

1. Intended use / Indication

Light-curable polymerizable resin intended to be used in conjunction with extraoral curing light equipment for the fabrication, by additive manufacturing, of dental appliances. Indicated for the fabrication and repair of full and partial removable dentures and baseplates.

2. Contraindication

ACRY Print 3D RU-004 Denture HI

restorations are contraindicated ...

- ... if a patient is known to be allergic to any of the ingredients.
- ... direct intraoral contact of uncured or partially uncured material.
- ... 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 - information available from:

exocad GmbH • Julius-Reiber-Strasse 37, 64293 Darmstadt, Germany

Hardware (3D Printing) - information available from:

ASIGA • 2/19-21 Bourke Road, Alexandria, NSW 2015, Australia

Hardware (Post Curing) - information available from:

pro3dure medical (CD-1, CD-2) • Am Burgberg 13, D-58642 Iserlohn, Germany

Additional specifications on www.pro3dure.com.

6. Material

ACRY Print 3D RU-004 Denture HI consists of functional (meth)acrylic resins, initiators, dyes and stabilisers.

7. Geometric presetting

- Lingual Ridge** ≥ 2.5 mm (Maxilla / Mandibula)
- Palatal/Lingual** ≥ 3.0 mm (Maxilla) / ≥ 2.5 (Mandibula)
- Facial/Buccal** ≥ 2.5 mm (Maxilla / Mandibula)

8. Material parameters

Radiation penetration depth controllable by exposure time
≥ 50 µm (4 mils)
≥ 100 µm (5 mils)

9. Manufacturing process (fig. 1-10)

- Prepare data (CAD & build preparation).
- Choose process parameters (build style, etc.).
- Transfer prepared data to 3D printing device.
- Prepare 3D printing – shake bottle.
- Fill resin tank of 3D printing device.
- Build the parts.
- Clean parts (with IPA ≥ 97 % or equivalent cleaning agent) approx. 4 min. in an ultrasonic bath or equivalent device – precleaning recommended.
- Dry parts, until there are no residues of IPA or equivalent cleaning agent.
- Post curing (10 min.): inert atmosphere recommended (use adequate light curing device).
- Finish parts.

10. Bonding of denture teeth

If using printed denture teeth – see additional IFU **ACRY Print 3D RU-001 Temporary It** for details. In order to realize the optimal bonding of artificial teeth to the dental object, it can be necessary to roughen the surface of the denture and to use an appropriate adhesive. The suitability of a bonding agent or adhesive must be approved prior use. Recommended bonding agent is VITA VIONIC® BOND. The commonly used techniques and dental work steps must be carefully considered when manufacturing the dentures. Please follow the instructions and indications of the corresponding suppliers.

11. Notice

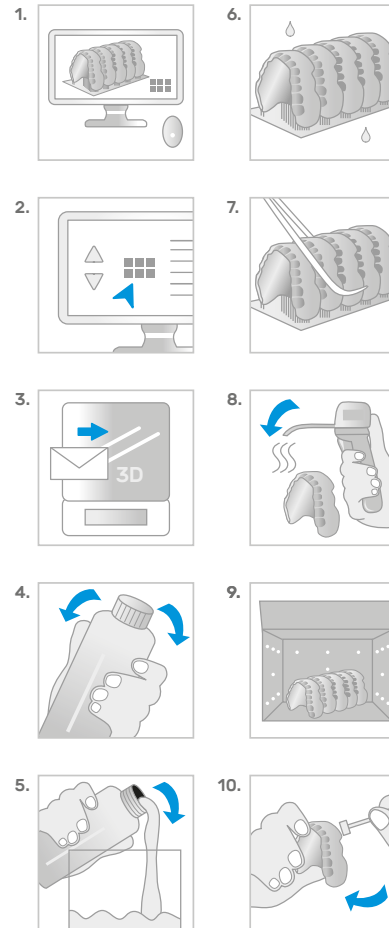
Please follow the instructions provided by the software manufacturer in terms of parameter settings and design recommendations. Please follow the instructions provided by the hardware manufacturer in terms of parameter settings/printing & post curing recommendations. To avoid detrimental effects on material 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:** 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. 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 or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash before reuse. Store in a well-ventilated place. Keep container tightly closed. Store locked up. Dispose of contents/container according to official regulations. Avoid re-release to the environment.

12. Hazard statements

Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause respiratory irritation.

RU-004 Denture HI

Instructions for use
Gebrauchsanweisung
Mode d'emploi • Instrucciones de uso
Istruzioni per l'uso
Instruções de utilização



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

**ACRY Print 3D
RU-004 Denture HI**

- Shore hardness D / Shore-Härte D / Dureté Shore D / Durezza Shore D / Durezza Shore D (ISO 48-4): > 80**
- Flexural strength / Biegefestigkeit / Résistance à la flexion / Fuerza flexible / Resistenza alla flessione / Resistência à flexão MPa (ISO 20795-1): ≥ 65
- Bending module / Biegemodul / Module de pliage / Módulo de flexión / Modulo di piegatura / Módulo de flexão MPa (ISO 20795-1): ≥ 2000
- Water absorption / Wasseraufnahme / Absorption de l'eau / Absorción de agua / Assorbimento dell'acqua / Absorção de água µg/mm³ (ISO 20795-1): ≤ 32
- Solubility / Löslichkeit / Solubilité / Solubilidad / Solubilità / Solubilidade µg/mm³ (ISO 20795-1): ≤ 1,6
- Fracture toughness / Bruchzähigkeit / Résistance à la rupture / Resistencia a la fractura / Resistenza a rottura / Resistência à fratura (ISO 20795-1): ≥ 1.9 MPa*m^(1/2)
- Total work of fracture / Gesamtbrucharbeit / Travail jusqu'à la rupture totale / Trabajo total de fractura / Lavoro totale di rottura (ISO 20795-1): ≥ 900 J/m²

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

**ACRY Print 3D
RU-004 Denture HI**

1 kg:
λ ≤ 405 nm

**orange-pink /
orange-pink /
orange-rose /
rosa-naranja /
rosa-arancione
rosa/laranja**
REF: 0220004

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

CE 0044 Made in Germany

* 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 un rappresentante 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

This side up. Diese Seite nach oben. Ce côté vers le haut. Estado lado arriba. Questo lato in su. Este lado para cima.	Temperature limit Temperaturgrenze Limite de temperatura Limite de temperatura Limite de temperatura	Warning Achtung Attention Atención Attenção:	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. Não utilizar se a embalagem estiver danificada.	Consult instructions for use. Gebrauchsanweisung beachten. Consulter le mode d'emploi. Consultar instrucciones de uso. Consultare le istruzioni per l'uso. Consultar as instruções de utilização.	Keep away from sunlight. Von Sonnenlicht fernhalten. Éloigner du soleil. Mantener alejado de la luz solar. Tenere lontano dalla luce del sole. Manter afastado da luz solar.	Rx only QTY: 1EA	Medical Device Medizinprodukt Dispositif médical Producto sanitario Dispositivo médico Dispositivos médicos	Use by date Haltbarkeitsdatum Utiliser par date Utilizar por fecha Usare entro la data Data limite de utilização	Catalogue number Katalognummer Número de catálogo Número de catálogo Número de catálogo	Lot number Chargennummer Número de lote Número de lote Número de lote	Date of manufacture Herstellungsdatum Date de fabrication Fecha de manufactura Data di produzione Data de fabrico

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