Reva® Thermoformable Sheet Materials

Instructions for Use

Intended Use

The Reva sheet materials are intended for prescription use in the fabrication of orthodontic and dental appliances.

Indications for Use

uLab Systems Dental Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.

Description

The Reva sheet materials enable the fabrication of orthodontic appliances. The material comes in three thicknesses intended for the creation of templates, aligners, and/or retainer devices. The Reva material has premium properties that when thermoformed into aligners, result in a very strong and durable orthodontic appliance which is aesthetically pleasing regarding clarity and stain resistance. The material has been tested and approved for biological safety in humans.

Contraindications

This material should not be used with patients that have a history of allergic reactions to plastic.

Working Instructions

- 1. Remove the Reva sheet from packaging.
- 2. The 3D model should be cured and dry. Trim model as needed.
- 3. Use block-out material to fill any holes or undercuts in model.
- 4. Apply separator if desired.
- 5. Please note that the Reva sheet material is slightly curved; it is recommended that the sheet be placed on the thermoforming equipment with the curved side up.
- 6. Place one sheet of material in the pressure chamber of the thermoforming machine.
- 7. Set temperature and heating time as indicated in the table below.
- 8. Set chamber pressure as indicated in the table below.
- 9. Observe the sheet as it heats.
- 10. When ready, close the pressure chamber on the model for thermoforming.
- 11. Complete the cooling time.
- 12. Open machine and inspect the resulting formed material.
- 13. Trim with standard trimming equipment.

Thermoforming Parameters:

1) Biostar Thermoforming Equipment

Reva Material	Heating Temperature	Heating Time	Cooling Time	Pressure	Code (If Any)
Aligner	Machine Default	30 Sec.	20 Sec.	≥4 Bar (58 psi) A higher pressure of 4 Bar (58 psi) is preferable.	701
Template		30 Sec.	20 Sec.		701
Retainer		30 Sec.	60 Sec.		702

- The Biostar thermoforming equipment will read the below code or barcode to setup the thermoforming conditions for the respective Aligner, Template, and Retainer Sheet material. Press "code" button and if there is a laser scan available, the barcode can be scanned to start the thermoforming process, or the respective code can be entered and press "code" button again to start the process.

Use Code 701 or scan the barcode below for both Aligner & Template material.



Use Code 702 or scan the barcode below for Retainer material.



2) Ministar Thermoforming Equipment

Reva Material	Heating Temperature	Heating Time	Cooling Time	Pressure	Code (If Any)
Aligner	Machine Default or 60°C	30 Sec.	60 Sec.	A higher pressure of 4	122
Template		25 Sec.	60 Sec.		112
Retainer		35 Sec.	60 Sec.		132

3) Ministar S Thermoforming Equipment

Reva Material	Heating Temperature	Heating Time	Cooling Time	Pressure	Code (If Any)
Aligner	Machine Default or 60°C	30 Sec.	60 Sec.	≥4 Bar (58 psi) A higher pressure of 4 Bar (58 psi) is preferable.	122
Template		25 Sec.	60 Sec.		112
Retainer		35 Sec.	60 Sec.		132

4) Drufomat Thermoforming Equipment

Reva Material	Heating Temperature	Heating Time	Cooling Time	Pressure	Code (If Any)
Aligner		75 Sec.	30 Sec.	≥4.5 Bar (65 psi)	
Template	Machine	55 Sec.	30 Sec.	A higher pressure of 4.5	N/A
Retainer	Default	80 Sec.	30 Sec.	Bar (65 psi) is preferable.	

Notes:

- Heating times may vary for different equipment.
- If the Reva material does not form well on the model, add or reduce time in 5 sec increments until satisfied with conformation.

Storage Conditions

- Storage should be in a dry environment at room temperature.
- Keep unused sheets in the original packaging.
- Desiccant is not necessary for storage.

Manufacturer

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