



Manufactured For:

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Made in USA

Patient Instructions

About Removable Appliances

Myoaligner® Removable Device is a removable dental appliance.

Removable dental appliance therapy is a treatment modality in which the patient wears a removable appliance that overlays the teeth or dental arches. Based on the treating doctor's diagnosis and treatment plan, these removable appliances may help improve various symptoms a patient may be experiencing (i.e., headaches, joint pain, grinding of teeth, etc.)

Other benefits include:

- The removable appliances are shaped like natural teeth so they will look and feel like natural teeth.
- The removable dental appliances are removable, allowing you to brush and floss your natural dentition with freedom.

Myoaligner® appliance is not an orthodontic aligner or for aesthetic use. It is not intended to be used as a dental crown or bridge.

Intended Use

The Myoaligner® appliance is intended for protection against teeth grinding, bruxism, and jaw clenching; protection of restorations from injury due to bruxism or clenching; relief of bruxism related headaches, migraines and pain; short-term relief from muscle spasm due to occlusal interference; prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscles; and temporary treatment of temporal mandibular disorder (TMD) along with the relief of associated headaches and pains in adults 18 years of age or older.

Federal law restricts this device to sale by or on the order of a dentist.

Contraindications

The device is contraindicated for patients who:

- Have severe obstructive sleep apnea.
- Have severe respiratory disorders.
- Have loose teeth.
- Have advanced periodontal disease.
- Are under 18 years of age.
- Are allergic to acrylic (polymethyl methacrylate).
- Any factors that significantly affect the insertion and removal or stable fit of the device, such as:
 - Have severe tooth crowding such that you cannot floss between your teeth,
 - Severe misalignment of teeth

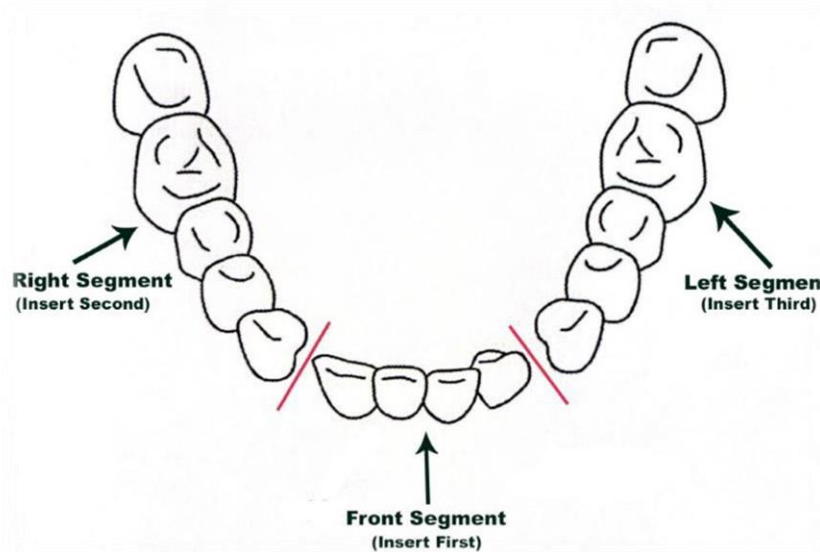
- Missing two consecutive teeth,
- Broken teeth,
- Multiple holes or gouges on the teeth, and
- Severe tooth wear.

Instructions for Use

- 1) Brush and floss natural teeth prior to use.
- 2) Carefully match each segment to the corresponding teeth.

Example: Match the lower front segment to the lower front teeth, match the upper front segment to the upper front teeth, match the lower right back segment to the lower right back teeth, match the upper right back segment to the upper right back teeth, match the lower left back segment to the lower left back teeth and the upper right back segment to the upper right back teeth.

- 3) Unless otherwise is recommended by your dentist, consider starting with the upper or lower front segment first, followed by the back segments.



- 4) Once each segment is matched to the receiving teeth, press lightly with your fingers to seat until you feel resistance.
- 5) Bite down gently to assure complete seat of the appliance.
- 6) Wear the device for 8-10 hours day or night as prescribed by your dentist.
- 7) Remove each segment by gripping the sides of each segment firmly with your fingers and applying gentle pressure away from the teeth or at the gumline to gently lift the appliance from the teeth.
- 8) After each use, brush the device with a toothbrush and water, store in a dental retainer container.

Discontinue use and see your dentist if you notice any of the followings:

- 1) The device no longer comfortably fits over the teeth.
- 2) The device fits loosely on the teeth.
- 3) Change in the bite or the way the teeth mesh together.
- 4) Loose teeth
- 5) Increased grinding and or clenching of teeth.
- 6) Any soreness or pain from the teeth, gums, jaw, muscles and joints
- 7) Any change in the integrity of the device, i.e., the device appears worn, cracked or any piece is broken off.

Cleaning

The device may be cleared with a toothbrush and water. Alternatively, it can be soaked in any cleaner made for dental prosthesis or in an ultrasonic dental retainer case for enhanced cleaning.

Precautions

- Remove the device prior to eating; removable devices are not intended for chewing.
- Discontinue use if you notice irritation, soreness or pain from the teeth, gums, jaws or muscles and see your dentist.
- Dental devices may temporarily change the alignment bite or the way the teeth mesh together. Discontinue use and report any changes to your dentist.
- Do not adjust or alter the device.

Warnings

- Risk of swallowing the device or choking should it become dislodged in the mouth.
- Discontinue use immediately in case of an allergic reaction. Contact your dentist.