



Manufactured For:

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Made in USA

Patient Instructions

About Removable Dental Devices

Myoaligner® is a Segmented Removable Dental Device. Depending on your dental anatomy and treatment modality, it may come in 2-3 segments covering the entire dental arch, or in one segment covering a specific section of the dental arch.

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

Other benefits include:

- Myoaligner® devices are shaped like natural teeth so they will look and feel like natural teeth.
- The removable feature of the Myoaligner® device allows you remove the device prior to chewing and allows for brushing and flossing of the teeth with freedom.
- It is not recommended to chew with removable devices, unless they are secured on the receiving teeth with dental adhesives.

Myoaligner® is not an orthodontic aligner. It is not intended to be used as permanent dental crown or bridges. When temporarily adhered to the teeth with dental adhesives, Myoaligner® devices can be used as temporary crown or bridges, for aesthetic and restorative applications

Intended Use

The Myoaligner® devices are 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 a licensed dentist or on the order of a licensed dentist.

Contraindications

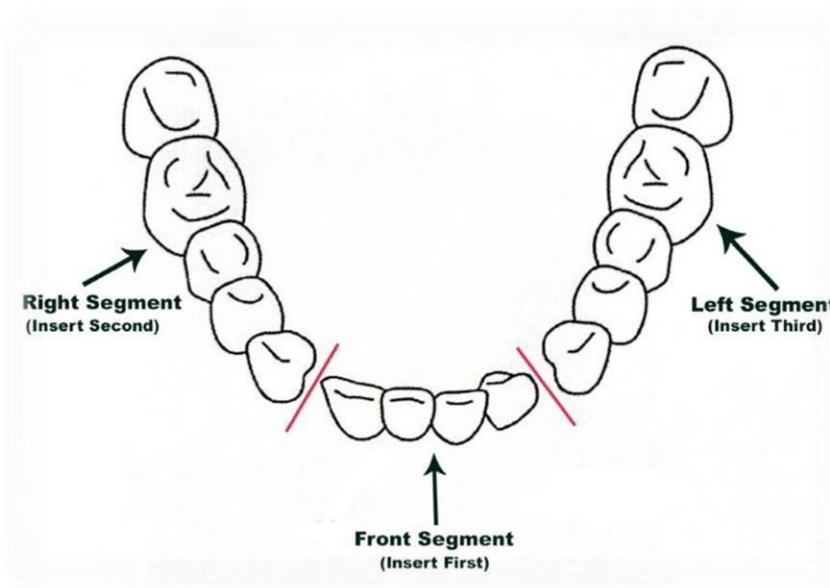
Removable devices are contraindicated for patients who:

- Have severe obstructive sleep apnea.
- Have severe respiratory disorders.
- Have severe tooth crowding or angulations.
- Have loose teeth.

- Have advanced periodontal disease.
- Are under 18 years of age.
- Are allergic to acrylic (polymethyl methacrylate).
- Have any factors that significantly affect the retention, insertion, removal or stable fit of the device, such as:
 - Severe misalignment of teeth
 - Severe tooth crowding that makes flossing difficult
 - Missing two consecutive teeth
 - Broken teeth
 - Multiple holes, abfractions or gouges on the teeth
 - Severe tooth wear

Instructions For Use

- 1) Brush and floss natural teeth prior to use.
- 2) Carefully match each segment of Myoaligner® device 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, gently bite on the front segment to learn the correct jaw alignment, and then insert 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 device.
- 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 device 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 following:

- 1) The device no longer comfortably fits over the teeth.
- 2) The device fits loosely on the teeth.
- 3) Unexpected change in the bite alignment or the way the teeth mesh.
- 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 bath for enhanced cleaning.

Precautions

- Remove the device prior to eating; removable devices are not intended for chewing.
- You can chew soft food when the device is secured on the teeth with dental adhesives.
- 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 of the jaw or the way the teeth mesh together. Discontinue use and report any unexpected changes to your dentist.
- Do not adjust or alter the device.
- The Device can be adjusted or altered by the treating dentist.

Warnings

- Risk of swallowing the device or choking should it become dislodged in the mouth.
- Risk of tooth decay and periodontal disease. Continue regular check-ups with your dentist to reduce the risk.
- Discontinue use immediately in case of an allergic reaction. Contact your dentist.