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:
Erkoflex is thermoformed to fabricate intra-oral appliances such as positioners, bracket transfer splints, soft splints, radiation protection splints, Playsafe sports mouthguards.

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 Erkoflex (EVA).

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 manufactoring of the plastic appliance may cause the appliance to crack/break, resulting in sharp edges, loose pieces and possible aspiration of pieces.

Precautions:
- Erkoflex 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

ERKODENT®

Instruction for use: **Erkoflex,** transparent • color • freestyle

Chemical characteristics:
EVA, ethyl-vinyl-acetate • 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:
Flexible material with high elasticity and dimensional stability. Erkoflex can be bonded to Erkoflex by heat and can be adjusted with Erkoflex-82-sticks.

Accessories: Erkoflexsticks-82, identical to Erkoflex, for hot glue guns.

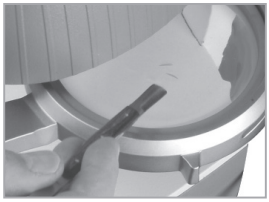
Availabilities: Thicknesses from 1.0 to 5.0 mm, 120 and 125 mm round and 125 x 125 mm square.
Please refer to the Erkodent Material Card, Catalogue, Thermoforming Technique Brochure or to www.erkodent.com.

Technical data:

Density, 0.95 g/cm²	Water absorption, 0.2 %	Tensile strength, 24 N/mm²	Flectional strength, -
Impact strength, no break	Notch impact, no break	Yield stress, 15 MPa	Elongation at break, 850 %
E-modulus, 20 N/mm²	Hardness, Shore A 82	Ball indent. hardness, -	Vicat softening point, 40 °C
Temp. resistance, 54 °C	Glass trans. temp., 72 °C	Shrinkage (intended use), < 2.0 %	

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. Erkoflex 2.0 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 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.

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