



Patient Informed Consent Form

Successful restorative dental treatment is a partnership between the doctor and the patient. Generally, informed and cooperative patients can achieve positive results. While recognizing the benefits of a beautiful healthy smile, you should also be aware that, as with all healing arts, dental treatment has limitations and potential risks. These are seldom serious enough to indicate that you should not have treatment; however, all patients should consider the option of no treatment at all by accepting their present oral condition. You should also ensure that you have discussed all other available dental alternatives with your doctor prior to beginning treatment.

Please read this information carefully and ask your doctor to explain anything you do not fully understand. Ensure you know what is expected of you as the patient (or as the parent/guardian of a minor patient) during treatment.

About Removable Appliances

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 any various symptoms a patient may be experiencing (i.e. headaches, TMJ related pain, severe wear, sensitivity on teeth etc.) Removable dental appliances may be recommended by the practitioner for improving bite function and/or aesthetic appearance.

Other benefits include:

- The removable appliances are shaped like natural teeth so they will look and feel like natural teeth. They may be more comfortable than other types of oral removable appliances. People may not even notice you wearing them.
- The removable appliances made by Myoaligner® have been reported to be more comfortable than traditional appliances.
- The removable dental appliances are removable, allowing you to brush and floss your natural dentition with freedom.

Although the benefits generally outweigh the potential risks, all factors should be reviewed before making the decision to wear these removable appliances. If you choose to undergo removable dental appliance treatment, Myohealth Technologies LLC ("Myoaligner®"), an Oregon-based dental company, will design and/or manufacture the customized removable appliance for your dental models based on your doctor's prescription. Your doctor will be providing the treatment. Your doctor (not Myoaligner®) is responsible for determining indications of use, the treatment outcome, obtaining your informed consent, delivering the appliance and any adjustments, for reviewing the care instructions and managing your continued care.

Potential Risks of Removable Appliance Therapy

As with other removable appliances, the removable appliances made by Myoaligner® may carry some of the potential risks described below:

- Treatment time may be longer than anticipated based on the following situations: lack of compliance to your treating doctor's instructions, wearing the appliance less than the recommended time prescribed by

the treating doctor, missed post- delivery adjustment appointments, other medical conditions contributing to symptoms, severity of the existing condition, poor oral hygiene, etc.

- Damaged appliances could potentially lengthen treatment time, increase the cost, and affect the quality of the end results.
- The fit of appliance is highly affected by the shape and alignment of the teeth and shape of the dental arches. For instance, short clinical crowns could negatively affect the retention of the appliance. Unusually shaped teeth can also affect the aesthetics and the fit of the appliance and may extend treatment time and affect the end results.
- Tooth decay, periodontal disease, decalcification (permanent markings on the teeth), or inflammation of the gums may occur if proper oral hygiene and preventative maintenance are not maintained, whether wearing appliance or otherwise.
- Sores and irritation of the soft tissue of the mouth (gums, cheeks, tongue and lips) are possible but rarely occur due to wearing appliances.
- Initially, the appliances may temporarily affect your speech. Patients generally adapt quickly to wearing the appliance and it is rare that speech is impaired for an extended period.
- While wearing the appliance, you may experience a temporary increase in salivation or dryness of the mouth. Certain medications can increase such symptoms.
- It may be necessary to temporarily affix the appliance (using a temporary adhesive or a more definitive adhesive based on your doctor's recommendations) to your teeth to assist with retention of the appliance.
- Any medications you may be taking, and your overall medical condition can affect your appliance therapy.
- Though uncommon, allergic reactions to the material used during treatment may occur. If you believe you are experiencing an adverse reaction, STOP USING YOUR APPLIANCE AND inform your doctor immediately.
- Tooth sensitivity and tenderness of the mouth may occur during treatment—especially at the beginning of treatment when your mouth is getting used to the appliance.
- Bone and gums, both of which support the teeth, can be affected by wearing the appliance. In some cases, their health may be impaired, or an existing condition may be aggravated.
- Oral surgery may be required to correct pre-existing jaw imbalances. All risks of oral surgery, such as those associated with anesthesia and proper healing, must be considered before treatment.
- Wearing the appliance may aggravate teeth—previously traumatized or not. Some teeth may require additional dental treatment such as endodontic treatment or other restorative treatment, the useful life of the teeth may be shortened, or the teeth may be lost
- Existing dental restorations, such as crowns and bridges, may be affected by wearing the appliance. They may become dislodged and require re-cementation or in some instances, replacement. Before any dental restorations are replaced or added, consult your doctor, as they can affect the way your appliance fits.
- Teeth may move out of their existing position while wearing these appliances.

- In cases of severe crowding or multiple missing teeth, it is more likely that the appliance may break. Contact your doctor as soon as possible if this occurs.
- Because this appliance is worn in the mouth, ACCIDENTALLY SWALLOWING or aspirating the appliance—in whole or in part—may occur however can be mitigated by using an ADHESIVE while in function as well as when sleeping.
- In case of poor fit or retention issues, STOP USING THE APPLIANCE AND contact your doctor before using the appliance again.
- Though rare, while wearing the appliance, problems may occur in the jaw joint and with the bite, causing joint pain, discomfort, headaches or ear problems. Inform your doctor of any such problems immediately.
- Appliance not worn as prescribed may delay treatment results and result in complications including (but not limited to) patient discomfort. Always wear your appliance in the order specified by your treating doctor.
- Proper care, cleaning and maintenance of your appliance is necessary, in order to maintain the integrity of the appliance as well as your oral health.
- A successful treatment outcome cannot be guaranteed. Some cases may require refinement with additional appliances. Other treatments such as orthodontic treatment, restorative treatment or cosmetic procedures like crowns or veneers may be recommended to achieve ideal long-term results. There may be additional costs to you if you require such procedures. Always follow the directions for use (included with each appliance package when delivered) for best results.

Informed Consent & Agreement

I have read and understand the content of this document describing considerations and risks of wearing oral appliances. I have been sufficiently informed and have been given the opportunity to discuss this form and its contents with the undersigned doctor. My questions adequately answered. I have been asked to make a choice about my treatment, and I hereby consent to receive treatment with oral appliances manufactured by Myoaligner® as planned, prescribed and provided by the undersigned doctor. I agree to follow my doctor's treatment exactly as s/he plans, prescribes and provides it for me. I understand that any questions, concerns or complaints I have regarding my treatment must be communicated to my doctor as soon as they arise.

- I acknowledge that neither my doctor nor Myoaligner®, its employees, representatives, successors, assigns, or agents, have, can, or will make any promises or guarantees as to the success of my treatment or give any assurances of any kind concerning any particular result of my treatment. I understand that Myoaligner®, does not practice dentistry or give medical advice. I understand that Myoaligner® manufactures the oral appliances based on instructions from the prescribing doctor. I understand that I should always contact my doctor in the first instance (not Myoaligner®) regarding my expectations, difficulties, results, or any other aspects of my treatment.
- I understand that it may be necessary to take impressions, intraoral scans, digital model scans, radiographs (x-rays), and/or photographs for diagnosis, professional review by my doctor or other consulting dentists, and submission to Myoaligner®. I recognize that these will be included in my medical records, which records encompass "individually identifiable health information" as that term is defined and protected by the HIPAA Privacy Rule. I understand that my doctor, as a covered entity under HIPAA, is not required to obtain my consent to use and disclose my individually identifiable health information for

treatment, payment, and health care operations activities, but have chosen to do so voluntarily through this document. I further agree that my doctor or Myoaligner® may use my medical records for research and educational purposes, but only to the extent that no individual identifiers, including but not limited to my name or address, are disclosed. I hereby consent to such uses and disclosure(s) as described herein.

- Unless otherwise permitted or required by law, other uses and disclosures of my medical records, including advertising or marketing by either my doctor or Myoaligner®, shall be made only with my prior written authorization (for which I acknowledge my doctor or Myoaligner® may use my contact information to seek to obtain). I acknowledge I will not, nor shall anyone on my behalf, seek or obtain damages or remedies—legal, equitable, monetary, or otherwise—arising from any use of my medical records that complies with the terms of this Informed Consent and Agreement.

- I acknowledge I have read, understand, and voluntarily consent to the use of oral appliances in accordance with terms of this Informed Consent and Agreement.

Patient Name: _____

Patient or Guardian Signature:

Date:

Time:

Dentist Signature:
