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Instructions For Use

ICONIC ALIGN

INTENDED USE

Iconic Align is used in the manufacture of removable thermoformed appliances to fabricate intra-oral appliances such
as aligners, retainers, bite planes, splints, snoring appliances, bruxing appliances and nightguards. Iconic Align's
material properties are especially suited for use in orthodontic aligner treatment.

INDICATION

 Dental appliances formed by Iconic thermoforming materials are indicated for use in patients requiring orthodontic treatment.

PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS

 Performance characteristics of Iconic thermoforming materials include strength, durability, clarity, resistant to fracture, easy to remove from model and easy to trim. The clinical benefits of the dental appliances formed from Iconic material are the correction of malocclusion and an overall improvement in tooth health.

CONTRA-INDICATIONS

• Patients with a history of allergic reactions to plastics should not use this product.

WARNINGS

- Iconic Align is formed at extremely high temperatures, care must be taken when thermoforming.
- · When thermoforming never leave the machine unattended.
- · Excessive heating of Iconic Align may result in the material deteriorating resulting in reduced patient wear time.
- 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.

PRECAUTIONS

- Iconic Alian should be stored between 5°C 25°C, in a dry place.
- Keep away from direct sunlight, if exposed for prolonged periods material could become prone to degradation and discoloration.
- Iconic Align should only be used as outlined in the indications of use, any use of Iconic Align inconsistent with these
 indications of use is at the discretion and sole responsibility of the practitioner.
- Patients with a history of allergic reactions to plastics should not use this product. Iconic Align does not contain Bisphenol A (BPA).

ADVERSE REACTIONS

· Allergic reactions.

DIRECTIONS FOR USE

1) Iconic Align is supplied with an easy peel heat resistant protective film on both surfaces of the blank. For best results

remove the film on the heat contact surface of the blank, leaving the film on the model contact surface of the blank. This will prevent the need to isolate the model, improving clarity. This also creates a micro gap preventing the need to black out minor undercuts.

- 2) The model should be trimmed to a depth of 20mm (3/4") in height.
- 3) Remove the palate of full arch models.
- 4) Vacuum / Pressure form using a machine conventionally used for thermoforming.
- 5) Ensure Iconic Align has cooled before removing material from model. For best results use Iconic Tricutter. DBL4-101/1063 or Iconic Wheel Saw DBL4-0150.
- 6) Remove heat resistant film from Iconic Align.
- 7) Trim and finish appliance as needed. For best results use Iconic Polishing Disk Fine 4S04-1381.

Heating time may vary upon machine. If Iconic Align does not adapt to model, add heating time until full adaptation occurs. If Iconic Align "folds" when thermoformed, reduce heating time until this does not occur.

Thickness	Vacuum Heat Time*	Biostar Code*	Drufomat*
0.8mm (.030")	45 Seconds	152 (45Sec)	75 Seconds
1.0mm (.040")	55 Seconds	173 (55Sec)	85 Seconds

^{*}After preheating machine

SAFE DISPOSAL

 Used dental appliances may be considered a biohazard. Follow your country-specific laws, directives, standards and guidelines for the disposal of used devices.

CARE ADVICE FOR YOUR APPLIANCE

- · After brushing teeth brush the top and bottom of the aligner / retainer with a soft toothbrush.
- Do not brush aligner / retainer with toothpaste as this will significantly reduce the life of the material.
- Use cold water to wash the aligner / retainer. Iconic Align can also be cleaned with Retainer Brite or similar cleaning solution.
- · Hot water will distort Iconic Align.
- · Rinse well before and after use and dry thoroughly.
- Handle Iconic Align with care and store in a retainer box when not in mouth.
- When removing the aligner/ retainer apply equal pressure to all sides of the appliance retainer retrievers recommended for this purpose.
- If the appliance becomes too tight do not force it, call your Orthodontist or Dentist.
- Do not eat or drink when wearing the aligner /retainer, as acids in food and drink can considerably reduce the life of the retainer / aligner.

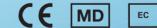














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