





Instruction for use: **Erkoloc-pro**, transparent • blu • green • -pink


Labeling:

 Consult accompanying documents


 Read instructions for use


 Single use only


 For prescription use only

 EC-directive 93/42/EEC

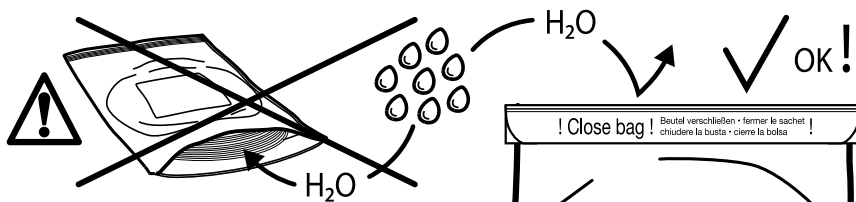
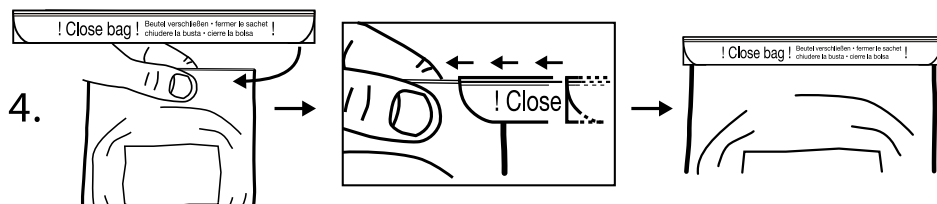
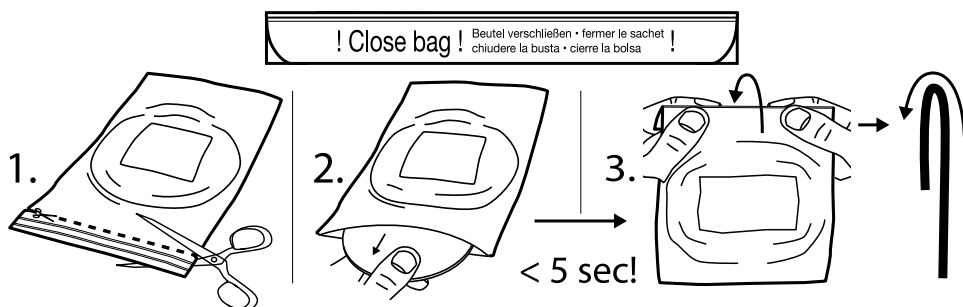
Storage:

 Keep away from sunlight

 Keep dry

 35 °C/95 °F
5 °C/41 °F Recommended storage temperature

Handling of the aluminium bag to avoid moisture absorption of the material:



(manufacturer)

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EN ISO • 13485:2016 • ISO 9001:2015

 **ERKODENT®**



Instruction for use: **Erkoloc-pro**, transparent • blu • green • pink

Indications for use (general):

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

Intended Use:

Erkoloc-pro is thermoformed to fabricate comfortable intra-oral appliances such as occlusal splints, bruxism splints, correction splints (aligners), anti snoring appliances.

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 Erkoloc-pro (PETG/TPU).

Warning:


- Use strictly limited for the fabrication of orthodontic and dental appliances.
- The use is subject to the responsibility of a therapist.
- Use only on the recommendation or prescription of an authorized practitioner.
- 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:

- Erkoloc-pro is not recommended for other dental applications than as described above under intended use.
- Single use only.
- Pay attention to the storage instructions.
- **Attention, sensitive to humidity:**
Reclose the aluminium bag immediately and keep it tightly closed (see handling of the aluminium bag).

Chemical characteristics:

PETG, copolyester, hard side • TPU, polyurethane, soft side • 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:

Durable, resistant double-layer plate, hard/soft. Hard layer bonds to acrylate (e. g. Resilit-S, 817 501 + 817 503).

Availabilities:

Thicknesses from 1.0 to 5.0 mm, 120 and 125 mm round and 125x125 mm square. **Please refer to the Erkodent Material Card, Catalogue, Thermoforming Technique Brochure or to www.erkodent.com**

Technical data hard layer (PETG):

Density, 1.27 g/cm ²	Water absorption, 0.2 %	Tensile strength, 50 N/mm ²	Flexional strength, 72 N/mm ²
Impact strength, 10 kJ/m ²	Notch impact, 12 kJ/m ²	Yield stress, 56 MPa	Elongation at break, 50 %
E-modulus, 2200 N/mm ²	Hardness, shore -	Ball indent. hardness, 115 N/mm ²	Vicat softening point, 80 °C
Temp. resistance, 67 °C	Glass trans. temp., 80 °C	Shrinkage (intended use), 0.4 %	

Technical data soft layer (TPU):

Density, 1.12 g/cm ²	Water absorption, 0.3 %	Tensile strength, 39 N/mm ²	Flexional strength, -
Impact strength, no break	Notch impact, no break	Yield stress, 8 MPa	Elongation at break, 590 %
E-modulus, 27 N/mm ²	Hardness, Shore A 85	Ball indent. hardness, -	Vicat softening point, 80 °C
Temp. resistance, 70 °C	Glass trans. temp., 160 °C	Shrinkage (intended use), 1.1 %	

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. Erkoloc-pro 3.0 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: Adjustment is possible with the Occluform (-3), by grinding or by addition (see brochure thermoforming technique). Recommended finishing set Quick 3 (110 830), high polish will be obtained with polishes for plastic. The spacer foil will be taken off only after thermoforming and finishing. Moisten the area that has to be adjusted with acrylate at first with little monomer.

