when not in use. Lucitone Digital Fuse Step 3 sealers are volatile and highly flammable. Keep away from heat, sparks, and flames. The product is sensitive to light - minimize exposure to light and keep the lid on the container to maintain its effective use.

Performance

Meets requirements of ISO 20795-1, Type 4

Adverse Reactions

- Allergic contact dermatitis and other allergic reaction may occur in susceptible individuals. Product may cause skin dryness, sensitization or other allergic reactions.
- Proper ventilation and personal protective equipment should be used when grinding devices as the particulate generated during grinding may cause respiratory, skin and/or eye irritation.

Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local and national regulations.

STEP-BY-STEP INSTRUCTIONS

CAUTION:

- Any unauthorized changes to the process equipment, parameters, or software may result in a device that is out of specification and is not recommended. Contact Dentsply Sirona for a list of compatible components.
- Lucitone Digital Print Denture System workflow validations include processes, materials, equipment, CAD/CAM parameters, and software. Deviations may result in a device that is out of specification. Contact Dentsply Sirona for a list of compatible components.
  - Validated printers for use with the Lucitone Digital Print Denture System: SprintRay Pro 95 [4]
  - Validated hotplates: VWR® Hotplates (REF #906235 and 906237) and OHAUS® Guardian™ 5000 Hotplates (REF #906236 and 906238). [5,6]
  - Validated post-processing units: Dentsply Sirona Digital Cure (REF #909188).
- Use proper ventilation. Wear protective gloves, eye protection, and protective clothing.
- For detailed step-by-step instructions with images, refer to the Dentsply Sirona Print to Finish Illustrated Technique Guide for the specific printer manufacturer.

A. PRINT

1. Follow the CAD manufacturer's instructions to create a .stl file per design. Use the printer's CAM software to upload the .stl file(s) for the print job. [7] **Note:** Ensure the latest software version load for complete material availability.
2. Add resin to the printer and start the printer. [7]

[7] For detailed print instructions refer to the printer manufacturer's Instructions for Use/User Guide and the Dentsply Sirona Illustrated Technique Guide for the specific printer manufacturer.

B. RECYCLE

CAUTION:
- Follow the printer manufacturer's Instructions for Use.
- Do not leave resin in the cassette/vat for an extended period of time; minimize the exposure to ambient light with resin in the cassette/vat, and pour resin back into the bottle immediately after the print job is complete.
- Do not mix resin shades.

1. Filter left-over resin into the original container. Refer to Table I for recycle timeframes.

Table I

Printer	Material	Recycle Timeframe
SprintRay Pro 95	Lucitone Digital Print - 3D Denture Base	up to 3 months
	Lucitone Digital Value - 3D Economy Tooth & Trial Placement	
	Lucitone Digital IPN - 3D Premium Tooth	

C. CLEAN

CAUTION:
- Isopropyl Alcohol is highly flammable. Keep containers tightly closed and use/store away from sources of ignition.

1. Remove the print job from the printer.
2. Detach the part(s) by hand, using moderate pressure, or use a spatula/scraper.
3. Break off the part supports. Leave the bar supports in place - removal will occur after the post-cure step.
4. Place the part(s) in a plastic container, add ≥99% Isopropyl Alcohol (IPA) covering the part(s) and seal with the container lid. **Note:** Use new IPA only for both cycles.
   Cycle 1: Place the container in an ultrasonic bath for two (2) minutes. Remove the container and clean the part(s) using a brush soaked with ≥99% IPA to remove the residual resin.
   Cycle 2: Using new IPA, return the container to the ultrasonic bath for one (1) minute. Once the cycle is complete, remove the container and check the part(s) as it is critical to ensure there is no residual resin. Use a brush soaked with ≥99% IPA to remove any residual resin.
5. Use compressed air to thoroughly dry all parts before the Fuse step.

D. FUSE (BOND)

For Trial Placement (Try-In Appliances) skip to section E.

Table II

Summary of Fuse Steps	Digital Tooth Materials
	Lucitone Digital IPN
Tooth Preparation for Milled Denture Teeth	Not Applicable
Tooth Preparation for Printed Denture Teeth	Remove the printing supports, open the interproximals, shape/contour the teeth, and clean debris with IPA.
Dry Fit	Place the tooth segments, full arch, or single teeth into the denture base. Some gaps may be visible within the pockets - these gaps will be filled with Fuse Step 2 resin.
Lucitone Digital Fuse Step 1 - 3D Tooth Conditioning Agent	Not Applicable
Lucitone Digital Fuse Step 2 - 3D Denture Bonding Resin	See Table IV **Single Teeth, Segments or Full Arch**
Lucitone Digital Fuse Step 3 *Sealers*	See Table V **Lucitone Digital IPN**

Lucitone Digital Fuse Step 2 - 3D Tooth Bonding Resin

CAUTION:

- Use proper ventilation. Wear protective gloves, eye protection, and protective clothing.
- Keep the metal container and the foam insert free of any solid buildup. Buildup can compromise the tooth bond strength.

Table III

	Single Teeth	Segments	Full Arch
1	Apply Step 2 resin to tooth pocket(s) - no more than two teeth at a time - avoiding adjacent pockets.	Apply Step 2 resin to tooth quadrant indentation on the denture base.	Apply Step 2 resin to full arch indentation on the denture base.
2	Insert **tooth/teeth**, fully seat, and clean excess resin with 4X4 gauze.	Insert **segment**, fully seat, and clean excess resin with 4X4 gauze.	Insert **full arch**, fully seat, and clean excess resin with 4X4 gauze.
3	Tack cure the buccal and lingual surfaces with the UV Tack-Cure Light for ten seconds, two teeth at a time.		
4	Repeat above steps 1-3 for any remaining teeth.	Repeat above steps 1-3 for remaining segments.	Not Applicable

NOTE: Fuse Step 2 is available in all Lucitone Digital Print 3D Denture Base shades. Original shade may be used as a universal shade option except for with dark reddish pink.

Lucitone Digital Fuse Step 3 Sealers

For Lucitone Digital IPN (premium printed teeth), only use Step 3 – Total – see Table IV.

Table IV

Sealers	Lucitone Digital IPN
OPTION 1 Lucitone Digital Fuse Step 3 - **3D Sealer**	Not Applicable - Only use Step 3 Total
OPTION 2 Lucitone Digital Fuse Step 3 - **Total**	Apply a thin layer of Total sealer to the entire tooth structures, including the cervicals, using a flat brush. Optional (not required): Apply the sealer to all or part of the denture base surface (including the intaglio/tissue) per laboratory preference.

E. CURE

CAUTION:
- Only use validated post-processing units: Dentsply Sirona Digital Cure. Read the curing unit User Manual prior to operating the unit.
- Failure to follow specific cure instructions will result in poor appliance strength, bond, and accuracy.

Table V
The post processing units are validated for the following Lucitone Digital Print Denture System materials and appliances:

Application	Dentsply Sirona Digital Materials	Appliance Type
Denture Base	Lucitone Digital Print 3D Denture Base	Denture
Denture Teeth	Lucitone Digital IPN 3D Premium Tooth	
Denture Try-In	Lucitone Digital Value 3D Economy Tooth & Trial Placement	Denture/Try-In

CURE UNIT: Dentsply Sirona Digital Cure

CAUTION:
- Do not stack appliances - correct positioning is a requirement for proper cure.
- Appliance quantity per cure cycle varies by appliance sizes - do not exceed five (5) appliances per cure cycle. Regardless of the appliance quantity, always place appliances with the anterior facing the center of the turntable.
- Allow appliances cleaned with Isopropyl alcohol to dry completely before post-processing due to flammability.
- Once the program cycle starts do not stop and restart, open the door, or add appliances; a complete, uninterrupted program run is required.
- Regardless of the appliance quantity, always use the Lucitone menu selection (preset). Do not use the custom menu selection to process Lucitone Digital Print Denture appliances.
- Failure to follow specific cure instructions will result in poor appliance strength, bond, and accuracy.

Table VI

Menu Selection		Total Time
Lucitone		Approximately 60 minutes (maximum 70 minutes)
1	Place the appliance(s) on the turntable, occlusal side up, and the anterior facing the center of the turntable. Load multiple appliances using the Start/stop button to the right of the menu dial. Hold the power button to rotate the turntable and place the appliances. Ensure the appliance(s) do not overlap or extend beyond the turntable. Do not load more than five appliances per cycle.	
	IMPORTANT: When curing one appliance, do not place the appliance in the center of the turntable covering the turnable spindle. Ensure the appliance is facing anterior towards the center and approximately 1 cm from the turntable spindle/center.	
2	In the home menu screen, use the menu dial to toggle and select (push menu dial) the "Preset Cycle" setting and then the "Lucitone" program. Hold the Start/stop button until the unit beeps to start the program. The program will automatically run and advance through the following steps: **LED Test Cycle** - 20 seconds, **Tack curing** - 12 seconds, **Heating** - 10 to 15 minutes, **Curing** - 25 minutes, and **Cooling** - up to 30 minutes. Synchronous dots will appear behind the step name on the menu screen indicating the program operation. Note: the chamber is lit during the Tack Curing and Curing steps only. Following the final step, the menu screen "Program Complete" will appear indicating the program completion. The appliances are ready for removal.	

F. FINISH

CAUTION:

- Use proper ventilation and personal protective equipment when grinding devices as the particulate generated during grinding may cause respiratory, skin, and/or eye irritation.
- Do not steam clean Lucitone Digital Print Denture appliances.

1. Remove bar supports using a cut-off disc or similar tool. Grind away any remaining support structure.
2. Finish, festoon, stipple, and polish as desired.

Dentures sealed with Lucitone Digital Fuse Step 3 - *Total* require minimal polishing.

IMPORTANT: Avoid extensive polishing for dentures designed with the Dentsply Sirona Highly Characterized Denture Tooth Libraries to preserve the premium features and characterization.

G. REPAIRS

CAUTION: Do not steam clean Lucitone Digital Print Denture appliances.

Table IX

	Surface	Fracture [8]
1	Not Applicable	Tack fractured denture with adhesive glue or sticky wax. Fabricate a putty model with silicone putty.
2	Grind and roughen the repair surface with a carbide bur.	
3	Not Applicable	Not Applicable
4	Apply Lucitone Digital Fuse Step 1 to the repair area and air-dry for 1 minute.	
5	Not Applicable	Secure the denture on the putty model with sticky wax or similar type material.
6	Apply Lucitone Digital Fuse Step 2 to the repair area with a brush. Allow the material to flow into the repair area to avoid air pockets - do not brush.	
7	Tack cure with the UV Tack-Cure Light for 10 seconds. Repeat Lucitone Digital Fuse Step 2 and UV light cure to achieve a desired thickness.	
8	**IPN 3D:** Apply a thin layer of Lucitone Digital Fuse Step 3 (3D Sealer or Total) to the margins and interproximals using a flocked applicator tip. **Surface & Fracture:** Apply Lucitone Digital Fuse Step 3 (3D Sealer or Total) to the repair area.	
9	**Dentsply Sirona Digital Cure:** In the home menu screen, use the menu dial to toggle and select (push menu dial) the "Preset Cycle" setting and then the "Lucitone" program. Hold the Start/stop button until the unit beeps to start the program. The program will automatically run and advance through the following steps: **LED Test Cycle** - 20 seconds, **Tack curing** - 12 seconds, **Heating** - 10 to 15 minutes, **Curing** - 25 minutes, and **Cooling** - up to 30 minutes. Synchronous dots will appear behind the step name on the menu screen indicating the program operation. Note: the chamber is lit during the Tack Curing and Curing steps only. Following the final step, the menu screen "Program Complete" will appear indicating the program completion. The appliances are ready for removal.	
10	Finish and polish the denture using conventional techniques.	

[8] Lucitone® HIPA - High Impact Pour Acrylic is an alternative fracture repair technique. Refer to the Lucitone HIPA - High Impact Pour Acrylic Instructions for Use "Repair Procedure" section for step-by-step instructions.

H. RELINE

Hard Reline

Refer to the Lucitone® HIPA - High Impact Pour Acrylic Instructions for Use “Indirect Reline Procedure” section for step-by-step instructions.

Soft Reline

The following materials are compatible for use with Lucitone Digital Print Dentures:

- Tokuyama SOFRELINER TOUGH® Soft and SOFRELINER TOUGH® Medium [9]
- GC Corporation GC RELINE™ II Soft, RELINE™ II Extra Soft, and GC RELINE™ II Extra Extra Soft [10]

QUESTIONS AND SUPPORT

USA - Email: dsdigitaldentures@dentsplysirona.com or Phone: 800-243-1942.

CANADA - Contact your local Dentsply Sirona Representative.

OUTSIDE OF NORTH AMERICA - Contact your local Dentsply Sirona Representative.

[4] SprintRay Pro 95 is a trademarks of SprintRay Inc.
[5] VWR is a registered trademark of VWR International, LLC.
[6] OHAUS and Guardian are trademarks of OHAUS Corporation.
[9] SOFRELINER TOUGH® Soft and SOFRELINER TOUGH® Medium are registered trademarks of Tokuyama Corporation.
[10] GC RELINE™ II Soft, RELINE™ II Extra Soft and GC RELINE™ II Extra Extra Soft are trademarks of GC Corporation.

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