

DENTAL SHEET

0.45-D105, 0.45-L105, 0.45-D120, 0.45-L120, 0.45-D125, 0.45-L125, 0.65-D105, 0.65-L105, 0.65-D120, 0.65-L120, 0.65-D125, 0.65-L125, 0.75-D105, 0.75-L105, 0.75-D120, 0.75-L120, 0.75-D125, 0.75-L125, 0.85-D105, 0.85-L105, 0.85-D120, 0.85-L120, 0.85-D125, 0.85-L125, 1.0-D105, 1.0-L105, 1.0-D120, 1.0-L120, 1.0-D125, 1.0-L125, 1.5-D105, 1.5-L105, 1.5-D120, 1.5-L120, 1.5-D125, 1.5-L125, 2.0-D105, 2.0-L105, 2.0-D120, 2.0-L120, 2.0-D125, 2.0-L125

Instructions for Use With Pressure Forming Equipment

Intended Use:

4Adent® Dura Aligner Sheet Materials are intended for prescription use in the fabrication of orthodontic and dental appliances.

Description

4Adent® Dura Aligner Sheet Materials are made of polyethylene terephthalate-ethylene glycol copolyester and thermoplastic polyurethane composite. For the production of orthodontic appliances, orthodontic retainers, oral protectors, occlusal splints, arch expanders, etc.

Date of preparation: November 2022

Product composition

The product is made of polyethylene terephthalate-ethylene glycol copolyester and thermoplastic polyurethane composite.

Product performance

This product is an odorless polymeric membrane made of amorphous copolyester with excellent appearance, toughness, hydrolytic stability, heat resistance and chemical resistance, and high biocompatibility.

Scope of application

For the production of orthodontic appliances, orthodontic retainers, oral protectors, occlusal pads, bow expander etc.

Usage

- 1) Check the appearance of the membrane, which should be smooth and have no visible impurities and foreign matters;
- 2) Place the membrane in a press machine for press.

Precautions

Do not wash the product with alcohol cleaning agent, vegetable cleaning agent, hot water or water jet.

Contraindications

Patients who had history of allergy to the raw material are forbidden to use this product.

Maintenance

After removing the product from the bag, please seal the packaging bag in time, and use the removed product within 15 minutes.

Transportation and storage

The product should be stored in a cool, dry, well ventilated and clean environment without corrosive gases.

Manufacture date

See the label on the package.

Shelf life: Four years as of the manufacture date.

Contraindications

Patients with a history of raw material allergy are forbidden to use this product.

⚠ Caution

Do not wash the product with an alcohol cleaning agent, vegetable cleaning agent, hot water or water jet.

Model Preparation

Check the model, which should be smooth and have no visible impurities and foreign matter

The model should be well-cured and dry.

1. The prototype should be thoroughly dried and cured.
2. The trimmed height of the prototype should be around 20-25mm.
3. Fill the holes or undercuts on the prototype with baseplate wax and let it dry.

Recommendation: For prototypes that are difficult to remove the film from, you can saturate the surface of the prototype with soapy water. Completely soak the surface with a thin layer of soapy water, then proceed with pressure forming (to prevent the film from sticking to the prototype).

Thermoforming

1. Turn on the thermoformer and enter the correct code.
2. Preheat the pressure-forming equipment before inserting the aligner sheet.
3. Open the aluminum foil bag and take out one piece of dental film. Place it on the heating plate to the left side of the pressure-forming machine (with the protective film facing up). Secure the film by sliding the clamp from right to left.
4. Move the heating tube above the heating plate for heating. At the same time, place the prototype to be processed on the pressure-forming plate on the right side of the machine. When the countdown window reaches zero, quickly move away the heating tube. Then, invert the heating plate from left to right onto the pressure forming plate, secure it with the air pressure valve from right to left, and start the pressure and automatic countdown. After the countdown is complete, press the pressure relief button to release the pressure.
5. After releasing the pressure, open the heating plate and remove the product.

Trimming Instructions

1. Trim off the excess film material from the completed pressure-formed product using scissors (it is recommended to leave at least 3mm in the gingival area).
2. Polish the edges of the aligner using an edge-polishing machine at a speed of approximately 10,000 revolutions per minute (rpm).
3. Rinse the appliance with cool water and mild soap before delivering./ Before delivery, clean the product with cold water and soap.

Thickness(mm)	Machines	Temperature (°C)	Heating Time (sec)	Pressure (Bar)
0.65mm	MiniSTAR@	220	25	4
	MiniSTAR@S	220	20	4
	Druformat Scan	/	65	4
	Erkodent@ Units	205-210	75	3-6
	Erkopres ci motion	/	75	7
0.75mm	MiniSTAR@	220	30	4
	MiniSTAR@S	220	25	4
	Druformat Scan	/	70	4
	Erkodent@ Units	205-210	80	3-6
	Erkopres ci motion	/	80	7
0.85mm	MiniSTAR@	220	35	4
	MiniSTAR@S	220	30	4
	Druformat Scan	/	75	4
	Erkodent@ Units	205-210	85	3-6
	Erkopres ci motion	/	85	7
0.9mm	MiniSTAR@	220	35	4
	MiniSTAR@S	220	30	4
	Druformat Scan	/	75	4
	Erkodent@ Units	205-210	85	3-6
	Erkopres ci motion	/	85	7
1.0mm	MiniSTAR@	220	35	4
	MiniSTAR@S	220	30	4
	Druformat Scan	/	85	4
	Erkodent@ Units	205-210	90	3-6
	Erkopres ci motion	/	90	7

Suggested 4Adent Pressure thermoforming settings

Note: Heating times vary between different machines.

1.If the plastic doesn't form well to the model, add 5 seconds of heating time until confirmation is acceptable.

2.If plastic forms webs or folds, reduce the heating time until webbing does not occur.

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Erkodent is trademark of ERKODENT Erich Kopp GmbH.

Frequently asked questions during the use of dental sheet:

Q: Why do bubbles appear after pressure forming the aligner sheet?

There are mainly two reasons for bubbles appearing after pressure forming:

1.The aligner sheet was not used promptly after opening the sealed bag, resulting in prolonged exposure to air and moisture absorption.

2.Insufficient heating time during pressure forming.

Solutions:

To prevent moisture absorption from prolonged exposure, use the aligner sheet within 15 minutes after opening the sealed bag.

Extend the heating time during pressure forming (recommend extending by 5 seconds).

Q: Why do the aligner sheet and the prototype lack fit after pressure forming?

A: There could be two reasons for the lack of fit:

1.Insufficient pressure application time.

2. leakage in the pressure-forming machine.

Solutions:

1.Increase the pressure application time appropriately.

2.Check for any air leakage in the pressure-forming machine.

Since the aligner sheet is engineered to have exceptionally high strength, learning to fabricate appliances with this material may require some experimentation. We encourage you to visit our official website: www.4adent.com for more tips.

Labels, Packing Logo Design

Symbol	Introductions	Symbol	Introductions
	CE Symbol		Authorised representative in the european community
	Manufacturer Name Address		Manufacture Date
	Batch Code		Consult instructions for use
	Warnings and Precautions		Non-sterile
	Medical device		Use-by date
	Keep dry		Keep away from Sunlight

Manufacturer Information



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