

**1. Intended use / Indication**

Polyurethane material for the production of earmolds.

**2. Contraindication**

- SysTherm® PU is contraindicated ...
- 1. ... if a patient is known to be allergic to any of the ingredients.
- 2. ... direct contact to uncured or partially uncured material.
- 3. ... for every application that is not part of the indication (see above).

**3. Patient Target Group**

Persons for whom an earmold is to be created.

**4. Intended Users**

Earmold laboratory, ENT specialist, hearing aid acoustician

**5. Requirements**

The SysTherm® dispensing gun and SysTherm® mixing cannula are required for the processing. Additional required tools and materials depend on applied processing method (see chapter 11-12).

**6. Material**

SysTherm® PU is a polyurethane based 2-component material consisting of a base and a catalyst.

**7. Preparation**

1. Open the SysTherm® secondary packaging (fig. 1).
2. Place the cartridge upright and wait for at least 30 min. at room temperature, at least 15 min. at 37 °C (fig. 2).
3. Twist off the cartridge top and attach the mixing cannula (fig. 3 and 4).
4. Insert the cartridge into the SysTherm® dispenser. Note that the cartridge shall remain upright (fig. 5).
5. Before dispensing into a mold, please pump a pearl-sized amount of SysTherm® (at least 1 ml) through the mixing tip in order to ensure a perfect mixture of the material (fig. 6).
6. Depending on the chosen production process, please proceed to one of the corresponding sections below.

**8. Notice**

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 date. Deviations from the described manufacturing processes or storing conditions may lead to different mechanical and optical properties of the material. For storing an opened SysTherm® cartridge, please leave the mixing cannula on the cartridge. Due to its chemical base, SysTherm® is moisture sensitive and should be stored dry at room temperature. 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.

**9. Precautionary statements**

**A-Component:** 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 water.  
**B-Component:** 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. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF exposed or concerned: Get medical advice/attention. Call a POISON CENTER/doctor if you feel unwell. Store in a well-ventilated place. Keep container tightly closed. Store locked up. Dispose of contents/container according to official regulation.

**10. Hazard statements**

**A-Component:** May cause an allergic skin reaction.  
**B-Component:** May cause drowsiness or dizziness. Suspected of damaging fertility or the unborn child.

**11. Application A**

Production process based on 3D-printed molds (audioprint® GR-12.2) with SysTherm® separator (SysTherm® SPT-1)

- 1) Print cast shells out of audioprint® GR-12.2 (Make sure air-vents are the same height as filling inlet, otherwise PU material will leak out during curing) (fig. 7).
- 2) After printing, thoroughly clean the parts using IPA and then fresh IPA, for 5 min. each (fig. 8).
- 3) Dry the parts with compressed air (fig. 9).
- 4) Dry the parts in oven at 40 °C for at least 30 min. to eliminate residual IPA. Parts must be odor free.
- 5) Cure the parts under nitrogen for 2 min. in CD-2.
- 6) Dip the casts into separator liquid SysTherm® SPT-1 (fig. 10).
- 7) Thoroughly dry the cast with compressed air (fig. 11).
- 8) Dry in oven at 40 °C for 30 min. (fig. 12).
- 9) Thoroughly dry the cast with compressed air. Note: the separator will stay as a thin liquid film on the surface (fig. 11).
- 10) Fill in SysTherm® PU carefully and avoid trapped air. Fill the inlet as a reservoir for possible polymerization shrinkage (fig. 13).
- 11) Put the filled casts into a dry pressure pot – make sure SysTherm® will not flow out.
- 12) Cure SysTherm® at 60 °C / 2 bar for 2 hours. Keep heating up time into account (fig. 14).
- 13) Crack the shells carefully. Use eye protection and appropriate tools (fig. 15).
- 14) Peel off cracked cast parts.
- 15) Clean and finish SysTherm® parts.

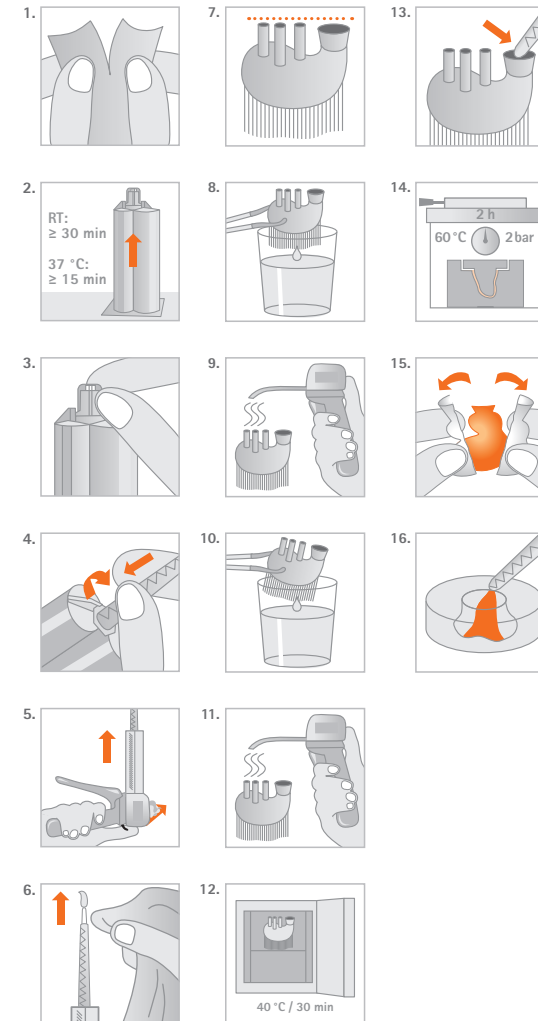
**12. Application B**

Production process based on PNP method using form silicones

- 1) Preparation of negative mould out of FS-2 silicone (see instruction for use).
- 2) If necessary, clean mold and dry (40 °C, 30 min.) to avoid moisture (fig. 12).
- 3) Fill in SysTherm® PU carefully and avoid trapped air (fig. 16).
- 4) Put the filled casts into a dry pressure pot – make sure SysTherm® will not flow out.
- 5) Cure SysTherm® at 60 °C / 2 bar for 2 hours. Keep heating up time into account (fig. 14).
- 6) Clean and finish SysTherm® parts.

**Polyurethane material**

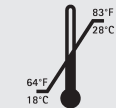
**Instructions for use**



**Physical properties\*:**

**SysTherm® PU**

- Setting time: 120 min. at 60 °C / 140 °F in pressure pot
- Final hardness: Shore A: 23°:85 ±5 Shore A: 37°:70 ±5
- Application: at 23 ± 2 °C, 50 ± 5 % rel. humidity
- Storage:



**Ordering information:**

**SysTherm® PU 4:1**

- Standard package**  
2 x 50 ml + 4 mixing canulas
- clear-transparent**  
REF: A4020124
- reddish-orange**  
REF: A4020143
- rose-transparent**  
REF: A4020144
- red**  
REF: A4020145
- blue**  
REF: A4020146
- black**  
REF: A4020147

**SysTherm® PU 2:1**

- Standard package**  
2 x 50 ml + 4 mixing canulas
- clear-transparent**  
REF: A4020224

**SysTherm® SPT-1**  
Separator  
500 g bottle  
REF: A4020126

**SysTherm®**  
mixing cannula  
REF: A4020127

**SysTherm®**  
4:1 dispenser  
REF: A4020128

\* These data come from measurements of a representative sample that was determined as part of our quality assurance.



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: 952-426-1928

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