

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 of drill-guides and splints.

2. Contraindication

IMPRIMO® LC Splint is contraindicated...

- ... if a patient is known to be allergic to any of the ingredients
- ... for bruxism splints and splints with wall thickness ≤ 1.5 mm
- ... for denture bases
- ... 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 technicians

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

IMPRIMO® LC Splint consists of functional (meth)acrylic resins, initiators, dyes and stabilisers.

7. Geometric presetting

Minimum wall thickness: 1.5 mm

8. Material parameters

Radiation penetration depth controllable by exposure time

50 μ m

100 μ m

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 $\geq 97\%$ 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 (4 min.): inert atmosphere recommended (use adequate light curing device).
- Finish parts.

10. Finishing processes

Polishing

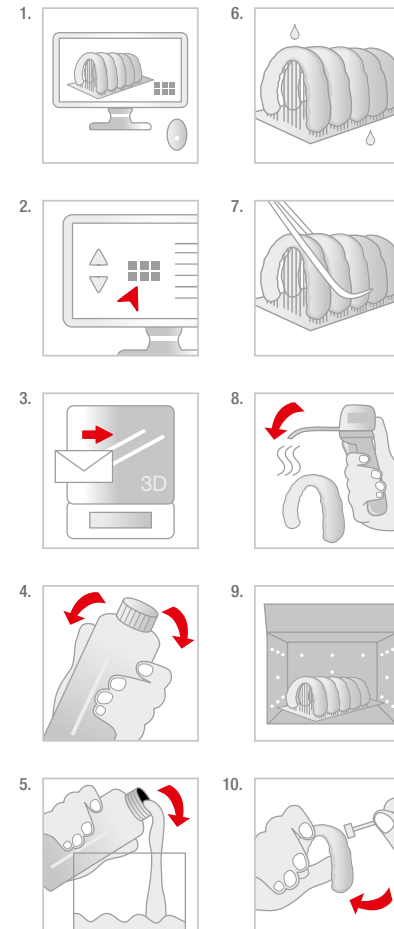
11. Notice

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. 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. 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.

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



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

IMPRIMO® LC Splint

■ 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
MPa (ISO 20795-2):
≥ 50

■ Bending module/
Biegemodul/
Module de pliage/
Módulo de flexión/
Modulo di piegatura
MPa (ISO 20795-2):
≥ 1500

■ Water absorption/
Wasseraufnahme/
Absorption de l'eau/
Absorción de agua/
Assorbimento dell'acqua
 μ g/mm³ (ISO 20795-2):
≤ 32

■ Solubility/
Löslichkeit/
Solubilité/
Solubilidad/
Solubilità
 μ g/mm³ (ISO 20795-2):
< 5

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

IMPRIMO® LC Splint

1 kg:
 $\lambda \leq 405$ nm

clear-transparent/
klar-transparent/
incoloro-transparent/
incoloro-transparente/
incoloro-transparente

REF: 6503.1

* 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.



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



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.
Vor Sonnenlicht fernhalten.
Éloigner du soleil.
Mantenere 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
Número de catalogue
Número de catalogo
Numero di catalogo



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



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

Manufactured by:

pro3dure medical GmbH
Am Burgberg 13
D-58642 Iserlohn, Germany
Phone: +49 2374 920050-0

info@pro3dure.com
www.pro3dure.com



Made in Germany

Manufactured for & distributed by:

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