

GB 1. Intended use / Indication

US 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. **printodont[®] GR-17 temporary** is indicated for the fabrication, by additive manufacturing, of temporary anterior dental restorations. **printodont[®] GR-17.1 temporary It** 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

printodont[®] GR-17 temporary and **printodont[®] GR-17.1 temporary It** restorations are contraindicated ...

1. ... if a patient is known to be allergic to any of the ingredients.
2. ... for bridges with more than one pontic.
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:

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

printodont[®] GR-17 temporary and **printodont[®] GR-17.1 temporary It** consists of functional methacrylic resins and inorganic fillers with particle sizes from 0.4 to 3 microns.

7. Geometric presetting

Connector areas (minimum):

anterior bridges 12 mm²
posterior bridges 14 mm²

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)

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 (with compressed air until 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. 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

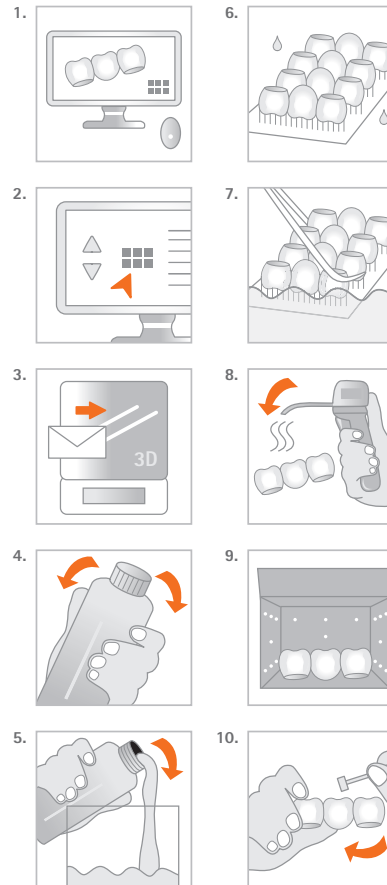
Please follow the instructions provided by the software manufacturer in terms of parameter settings and design recommendations. Please follow the instructions provided by the hardware manufacturer in terms of parameter settings/printing & post curing recommendations. To avoid detrimental effects on material 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:** 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 irritation. May cause respiratory irritation. Toxic to aquatic life with long lasting effects.

Generative Resin
GR-17 temporary
GR-17.1 temporary It

Instructions for use · Gebrauchsanweisung
Mode d'emploi · Instrucciones de uso
Istruzioni per l'uso



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

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

printodont[®] GR-17 temporary

- Flexural strength/ Biegefestigkeit/ Résistance à la flexion/ Fuerza flexible/ Resistenza alla flessione: > 50 MPa DIN EN ISO 10477
- Modulus of elasticity/ Elastizitätsmodul/ Module d'élasticité/ Modulo di elasticità/ Módulo de elasticidad: > 2000 MPa DIN EN ISO 10477
- Water absorption/ Wasseraufnahme/ Absorption de l'eau/ Absorción de agua/ Assorbimento dell'acqua: complies with/ erfüllt/ est conforme/ conforme a/ cumple con DIN EN ISO 10477
- Solubility/ Löslichkeit/ Solubilité/ Solubilidad/ Solubilità: complies with/ erfüllt/ est conforme/ cumple con/ conforme a DIN EN ISO 10477
- Inorganic filler/ Anorganischer Füllstoff/ Charge inorganique/ Relleno inorgánico/ Riempitivo inorganico: 20.0 m-%

printodont[®] GR-17 temporary

1 kg: λ ≤ 405 nm
A1 REF: D1001432
A2 REF: D1001433
A3 REF: D1001431
A3.5 REF: D1001615
B1 REF: D1001616
B2 REF: D1001627
bleach REF: D1001629

500 g: λ ≤ 405 nm

A1 REF: D1001444
A2 REF: D1001445
A3 REF: D1001446
A3.5 REF: D1001619
B1 REF: D1001621
B2 REF: D1001628
bleach REF: D1001630

printodont[®] GR-17.1 temporary It

- Flexural strength/ Biegefestigkeit/ Résistance à la flexion/ Fuerza flexible/ Resistenza alla flessione: > 100 MPa DIN EN ISO 4049
- Modulus of elasticity/ Elastizitätsmodul/ Module d'élasticité/ Modulo di elasticità/ Módulo de elasticidad: > 2000 MPa DIN EN ISO 4049
- Water absorption/ Wasseraufnahme/ Absorption de l'eau/ Absorción de agua/ Assorbimento dell'acqua: complies with/ erfüllt/ est conforme/ conforme a/ cumple con DIN EN ISO 10477
- Solubility/ Löslichkeit/ Solubilité/ Solubilidad/ Solubilità: complies with/ erfüllt/ est conforme/ cumple con/ conforme a DIN EN ISO 10477
- Inorganic filler/ Anorganischer Füllstoff/ Charge inorganique/ Relleno inorgánico/ Riempitivo inorganico: 40.0 m-%

printodont[®] GR-17.1 temporary It

1 kg: λ ≤ 405 nm
A1 REF: D1001441
A2 REF: D1001442
A3 REF: D1001443
A3.5 REF: D1001617
B1 REF: D1001618
B2 REF: D1001623
bleach REF: D1001624

500 g: λ ≤ 405 nm

A1 REF: D1001612
A2 REF: D1001613
A3 REF: D1001614
A3.5 REF: D1001620
B1 REF: D1001622
B2 REF: D1001625
bleach REF: D1001626

* 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 representante muestra que se determinó como parte de nuestro gobierno de calidad. / * Questi dati provengono dalle misurazioni di un rappresentante campione che è stato determinato nell'ambito della nostra garanzia di qualità.

↑↑ 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 / Limite de temperatura / Limite di temperatura

CE mark / CE Zeichen / CE marque / CE marca / CE marchio

Warning / Achtung / Attention / Atención / 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.

Rx only

QTY: 1EA

Medical Device / Medizinprodukt / Dispositif médical / Producto sanitario / Dispositivo medico

Use by date / Haltbarkeitsdatum / Utiliser par date / Usare entro la data

REF

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

LOT

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

Distributor (US):
pro3dure medical LLC
9825 Valley View Road · Eden Prairie, MN 55344
Phone: 952-426-1928 · Fax: 952-681-7515
info@pro3dure.com · www.pro3dure.com · Made in Germany

