

Clinician 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 central or severe obstructive sleep apnea.
- Have severe respiratory disorders.
- Have advanced periodontal disease.
- Have loose teeth.
- Are under 18 years of age.
- Are allergic to acrylic (polymethyl methacrylate).
- Any factors that could negatively impact the draw and retention of a removable device, such as:
 - Significant malocclusion,
 - Severe tooth crowding,
 - Severe tooth malalignment,

- Poor tooth anatomy,
- Multiple missing teeth or two consecutive missing teeth,
- Broken teeth,
- Multiple areas of voids or undercuts on teeth and
- Severe tooth wear.

Partial appliances should not be prescribed to heavy bruxers.

Fitting the Appliance

The appliance should fit over the teeth (and any restoration) without putting any stress on the teeth. The appliance should not rub the gums. Confirm that the device has strong retention. Check the appliance bite function.

Go over instructions for use, cleaning, Warnings and Cautions with your patient. Confirm that your patient can adequately insert and remove the device before they take the device home.

Instructions for Use

Brush and floss natural teeth prior to use. Carefully match the device to corresponding teeth and press lightly to seat the device. Bite down gently to assure complete seat of the device. The device may be worn at night or partially during the day as prescribed by the dentist for 8-10 hours per day. Remove carefully by applying gentle pressure. After each use, brush the device with a toothbrush and water and store in a dental retainer container.

Discontinue use and see your dentist if you notice a change in the fit of the device, any soreness or pain from the teeth, gums or jaw, or any change in the integrity of the device, i.e. the device appears worn or any piece breaks 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.
- If the patient reports soreness or pain from the teeth or gums, adjust or smooth the internal wall of the appliance where it is putting pressure on the gums or teeth.
- If the patient reports pain in the jaw or muscles, adjust the bite using articulating paper to level the bite.
- If the patient presents with poor hygiene, instruct the patient on proper hygienic practices.
- Dental devices may temporarily change the alignment bite.

Warning

- 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.