

**1. Intended use / Indication**

The IMPRIMO® LC Splint comfort MSI resin is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of dental objects such as mouthguards, night-guards, splints, repositioners and retainers.

**2. Contraindication**

IMPRIMO® LC Splint comfort MSI is contraindicated ...

1. ... if a patient is known to be allergic to any of the ingredients.
2. ... for bruxism splints and splints with wall thickness ≤ 1.5 mm.
3. ... for denture bases.
4. ... for every application that is not part of the indication (see above).

**3. Product Description**

The IMPRIMO® LC Splint comfort MSI resin includes a lactam-based, biomimetic solution for multi-species inhibition\*. This reduces the formation of undesirable biofilms on orthodontic appliances without a microcidal effect.

\*c. albicans / s. mutans

**4. Patient Target Group**

Persons being treated in the context of a dental procedure.

**5. Intended Users**

Dentist, dental technicians

**6. 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](http://www.pro3dure.com)

**7. Material**

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

**8. Geometric presetting**

Minimum wall thickness: 1.5 mm

**9. Material parameters**

Radiation penetration depth controllable by exposure time

50 µm

100 µm

**10. 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 (4 min.): inert atmosphere recommended (use adequate light curing device).
10. Finish parts.

**11. Finishing processes**

Polishing

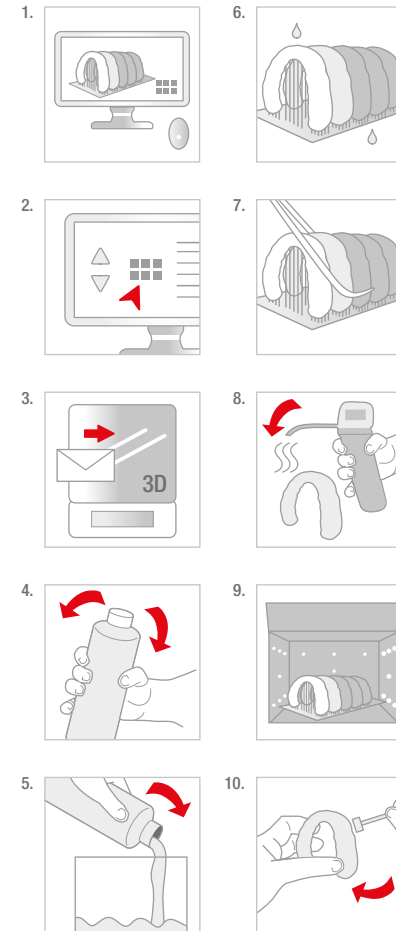
**12. Notice**

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:** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust/fume/gas/mist/vapours/spray. 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 IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **IF exposed or concerned:** Call a POISON CENTER/doctor. 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 locked up. Dispose of contents/container according to official regulations.

**13. Hazard statements**

Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. Suspected of damaging the unborn child. Toxic to aquatic life with long lasting effects.

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 comfort MSI

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

■ Ultimate flexural strength/  
Biegefestigkeit/  
Résistance à la flexion/  
Fuerza flexible/  
Resistenza alla flessione  
MPa (ISO 20795-2):  
≥ 50 \*\*

■ Flexural modulus/  
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  
µg/mm<sup>3</sup> (ISO 20795-2):  
≤ 32

■ Solubility/  
Löslichkeit/  
Solubilité/  
Solubilidad/  
Solubilità  
µg/mm<sup>3</sup> (ISO 20795-2):  
≤ 5

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

IMPRIMO® LC Splint comfort MSI

1 kg:  
λ ≤ 405 nm

ocean-blue/  
ocean-blau/  
bleu océan/  
azul oceano/  
blu oceano

REF: 6575.1

\* not applicable / nicht anwendbar / non applicable / no applicable / non applicabile

\*\* on the basis of / in Anlehnung an / s'inspirant de / basado en / sulla base di

\*\*\* 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



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.



Keep away from sunlight.  
Von Sonnenlicht fernhalten.  
Éloigner 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  
Halbbarkeitsdatum  
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

Distributor:  
SCHEU-DENTAL GmbH  
Am Burgberg 20 · 58642 Iserlohn, Germany  
Tel: +49 2374 9288-0 · Fax: +49 2374 9288-90  
service@scheu-dental.com · www.scheu-dental.com

