

Instruction for use: Erkoplast PLA-R/-T/-W rose • transparent • white
PLA-handles high/flat white



Labeling:

Consult accompanying documents



Read instructions for use



Single use only



For prescription use only



EC-directive 93/42/EEC



Storage:

Keep away from sunlight



Keep dry



35 °C/95 °F

5 °C/41 °F

Recommended storage temperature

Indications for use (general):

Thermoforming Sheet Materials and Accessories are indicated for the fabrication of orthodontic and dental appliances.

Intended Use:

Erkoplast PLA-T/-W is thermoformed to fabricate intra-oral appliances such as individual impression trays, Erkoplast PLA-R is thermoformed to fabricate intra-oral appliances such as bite plates. PLA-handles to be attached to individual impression trays made from Erkoplast PLA.

Contraindications:

- Before use on patients with a history of allergic reactions to plastics it has to be clarified that there is no specific allergic reaction on Erkoplast PLA-R/-T/-W (PLA) and PLA-handles.

Warning:

- Use strictly limited for the fabrication of orthodontic and dental appliances.
- The use is subject to the responsibility of a therapist.
- For prescription use only.
- Allergic reactions are unlikely but possible.
- Improper manufacturing of the plastic appliance may cause the appliance to crack/break, resulting in sharp edges, loose pieces and possible aspiration of pieces.

Precautions:

- Erkoplast PLA-R/-T/-W is not recommended for other dental appliances than as described above under intended use.
- Single use only.
- Pay attention to the storage instructions.

Chemical characteristics:

PLA, polylactid acid, based on lactic acid. Harmless to health. Thermoplast with tested biocompatibility. Insoluble in water, inactive, harmless to ground water.

Technical data:

Density, 1.24 g/cm ²	Water absorption, 0.1 %	Tensile strength, 53 N/mm ²	Flexional strength, 98 Nmm ²
Impact strength, 18 kJ/m ²	Notch impact, 4 kJ/m ²	Yield stress, 58 MPa	Elongation at break, 6 %
E-modulus, 3500 N/mm ²	Hardness, Shore -	Ball indent. hardness, 150 N/mm ²	Vicat softening point, 77 °C
Temp. resistance, 64 °C	Glass trans. temp., 120 °C	Shrinkage (intended use), 1.2 %	



(manufacturer)

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Material informations:

Viscous, hard material with high torsional strength. Bonds to acrylate (e. g. Resilit-S, 817 501 + 817 503). PLA-handles (222 500, 50 pcs high/222 550, 50 pcs flat), bond to Erkoplast PLA with heat.



Disposal/Recycling: General recycling for plastic if available, otherwise general waste.

Availabilities: Thickness Erkoplast PLA-R 1.5 mm, Erkoplast PLA-T/-W 3.0 mm and 4.0 mm, 120 mm and 125 mm round and 125 x 125 mm square

Please refer to the Erkodent Material Card, Catalogue, Thermoforming Technique Brochure or to www.erkodent.com

Plastification and working instructions Erkoplast PLA-R/-T/-W: (only Erkodent thermoforming units)

Always place the sheet in the devices in such a way that the spacer/insulating foil is pointing towards the model. Please refer to the Erkodent unit instructions for a step-by-step thermoforming process. Sheet data such as heating time or thermoforming temperature are integrated in the internal data base of the thermoforming unit. Please select sheet type and thickness (e. g. Erkoplast PLA-T 4.0 mm) and follow the working steps indicated by the unit or by the unit instructions. (Erkoform-RVE/-3 and Erkopress ES 200 E units: sheet data in the accompanying unit documents).

For units without control: Test softness of foil with an instrument. If permanent impressions result, thermoform, see picture.

Finishing: (see brochure thermoforming technique) Adjustment is possible (Erkoplast PLA-T/-W) with the Occluform (-3). Recommended finishing set Quick 3 (110 830).

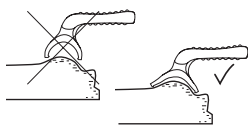


Working instructions: PLA-handles high/flat, white

PLA-handles will only bond to Erkoplast PLA by heat, no other bonding agent is needed. This is possible even during thermoforming in suitable devices.



- PLA-handle and ridge should roughly fit together (1).
- If necessary adapt handle by heating* (2+3). * hot air burner (177 540) or heat gun. Open flames are not suitable.



Fixation of the PLA-handle during thermoforming process.

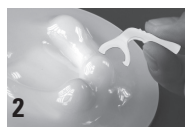
- Model preparation, cover residual dentition with Erkogum transparent (110 844) (1). • Cover the model with an Erkopor black foam disc (110 902, 40 pieces, thickness 3 mm) as a spacer (2). Do **not** moisten Erkopor black.
- Thermoform and immediately press PLA handle into the hot material (3+4).



Attention: After fixing the PLA-handle wait 30 min. before fully stressing!

Fixation of the PLA-handle after thermoforming process.

- Thermoformed plate should stay on the model for heating (1).
- Immediately press PLA handle into the hot material (pict. 2+3).



Attention: After fixing the PLA-handle wait 30 min. before fully stressing!