<table>
<thead>
<tr>
<th>Company</th>
<th>Airway Management Inc</th>
<th>Cadwell Therapeutics</th>
<th>Distar LLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>TAP</td>
<td>TAP 3 and TAP 3 Elite</td>
<td>TAP PAP</td>
</tr>
<tr>
<td>Warranty</td>
<td>1 year parts and workmanship, 60 day patient satisfaction guarantee</td>
<td>1 year parts and workmanship, 60 day patient satisfaction guarantee</td>
<td>1 year for workmanship and materials</td>
</tr>
<tr>
<td>FDA 510(k) clearance</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indications</td>
<td>Mild to moderate OSA</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Snoring</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Bruxism</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Materials</td>
<td>Hardware material choices are: medical grade SS, low nickel or nickel free. The trays have two hard outer layers of a durable polymer and the inner lining is one of two types designated by the dentist: 1. Triple Laminate (TL) is the most popular, using Durafin, which enables retention by comfortably gripping the teeth. 2. Thermacryl, which softens when heated to allow &quot;snapping&quot; and reshaping for patients who have dental work.</td>
<td>Hardware material choices are: medical grade SS, low nickel or nickel free. The trays have two hard outer layers of a durable polymer and the inner lining is one of two types designated by the dentist: 1. Triple Laminate (TL) is the most popular, using Durafin, which enables retention by comfortably gripping the teeth. 2. Thermacryl, which softens when heated to allow &quot;snapping&quot; and reshaping for patients who have dental work.</td>
<td>See materials for TAP. TAP PAP CM: Hard acrylic plastic with a silicone border. TAP PAP CS: Nasal pillows are medical grade silicone (see Fisher &amp; Paykel Opus pillow composition).</td>
</tr>
<tr>
<td>How does the oral appliance work?</td>
<td>E0486 code verified by Medicare, the TAP stabilizes the lower jaw in the appropriate protractive position, preventing airway collapse and tongue blockage while keeping the jaw closed during sleep. The TAP has a full range of adjustment beyond maximum protrusion on into maximum passive protrusion.</td>
<td>E0486 code verified by Medicare, the TAP 3 and 3 Elite stabilize the lower jaw in the appropriate protractive position, preventing airway collapse and tongue blockage while keeping the jaw closed during sleep. The TAP has a full range of adjustment beyond maximum protrusion on into maximum passive protrusion.</td>
<td>TAP PAP combines either a custom or noncustom strapless CPAP mask with the TAP (E0486 code verified by Medicare) or TAP 3 series appliance (E0486 code verified by Medicare). The two device types are connected via a kit provided by AMI. TAP PAP stabilizes the jaw and airway to improve delivery of PAP. Typically, patients where disease has progressed and need more treatment than OAT alone are very good candidates for TAP PAP.</td>
</tr>
<tr>
<td>Fitting description</td>
<td>The TAP is fabricated in a licensed dental laboratory and fitted by the dentist. The upper and lower trays are adjusted for retention, fit. Initial protrusion is set during fitting and can be easily modified. Posterior stops may be added for comfort if necessary.</td>
<td>The TAP 3, Elite is fabricated in a licensed dental laboratory and fitted by the dentist. The upper and lower trays are adjusted for retention, fit. Initial protrusion is set during fitting and can be easily modified. Posterior stops may be added for comfort if necessary.</td>
<td>TAP PAP (CM) Custom: the dentist uses a custom impression kit supplied by AMI and then takes a facial impression. The custom mask is fabricated by AMI. The dentist connects the mask to the TAP and fits the patient. TAP PAP (CS) Chairside: the dentist fits the patient using a kit supplied by AMI. The kit contains 3 sizes of nasal pillows and all necessary hardware.</td>
</tr>
<tr>
<td>Adjustment description</td>
<td>Unique to the TAP, infinite adj ustment is done by the patient while in the mouth. The TAP has an anterior dial with one point of adjustment that prevents unequal jaw torque. The dentist teaches a home titration schedule, which engages the patient in their own therapy. It may be easily adjusted in the sleep lab by the sleep tech during a sleep study.</td>
<td>Unique to the TAP 3 and 3 Elite, infinite adjustment is done by the patient while in the mouth. The TAP 3 series uses a handheld key with one point of adjustment that prevents unequal jaw torque. The dentist teaches a home titration schedule, which engages the patient in their own therapy. It may be easily adjusted in the sleep lab by the sleep tech during a sleep study.</td>
<td>Before attaching the mask, the dentist will set the TAP into a fixed protractive position, which also serves as an anchor to the mask. The dentist will adjust the mask and instruct the patient. The mask is strapless and does not leak.</td>
</tr>
<tr>
<td>Materials</td>
<td>Hardware material choices are: medical grade SS, low nickel or nickel free. The trays have two hard outer layers of a durable polymer and the inner lining is one of two types designated by the dentist: 1. Triple Laminate (TL) is the most popular, using Durafin, which enables retention by comfortably gripping the teeth. 2. Thermacryl, which softens when heated to allow &quot;snapping&quot; and reshaping for patients who have dental work.</td>
<td>Hardware material choices are: medical grade SS, low nickel or nickel free. The trays have two hard outer layers of a durable polymer and the inner lining is one of two types designated by the dentist: 1. Triple Laminate (TL) is the most popular, using Durafin, which enables retention by comfortably gripping the teeth. 2. Thermacryl, which softens when heated to allow &quot;snapping&quot; and reshaping for patients who have dental work.</td>
<td>See materials for TAP. TAP PAP CM: Hard acrylic plastic with a silicone border. TAP PAP CS: Nasal pillows are medical grade silicone (see Fisher &amp; Paykel Opus pillow composition).</td>
</tr>
<tr>
<td>Recommended cleaning and maintenance of the device</td>
<td>After use, clean with a toothbrush, cool water, and antibacterial soap. The TAP can be soaked weekly in a diluted peroxide solution for 5 minutes.</td>
<td>After use, clean with a toothbrush, cool water, and antibacterial soap. The TAP 3 series can be soaked weekly in a diluted peroxide solution for 5 minutes.</td>
<td>See cleaning for TAP. TAP PAP CM and CS masks are to be cleaned after each use in a mild detergent and water, air dry.</td>
</tr>
<tr>
<td>Published, peer-reviewed validation articles</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
## Oral Appliances

<table>
<thead>
<tr>
<th>Company</th>
<th>Distar LLC</th>
<th>Great Lakes Orthodontics Ltd</th>
<th>Modern Dental Laboratory USA</th>
<th>Myerson</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>TheraSnore II</td>
<td>Herbst Appliance</td>
<td>MPowRx</td>
<td>The Moses</td>
</tr>
<tr>
<td>Warranty</td>
<td>1 year</td>
<td>90 day for metal component; 1 year for body material</td>
<td>1 year against manufacturer defect</td>
<td>2 year</td>
</tr>
<tr>
<td>FDA 510(k) clearance</td>
<td>Pending</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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### Indications

<table>
<thead>
<tr>
<th>Mild to moderate OSA</th>
<th>Severe OSA</th>
<th>Snoring</th>
<th>Bruxism</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>X</td>
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<tr>
<td>X</td>
<td>X</td>
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</tbody>
</table>

### Type

- Custom
- Noncustom
- Boil and bite

### How does the oral appliance work?

- **Oral Appliance**
  - **Distar LLC (TheraSnore II)**: Gently holds the lower jaw in a protrusive position and prevents the tongue and soft palatal tissues from falling back and obstructing the airway during sleep. Adjustment springs allow for precise advancement of mandible.
  - **Great Lakes Orthodontics Ltd (Herbst Appliance)**: It works by repositioning and holding the mandible in a more protrusive position, thereby holding the tongue forward and airway open.
  - **Modern Dental Laboratory USA (MPowRx)**: This unique, noncustom device repositions the tongue forward instead of relying on the mandible. Uses gentle suction, rather than the alveolar ridge or dentition to stay in place.
  - **Myerson (The Moses)**: The Moses improves the simple mandibular advancement designs of the past by guiding the tongue to the optimum position on the roof of the mouth. It is the only appliance that incorporates Tongue Position Management, Mandibular Advancement, and Patient Compliance.
  - **EMA First Step**: EMA First Step is a 90-day trial appliance that uses interchangeable elastic straps and posterior bite pads attached to the thermoformed custom trays to allow gradual advancement of the mandible and increased vertical opening until treatment is successful.

### Fitting description

- **Distar LLC (TheraSnore II)**: Doctor sends impressions and a bite registration to Distar to fabricate the appliance. Very few adjustments are required. The hard acrylic snaps into place. When requested, retention clasps can be added. One size fits most.
- **Great Lakes Orthodontics Ltd (Herbst Appliance)**: Mandible can be adjusted forward or backward in the office by changing either the length or position of the spring. Vertical opening is also easily adjusted in the office. 0.25 mm adjustment with telescopic hardware, or 1 mm using advancement shims with the standard hardware option. Not required.
- **Modern Dental Laboratory USA (MPowRx)**: The Moses bite protocol is critical to achieving proper results. Dentists send the completed bite registration and upper/lower impressions to Modern Dental Laboratory USA for fabrication of each custom appliance.
- **Myerson (The Moses)**: A screw mechanism allows doctors to adjust for anterior mandibular movement. The Moses is titrated using a key provided; one turn advances the mandible 1/8 mm, up to 6 mm.
- **EMA First Step**: EMA First Step uses two different strengths of elastic straps and three different lengths to gradually titrate the mandible. The shorter or stronger the strap, the further the mandible is advanced.

### Adjustment description

- **Distar LLC (TheraSnore II)**: Brush appliance after each use to remove any debris. Clean every 2 days using OrthoFresh cold water cleaner.
- **Great Lakes Orthodontics Ltd (Herbst Appliance)**: Use of DentisOAK is recommended along with toothbrush and toothpaste daily. Must be stored dry.
- **Modern Dental Laboratory USA (MPowRx)**: Rinse and clean with a toothbrush for 30 seconds before and after use and store in a container of clean water.
- **Myerson (The Moses)**: Clean appliance in tepid water or soak it in a denture cleaning solution; no mouthwash.

### Materials

<table>
<thead>
<tr>
<th>Distar LLC (TheraSnore II)</th>
<th>Great Lakes Orthodontics Ltd (Herbst Appliance)</th>
<th>Modern Dental Laboratory USA (MPowRx)</th>
<th>Myerson (The Moses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dual laminate trays, stainless steel adjustment springs.</td>
<td>Standard hard acrylic but can be made of Verilox, a thermal-reactive option.</td>
<td>Thermoplastic elastomer.</td>
<td>The lower element is made of methyl-methylacrylate dental acrylic resin. The upper element is a 3 mm polypropylene-ethylene copolymer vacuum-formed splint covering all maxillary teeth.</td>
</tr>
<tr>
<td><strong>EMA First Step</strong></td>
<td>The EMA appliance is completely metal free. The custom trays are made from a proprietary thermoplastic and the straps are made of a latex-free polymer.</td>
<td><strong>EMA First Step</strong></td>
<td><strong>EMA First Step</strong> uses two different strengths of elastic straps and three different lengths to gradually titrate the mandible. The shorter or stronger the strap, the further the mandible is advanced.</td>
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### Recommended cleaning and maintenance of the device

- **Distar LLC (TheraSnore II)**: Brush appliance after each use to remove any debris. Clean every 2 days using OrthoFresh cold water cleaner.
- **Great Lakes Orthodontics Ltd (Herbst Appliance)**: Use of DentisOAK is recommended along with toothbrush and toothpaste daily. Must be stored dry.
- **Modern Dental Laboratory USA (MPowRx)**: Rinse and clean with a toothbrush for 30 seconds before and after use and store in a container of clean water.
- **Myerson (The Moses)**: Clean appliance in tepid water or soak it in a denture cleaning solution; no mouthwash.
<table>
<thead>
<tr>
<th>Company</th>
<th>Myerson EMA</th>
<th>SnoreSilencer Pro</th>
<th>NORAD Appliance</th>
<th>SomnoDent MAS</th>
<th>Lamberg Sleep Well (LSW-S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td></td>
<td></td>
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<tr>
<td>Warranty</td>
<td>n/a</td>
<td>30 days</td>
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<td>3 year against manufacturer’s defects or breakage</td>
<td>90 days</td>
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<tr>
<td>FDA 510(k) clearance</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Mild to moderate OSA</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Severe OSA</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Snoring</td>
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<td></td>
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<td></td>
<td></td>
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<tr>
<td>Bruxism</td>
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<td></td>
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<tr>
<td>Other</td>
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<tr>
<td>Custom</td>
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<tr>
<td>Noncustom</td>
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<td></td>
</tr>
<tr>
<td>boil and bite</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How does the oral appliance work?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMA uses interchangeable elastic straps and posterior bite pads attached to thermoformed custom trays to allow gradual advancement of the mandible and increased vertical opening until treatment is successful.</td>
<td>The SnoreSilencer Pro is a heat- and-fit mandibular advancement appliance. It incorporates patented hinge technology and custom-like qualities. Three lower trays each with a fixed pin setting, facilitate different advancement levels.</td>
<td>The NORAD works by advancing the mandible and opening the bite while providing lateral mobility and protrusive/vertical adjustability. Bola and bite design allows for immediate delivery.</td>
<td>The SomnoDent MAS advances the lower mandible, which slightly tightens the soft tissue and musculus of the upper airway, preventing obstruction while the patient sleeps.</td>
<td>This appliance advances the mandible in .5 mm increments and opens the vertical in 3 mm increments. The lower jaw has freedom of movement along the arc of opening/closing.</td>
<td></td>
</tr>
<tr>
<td>Fitting description</td>
<td>Fit the upper and lower appliances without the elastic straps to check for comfort and to make sure there is no gingival impingement. Check the posterior bite pads for even occlusion.</td>
<td>Fitting occurs in the dentist chair in less than 20 minutes. Three different jaw advancement levels are possible due to three separate lower trays, each with a fixed pin setting.</td>
<td>Heat the NORAD appliance in hot water to soften the thermal material and then seat upper and lower arches separately to ensure tight fit.</td>
<td>The SomnoDent MAS does not limit tongue space and is made up of two separate pieces so the patient can speak, yawn, and drink.</td>
<td>Applience does not require special fitting at delivery visit. It is only necessary to verify that the upper and lower members seat fully.</td>
</tr>
<tr>
<td>Adjustment description</td>
<td>The EMA appliance uses four different strengths of elastic straps in nine different lengths to gradually titrate the mandible. The shorter or stronger the strap, the further the mandible is advanced.</td>
<td>Bicomponent material provides a soft inner shell and helps to enhance ease of fitting and increase rigidity. Three lower trays help patients find an advancement level most satisfactory for them.</td>
<td>Protrusive and vertical adjustment is possible with the NORAD by engaging the upper and lower trays with the stoppost ramp in the anterior.</td>
<td>The adjustment mechanism allows the mandibular protrusion to be adjusted (titrated) in the range -0.5 mm to +5.5 mm from the preset level.</td>
<td>A series of “inserts” slide into the upper appliance to increase the amount of mandibular protrusion (up to 9 mm) in .5 mm increments. Vertical adjustment can also be achieved with a vertical “insert.”</td>
</tr>
<tr>
<td>Materials</td>
<td>The EMA appliance is completely metal free. The custom trays are made from a proprietary thermoplastic and the straps from a latex-free polymer.</td>
<td>Soft thermal plastic</td>
<td>The NORAD is a hard plastic shell containing thermal plastic lining that softens when heated. The upper and lower trays are locked together in the front and held on either side with elastic.</td>
<td>Hard acrylic outer layer with option for hard acrylic liner or SMH Flex liner: Stainless steel titration element, option available for nickel-free titration element.</td>
<td>Hard polycarbonate and hard acrylic</td>
</tr>
<tr>
<td>Recommended cleaning and maintenance of the device</td>
<td>Clean appliance in tepid water with a toothbrush and mouthwash or soak it in a denture cleaning solution; no mouthwash.</td>
<td>Brush the trays with a toothbrush or finger thoroughly under cold tap water.</td>
<td>Daily brushing and/or soaking in appliance cleaning solution.</td>
<td>Clean daily with soft toothbrush and mild soap. Store in clean water. Soak 5 minutes in partial denture cleaner weekly.</td>
<td>Clean appliance with a soft toothbrush and water daily and weekly with Retainer Brite and Sonic Dental Cleaner.</td>
</tr>
<tr>
<td>Published, peer-reviewed validation articles</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes (contact manufacturer for citations)</td>
<td>No</td>
</tr>
</tbody>
</table>
The Snor.X appliance—a one-size-fits-all tongue sleeve and extracoronal lip guard—gently and effectively holds the tongue forward during sleep, keeping the upper airway open and free from obstruction.

Extend the tongue forward into the tip of the tongue sleeve and apply a gentle squeeze to the tongue bulb to create a gentle vacuum that will hold the tongue extended in the bulb. The Snor.X requires a vacuum seal for the tongue to stay in the bulb. The notches on the side of the appliance stay outside the mouth.

A clear plastic ring is provided to adjust the tongue’s extension further, if needed. When the ring is used, extend the tongue in the sleeve first, place the ring with the lip rest onto the top part of the bulb, then hook the ring into the first notch of the tongue sleeve.

The 1-part SomnoGuard repositions the lower jaw forward and thereby prevents the collapse of the upper airway. With the device in place, the upper airway is wider and the patient can breathe more easily without snoring.

The 2-part SomnoGuard AP repositions the lower jaw forward and thereby prevents the collapse of the upper airway. With the device in place, the upper airway is wider and the patient can breathe more easily without snoring.

Fitting can be done by doctors or their trained staff in less than 10 minutes. No special accessories needed apart from a boiling water bath and a small pair of scissors.

Fitting can be done by doctors or their trained staff in less than 15 minutes. No special accessories needed apart from a boiling water bath, a small pair of scissors, and gripping tongs.

The lower jaw can be infinitely repositioned forward (titration) by any degree up to about 10 mm by an adjusting screw inserted into the screw guide of the lower jaw tray. Adjustments are quickly and easily made outside of the mouth. Protrusion changes can be done by doctors or the instructed patients themselves.

The lower jaw is put forward to approximately half the maximum extension possible. Next, the patient bites the plastic.

Rigid polycarbonate (rigid tray walls), soft thermal copolymer (lining); stainless steel adjusting screws.

With the soft moldable device in place, lower jaw is put forward to approximately half the maximum extension possible. Next, the patient bites the plastic.

The Snor.X requires a vacuum seal for the tongue to stay in the bulb. The notches on the side of the appliance stay outside the mouth.

The SomnoDent MAS does not require the elastic straps and posterior bite advancement level most satisfactory. The shorter or stronger the advancement level most satisfactory. The custom trays to allow gradual advancement of the mandible in .5 mm increments. Vertical adjustment elements are provided for each advancement level.

Soft thermal plastic.

Rigid polycarbonate (rigid tray walls), soft thermal copolymer (lining); stainless steel adjusting screws.

Clean appliance with Retainer Brites and Dental Sonic Cleaner.

Clean daily with soft toothbrush and a mild liquid soap or a liquid denture cleaner. Rinse, let the device dry in the open air.

Clean daily with soft toothbrush and mild liquid soap or a liquid denture cleaner. Rinse and let the device dry in the open air.

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