

GB 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. Indicated for the fabrication and repair of full and partial removable dentures and baseplates.

2. Contraindication

printo[®] GR-14.2 denture HI restorations are contraindicated ...
1. ... if a patient is known to be allergic to any of the ingredients.
2. ... direct intraoral contact of uncured or partially uncured material.
3. ... 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:

cocad 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

printo[®] GR-14.2 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
≥ 100 µm

9. Manufacturing process (fig. 1–10)

1. Prepare data (CAD & build preparation).
2. Choose process 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 (with IPA ≥ 97 % or equivalent cleaning agent) approx. 4 min. in an ultrasonic bath or equivalent device – precleaning recommended.
8. Dry parts, until there are no residues of IPA or equivalent cleaning agent.
9. Post curing (10 min.): inert atmosphere recommended (use adequate light curing device).
10. Finish parts.

10. Bonding of denture teeth

If using printed denture teeth – see additional IFU **printo[®] GR-17.1 temporary II** 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.

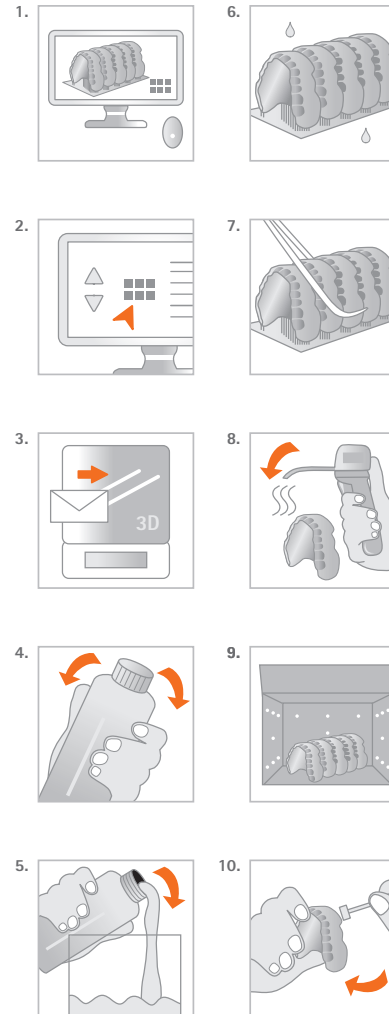
11. Notice

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:** 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. 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.

12. Hazard statements

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

UMDNS 16-697



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

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

printo[®] GR-14.2 denture HI

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■ Shore hardness D/
Shore-Härte D/
Dureté Shore D/
Durezza Shore D
(ISO 48-4):
> 80 **

1 kg:
λ ≤ 405 nm

■ Flexural strength/
Biegefestigkeit/
Résistance à la flexion/
Fuerza flexible/
Resistenza alla flessione
MPa (ISO 20795-1):
≥ 65

orange-pink/
orange-pink/
orange-rose/
rosa-naranja/
rosa-arancione
REF: D1001311

■ Bending module/
Biegemodul/
Module de pliage/
Módulo de flexión/
Modulo di piegatura
MPa (ISO 20795-1):
≥ 2000

light-pink/
hell-pink/
rosa-clair/
rosa-claro/
rosa-chiaro
REF: D1001312

■ Water absorption/
Wasseraufnahme/
Absorption de l'eau/
Absorción de agua/
Assorbimento dell'acqua
µg/mm³ (ISO 20795-1):
≤ 32

deep-pink/
dunkel-pink/
rosa-profond/
rosa-scuro
REF: D1001313

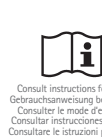
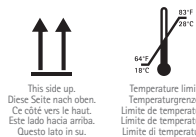
■ Solubility/
Löslichkeit/
Solubilité/
Solubilidad/
Solubilità
µg/mm³ (ISO 20795-1):
≤ 1,6

original-pink/
original-pink/
rosa-original/
rosa-originale
REF: D1001319

■ Fracture toughness/
Bruchzähigkeit/
Résistance à la rupture/
Resistencia a la fractura/
Resistenza a rottura
(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

* 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 rappresentativo 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.
*** on the basis of ... / in Anlehnung an ... / s'ispirant de ... / basado en ... / sulla base di ...
**** not applicable / nicht anwendbar / non applicable / no applicable / non applicabile



Rx only
QTY: 1EA



Manufacturer:
pro3dure medical GmbH
Am Burgberg 13 · 58642 Iserlohn, Germany
Phone: +49 (0)2374 920050-0

Distributor (US):
pro3dure medical LLC
9825 Valley View Road · Eden Prairie, MN 55344
Phone: +1 (952) 426-1928

info@pro3dure.com · www.pro3dure.com · Made in Germany

