

Instruction for Use

Product name: Thermoforming Sheet

Model: T-DALA-161, T-DALA-181, M-LA-100, M-LE-100, MKU-ST, MKU-CA

Key performance:

Tensile modulus: ≥ 500 MPa; Yield stress: ≥ 20 MPa; Yield strain: $\geq 3\%$; Angle tear strength: ≥ 80 KN/m.

Product composition: Polyurethane

Intend use: Maxflex thermoformable sheets are intended for prescription use in the fabrication of orthodontic and dental appliances.

Contraindication: It is forbidden for those who are allergic to the material of this product.

Intend user: Trained production personnel

Intend patients: Adults and teenagers

Caution:

1. After the product is unsealed, the aluminum foil bag containing the remaining sheets should be sealed in time. Do not use the product if the aluminum foil bag is damaged.
2. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Method of use:

- 1) Open the aluminum foil bag, take out a thermoforming sheet and fix it in the frame of the press machine, and place the tooth mold to be pressed at the bottom.
- 2) Move the heating element above the sheet and press the sheet under appropriate thermoforming conditions (refer to the thermoforming parameters in below table). Remove heating element after molding.

Reference process parameters















thickness (mm)	temperature ($^{\circ}$ C)	duration of heat (s)	pressure (bar)
0.40	220	15-25	3.2-3.5
0.50	220	15-25	3.5-3.8
0.63	220	25-35	3.5-3.8
0.76	220	25-35	3.5-3.8
1.00	220	35-45	3.8-4.2

- 3) Cool down.
- 4) Demould and trim the thermoformed article.

Storage and transportation conditions: The storage should be ventilated and the relative humidity must be no more than 80%.

Shelf life: 3 years.

Labeling:

	Manufacturer		Authorized representative in the European Community/European Union
	Date of manufacture		Use-by date
	Batch code		Do not use if package is damaged and consult instructions for use
	Country of manufacture		Keep away from sunlight
	Keep dry		Do not re-use
	Consult instructions for use or consult electronic instructions for use		Caution
	Medical device		CE marking



SHANGHAI MAXFLEX MEDICAL TECHNOLOGY CO.,LTD.
 Building 1, No. 1169 Yuanqu Road, Anting Town, Jiading District, Shanghai, China 201805
 Tel: +86-21-3401-0087 Fax: +86-21-6431-4248



Lotus NL B.V.
 Koningin Julianaplein 10, 1e Verd, The Hague, Netherlands
peter@lotusnl.com
 SRN:NL-AR-000000121