



Instructions for Use

Introduction to EMA-NOW™

Each EMA-NOW kit is comprised of custom-made upper and lower dental splints. This splint design utilizes a patented Elastic Mandibular Advancement (EMA) system in order to easily advance the lower jaw forward. A calibration key is provided to allow for ease of advancement.

Indications for use

EMA-NOW is a temporary, 30-day, semi-custom medical oral appliance that acts as a mandibular repositioner, and is indicated for the treatment of mild to moderate nighttime snoring and Obstructive Sleep Apnea (OSA).

Contraindications

Appliances are contraindicated for patients who:

- Have Central Sleep Apnea
- Have severe respiratory disorders
- Have loose teeth
- Have advanced periodontal disease
- Are under 18 years of age

What you need to get started:

1. Two bowls or cups
2. Hot water between 175-185° F
3. Cold water
4. Petroleum jelly or Vaseline
5. File or acrylic bur

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Precautions

Dentist should consider the medical history of the patient, including history of asthma, breathing or respiratory disorders, or other relevant health problems. Please refer the patient to the appropriate healthcare provider before prescribing an oral appliance. For professional use only. During the initial use of the device, the patient may experience some temporary side effects, such as slight tooth discomfort, jaw muscle/joint pain, increased salivation, dry mouth, irritation of the soft tissue in the mouth and/or slight change in patient's bite.

Non-sterile - rinse with soap and water prior to use.

EMA-NOW™ is a temporary appliance to be worn for up to 30 days.



DISTRIBUTED BY

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MANUFACTURED BY

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R_{Only}

MD



Contents:

This product contains an upper and lower plastic tray and 12 EMA® Advancement Straps (Yellow-medium strength).

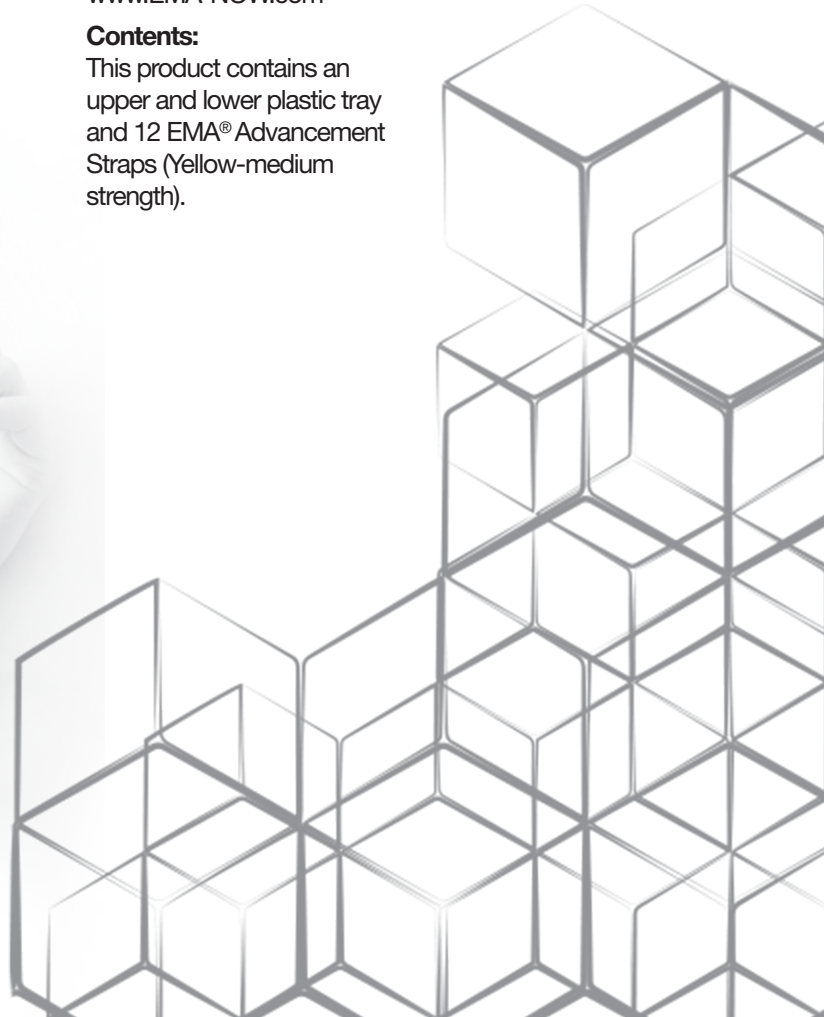
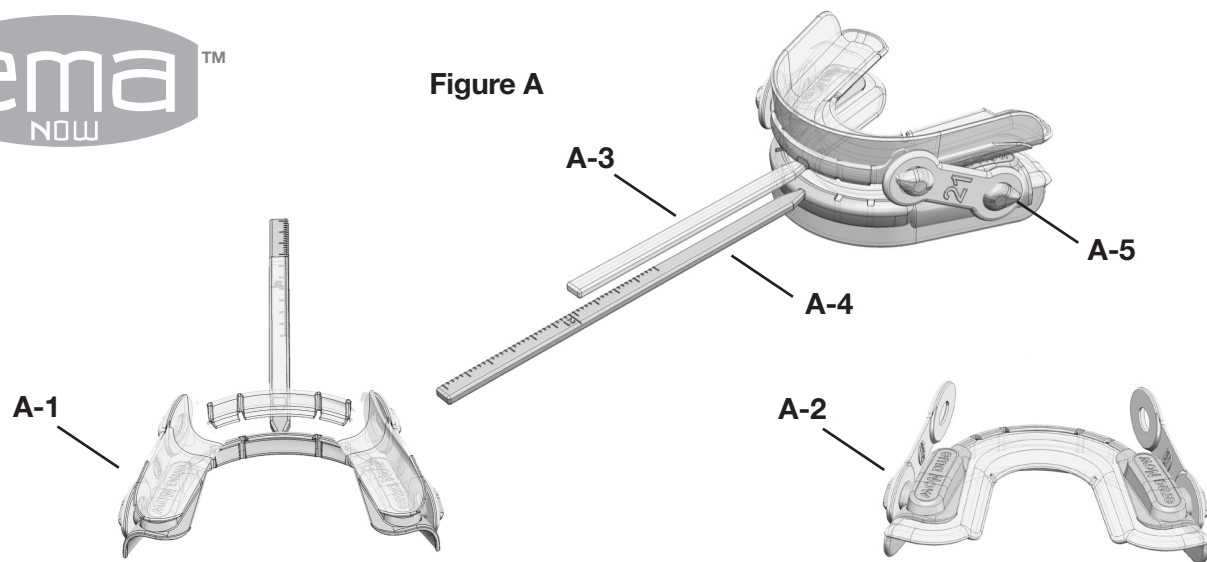


Figure A



Fitting the Upper Tray

- 1) Apply a generous portion of petroleum jelly or Vaseline to tips of gloves/fingertips to reduce stickiness and to help smooth and manipulate the trays prior to seating.
- 2) Place the upper tray (Fig. A-1) over the upper teeth to ensure that the maxillary arch fits within the borders of the tray. If not, follow heating instructions in Step 3 and dip tray into hot water for a few seconds to soften which will allow you to adjust the width to fit the patients arch.
- 3) In a bowl or cup, prepare hot water to approximate temperature of 175-185 degrees. Using the safety handle, (Fig. A-3) fully submerge the tray in hot water for 15-30 seconds OR until tray is completely clear/translucent. Please note: Submerging the tray in hot water for extended amount of time could result in the heat-to-fit tray walls to fold inward.
- 4) Remove tray from hot water and allow to cool slightly for 5 seconds and shake off excess water before fitting the tray to maxillary arch.
- 5) With the upper tray (Fig. A-1) still clear/translucent, place tray over the upper teeth with the safety handle (Fig. A-3) directly aligned under the nose and center to upper arch. Make sure the heat-to-fit tray borders remain parallel to buccal and lingual surfaces of upper teeth.
- 6) For at least 1 minute or until the heat-to-fit tray borders are no longer clear/transparent, gently massage and form tray to patients arch making sure to put pressure on the lingual and distal sides. Have the patient gently bite teeth together while closing their lips around the upper tray. Let lips naturally press against the upper tray while pressing the tongue to the roof of the mouth to create a sucking motion.
- 7) Once the tray has formed and begins to harden, use your fingers to smooth heat-to-fit over the molars.
- 8) The upper tray is ready for removal once it is no longer clear (2-3 minutes).
- 9) To remove tray, place fingers on top of the heat-to-fit tray borders above the molar area and pull downwards until tray is released from upper teeth. If tray is removed before the heat-to-fit tray sets, it may lack retention. However, placing it in ice cold water will allow the tray to completely set and therefore increase retention.

Fitting the Lower Tray

- 1) Using the lower tray (Fig. A-2), repeat steps 1-4 of upper tray fitting instructions.
- 2) With the lower tray (Fig. A-1) still clear/translucent, place the tray over the lower teeth with the safety handle (Fig. A-4) directly aligned under the nose and center to lower arch. Make sure the heat-to-fit tray borders remain parallel to buccal and lingual surfaces of lower teeth.
- 3) Once the tray has formed and begins to harden, use your fingers to smooth heat-to-fit over the molars.
- 4) For at least 1 minute or until the heat-to-fit tray borders are no longer transparent, have the patient gently bite teeth together while closing their lips around the lower tray. Let lips naturally press against the lower tray while resting the tongue and creating a sucking motion.
- 5) The lower tray is ready for removal once it is no longer clear (2-3 minutes).
- 6) To remove tray, place fingers onto top of the heat-to-fit tray borders below the molar area and pull upwards until tray is released from lower teeth. If tray is removed before the heat-to-fit tray sets, it may lack retention. However, placing it in ice cold water will allow the tray to completely set and therefore increase retention.
- 7) With both upper and lower trays properly fitted to the patient, determine desired EMA® Advancement Strap length using the measurement scale on the upper and lower safety handles. As you bring your patients lower jaw forward, it will indicate which band size to use based on the relationship of the upper handle as it relates to the number matrix system on the lower handle. (Fig. A-3 and A-4).
- 8) Once desired strap length is determined, remove the upper and lower safety handles (Fig. A-3 and A-4) by bending or twisting them off the arch until separated from both arches. Once the handles are removed, additional filing with acrylic bur may be necessary to create a smooth finish.
- 9) Place the desired EMA Advancement Straps (Fig. A-5) on the hooks of each tray and the EMA-NOW is ready!