





## Instruction for use: **Erkolen** transparent


**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:

Erkolen is thermoformed to fabricate intra-oral appliances such as moulded pieces, gingival dressings, provisional crowns and bridges, bracket transfer/etching masks as well as spacer for medication trays out of Erkoflex-foils (e. g. fluoride).

### 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 Erkolen (PE).

### 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:

- Erkolen is not recommended for other dental appliances than as described above under intended use.
- Single use only.
- Pay attention to the storage instructions.



(manufacturer)

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**EN ISO • 13485:2016 • ISO 9001:2015**

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### Chemical characteristics:

PE, polyethylene • Insulating foil: PE, polyethylene. Harmless to health. Thermoplast with tested biocompatibility. Insoluble in water, inactive, harmless to ground water.



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

### Material informations:

Soft, resilient material. Burns without residues. Does not bond to acrylate.

**Availabilities:** Thicknesses from 0.5 to 3.0 mm, 120 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](http://www.erkodent.com)**

### Technical data:

Density, 0.92 g/cm <sup>3</sup>	Water absorption, 0.1 %	Tensile strength, 25 N/mm <sup>2</sup>	Flexional strength,-
Impact strength, 100 kJ/m <sup>2</sup>	Notch impact, 44 kJ/m <sup>2</sup>	Yield stress, 9 MPa	Elongation at break, 650 %
E-modulus, 200 N/mm <sup>2</sup>	Hardness, Shore D 40	Ball indent. hardness, 18 N/mm <sup>2</sup>	Vicat softening point, 94 °C
Temp. resistance, 68 °C	Glass trans. temp., 111 °C	Shrinkage (intended use), 0.1 %	

### Plastification and working instructions: (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. Erkolen 1.0 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 (2,0/3,0 mm) with the Occluform (-3).

Recommended finishing set Quick 3 (110 830), also scissors 1,0 mm.

The spacer foil will be taken off only after thermoforming and finishing.

