

1. Intended use / Indication

Light-curable polymerizable resin intended to be used in conjunction with curing light equipment. Indicated for the fabrication of earpieces.

2. Contraindication

audioprint® INR-1 is contraindicated ...

1. ... if a patient is known to be allergic to any of the ingredients.
2. ... for every application that is not part of the indication (see above).

3. Patient Target Group

Persons for whom an earpiece is to be created.

4. Intended Users

Earmold laboratory, ENT specialist, hearing aid acoustician

5. Requirements

Software – information available from:

Cyflex AG - Binzmühlestrasse 15, 8050 Zürich, Switzerland
3SHAPE A/S - Holmens Kanal 7, 1060 Copenhagen, Denmark

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

audioprint® INR-1 consists of functional (meth)acrylic resins, initiators, dyes and stabilisers.

7. Geometric presetting

According to the appropriate design specifications (templates).

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

10. Finishing processes

Polishing

Coating (audioprint® L-1, audioprint® L-1 | MSI recommended)

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.

**In-Ear Resin
INR-1**

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



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

audioprint® INR-1

■ Density/
Dichte/
Densité/
Densidad/
Densità:
ca. 1.1 g/ml

■ Viscosity/
Viskosität/
Viscosité/
Viscosidad/
Viscosità:
< 1 Pas

■ Shore hardness D/
Shore-Härte D/
Dureté Shore D/
Durezza Shore D
(ISO48-4)**:
80 ± 5

■ Bending modulus/
Biegemodul/
Module de flexion/
Módulo de flexión/
Modulo di flessione
(ISO178)**:
≥ 1600 MPa

■ Bending stress/
Biegespannung/
Contrainte de flexion/
Esfuerzo de flexión/
Sollecitazione di flessione
(ISO178)**:
≥ 80 MPa

■ Elongation at break/
Bruchdehnung/
Allongement à la rupture/
Alargamiento a la rotura/
Allungamento a rottura
(ISO178)**:
> 8 %

1 385/405 nm

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

audioprint® INR-1

500 g:

clear-transparent/
klar-transparent/
incoloro-transparente/
incoloro-transparente/
incoloro-transparente
REF: A1000200

red-transparent/
rot-transparent/
rouge-transparente/
rojo-transparente/
rosso-transparente
REF: A1000202

blue-transparent/
blau-transparent/
bleu-transparent/
azul-transparente/
blu-transparente
REF: A1000204

amber/
bernstein/
ambre/
ámbar/
ambra
REF: A1000205

white-opaque/
weiß-opak/
blanc-opaque/
blanco-opaco/
bianco-opaco
REF: A1000225

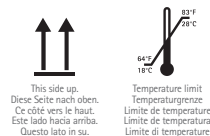
purple-opaque/
purple-opak/
purple-opaque/
purple-opaco/
purple-opaco
REF: A1000294

blue-opaque/
blau-opak/
bleu-opaque/
azul-opaco
blu-opaco
REF: A1000295

pink-opaque/
pink-opak/
pink-opaque/
pink-opaco/
pink-opaco
REF: A1000298

Other colors available upon request./ Weitere Farben auf Anfrage erhältlich./ D'autres couleurs sont disponibles sur demande./ Otros colores disponibles bajo pedido./ Altri colori disponibili su richiesta.

* 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 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



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

MD
Medical Device
Medizinprodukt
Dispositif médical
Producto sanitario
Dispositivo medico

Use by date
Haltbarkeitsdatum
Utiliser par date
Utilizar por fecha
Usare entro la data

REF
Catalogue number
Katalognummer
Número de catalogue
Número de catalogo
Numero di catalogo

LOT
Lot number
Chargennummer
Número de lote
Número de 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

