

GB  
US

## 1. Intended use / Indication

Light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of dental appliances. **SprintRay EU Temporary Crown & Teeth** is indicated for the fabrication, by additive manufacturing, of temporary dental restorations, and for the fabrication of preformed denture teeth to be used in a denture.

## 2. Contraindication

**SprintRay EU Temporary Crown & Teeth** restorations are contraindicated ...

- ... if a patient is known to be allergic to any of the ingredients.
- ... for bridges with more than one pontic.
- ... for every application that is not part of the indication (see above).

## 3. Patient Target Group

Persons being treated in the context of a dental procedure.

## 4. Intended Users

Dentist, dental technician

## 5. Requirements

### Software:

- RayWare (CAD)

### Hardware:

- Pro Desktop 3D (3D Printing)
- Pro Wash / Dry (Cleaning)
- ProCure (Post Curing)

SprintRay, Inc., 3577 North Figueroa St., Los Angeles, CA 90065

## 6. Material

**SprintRay EU Temporary Crown & Teeth** consists of functional (meth)acrylic resins and inorganic fillers with particle sizes from 0.4 to 3 microns.

## 7. Geometric presetting

Connector areas (minimum):

anterior bridges	12 mm <sup>2</sup>
posterior bridges	14 mm <sup>2</sup>

Minimum wall thickness:

occlusal	1.5 mm (central fissure)
circumferential	1 mm

## 8. Material parameters

Radiation penetration depth controllable by exposure time

- ≥ 100 µm (4 mils)
- ≥ 125 µm (5 mils)

\* These data come from measurements of a representative sample that was determined as part of our quality assurance. / \* Diese Daten stammen aus Messungen einer repräsentativen Probe, die im Rahmen unserer Qualitätssicherung ermittelt wurden. / \* Ces données proviennent des mesures d'un représentant échantillon qui a été déterminé dans le cadre de notre assurance qualité. / \* Estos datos provienen de mediciones de una representativa muestra que se determinó como parte de nuestra garantía de calidad. / \* Questi dati provengono dalle misurazioni di una rappresentativa campione che è stato determinato nell'ambito della nostra garanzia di qualità.

\*\* According to internal design and requirements specifications / \*\* Gemäß internen Design- und Anforderungsspezifikationen / \*\* Selon la conception interne et les spécifications des exigences / \*\* Según especificaciones de diseño y requisitos internos / \*\* Secondo la progettazione interna e le specifiche dei requisiti

## 9. Manufacturing process (fig. 1-10)

1. Prepare data (RayWare).
2. Choose prepared parameters (build style, etc.).
3. Transfer prepared data to 3D printing device.
4. Prepare 3D printing – shake bottle.
5. Fill resin tank of 3D printing device.
6. Build the parts.
7. Clean parts (ProWash / Dry):  
- blow surplus resin out of cavities with pressured air before washing  
- wash 5 min. / 5 min.
8. Dry parts (ProWash / Dry):  
- 3 min.  
- additional: dry with pressured air as required
9. Post curing (ProCure): 5 min. / 60°C.
10. Finish parts.

## 10. Individualization and cementation

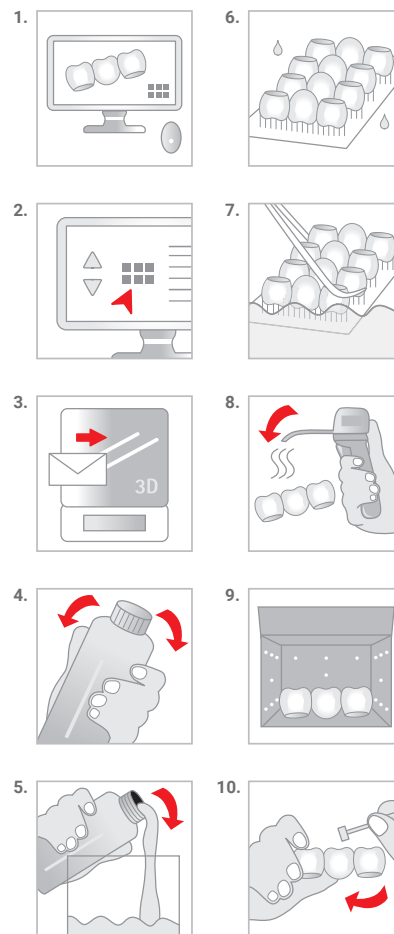
The temporary restorations can be individualized by light curing composite materials. The reduction of the restoration should not exceed 0.3 mm (incisal and vestibular area). Please follow the instructions of the light curing composite manufacturers. For cementation common provisional dental cements (free of Eugenol) and adhesives are suitable. The inner areas of the crown should be conditioned by sandblasting or other commonly used techniques. Please follow the instructions and indications of the corresponding manufacturers.

## 11. Notice

Please follow the instructions provided by the software manufacturer in terms of parameter settings and design recommendations. Please follow the instructions provided by the hardware manufacturer in terms of parameter settings/printing & post curing recommendations. To avoid detrimental effects on material quality do not expose the liquid material to irradiation under any circumstances. Deviations from the described manufacturing processes or storing conditions may lead to different mechanical and optical properties of the material. Ensure personal protective gear during processing. According to the EU Medical Devices Regulation, users/patients are obliged to report serious events with a medical device to the manufacturer and to the competent authority of the country in which they occurred. **Caution:** The lot number and the best before date are indicated on each packaging. In case of claims please always indicate the lot number of the product. Do not use the product after expiry of the best before date. Avoid breathing dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor/physician if you feel unwell. Specific treatment (see information on this label). If skin irritation occurs: Get medical advice/attention. If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Collect spillage. Store in a well-ventilated place. Keep container tightly closed. Store locked up. Dispose of contents/container according to official regulations.

## 12. Hazard statements

Causes skin irritation. May cause an allergic skin reaction. Causes serious eye damage. May cause respiratory irritation. Harmful to aquatic life with long lasting effects.



Physical properties\*/  
 Physikalische Eigenschaften\*/  
 Propriétés physiques\*/  
 Propiedades físicas\*/  
 Proprietà fisiche\*:

Ordering information/  
 Bestellinformationen/  
 Informations de commande/  
 Información sobre pedidos/  
 Informazioni sull'ordine:

### SprintRay EU Temporary Crown & Teeth

■ Flexural strength/  
 Biegefestigkeit/  
 Résistance à la flexion/  
 Fuerza flexible/  
 Resistenza alla flessione  
 MPa (ISO 4049):  
 > 100

■ Modulus of elasticity/  
 Elastizitätsmodul/  
 Module d'élasticité/  
 Modulo di elasticità/  
 Módulo de elasticidad  
 MPa (ISO 4049):  
 > 2000

■ Water absorption/  
 Wasseraufnahme/  
 Absorption de l'eau/  
 Absorción de agua/  
 Assorbimento dell'acqua:  
 complies with/ erfüllt/  
 est conforme/ conforme a/  
 cumple con ISO 10477

■ Solubility/  
 Löslichkeit/  
 Solubilité/  
 Solubilidad/  
 Solubilità:  
 complies with/  
 erfüllt/  
 est conforme/  
 cumple con/  
 conforme a  
 ISO 10477

■ Inorganic filler/  
 Anorganischer Füllstoff/  
 Charge inorganique/  
 Relleno inorgánico/  
 Riempitivo inorganico:  
 40.0 m-%

**1 kg:**  
 λ ≤ 405 nm

**A1**  
 REF: SRE-1001441

**A2**  
 REF: SRE-1001442

**A3**  
 REF: SRE-1001443

**A3.5**  
 REF: SRE-1001617

**B1**  
 REF: SRE-1001618

**B2**  
 REF: SRE-1001623

**bleach**  
 REF: SRE-1001624



This side up.  
 Diese Seite nach oben.  
 Ce côté vers le haut.  
 Este lado hacia arriba.  
 Questo lato in su.



Temperature limit  
 Temperaturgrenze  
 Limite de température  
 Límite de temperatura  
 Limite di temperatura



Warning  
 Achtung  
 Attention  
 Attenzione



Do not use if package is damaged.  
 Nicht verwenden, wenn das Paket beschädigt ist.  
 Ne pas utiliser si l'emballage est endommagé.  
 No lo use si el paquete está dañado.  
 Non usare se il pacchetto è danneggiato.



Consult instructions for use.  
 Gebrauchsanweisung beachten.  
 Consulter le mode d'emploi.  
 Consultar instrucciones de uso.  
 Consultare le istruzioni per l'uso.



Keep away from sunlight.  
 Von Sonnenlicht fernhalten.  
 Eloigner du soleil.  
 Mantener alejado de la luz solar.  
 Tenere lontano dalla luce del sole.

Rx only

QTY: 1EA



Medical Device  
 Medizinprodukt  
 Dispositif médical  
 Producto sanitario  
 Dispositivo medico



Use by date  
 Haltbarkeitsdatum  
 Utiliser par date  
 Utilizar por fecha  
 Usare entro la data



Catalogue number  
 Katalognummer  
 Numéro de catalogue  
 Número de catálogo  
 Numero di catalogo



Lot number  
 Chargennummer  
 Numéro de lot  
 Número de lote  
 Numero di lotto



Date of manufacture  
 Herstellungsdatum  
 Date de fabrication  
 Fecha de manufactura  
 Data di produzione



Manufacturer:  
 pro3dure medical GmbH  
 Am Burgberg 13 · 58642 Iserlohn, Germany  
 Phone: +49 (0)2374 920050-0  
 info@pro3dure.com · www.pro3dure.com · Made in Germany

Distributor:  
 SprintRay Europe GmbH  
 Brunnenweg 11 · 64331 Weiterstadt · Germany

