

Informed Consent: Even28 At-Home Clear Aligner Therapy

Your doctor has recommended *Even28 at-home* clear aligner system to correct your orthodontic condition. There are plenty of benefits to seeking orthodontic treatment with Even28 at-home clear aligner system. At the same time, there are also certain risks and limitations which you should be aware of prior to starting treatment. The following informed consent discusses some common usage instructions, benefits and risks of clear aligner therapy. Read carefully, ask your doctor any questions you have and then sign at the bottom.

Description of Even28 At-home Clear Aligner System

Even28 clear aligners are a series of plastic, removable dental appliances which are designed to move your teeth. Aligners incrementally move your teeth to correct minor orthodontic issues. Even28 at-home treatment is designed to move your teeth without requiring any adjustment or modification to your existing teeth. First, we receive impressions or scans of your teeth from your treating doctors. We follow your doctor's instructions to design a treatment plan to move your teeth into their new, desired position. We generate a computer animated overview of your tooth movement, known as *EvenCheck*. Once your dentist has approved your treatment plan and *EvenCheck*, we print a series of custom clear aligners designed specifically to move your teeth into their desired position. Your clear aligners will be shipped to you or your dentist (you get to choose how you want to receive them). Either way, you will receive all of your clear aligners upfront. It's your sole responsibility to make sure that you wear and use these clear aligners, as instructed by your dentist, to get satisfactory results.

How to Correctly Wear Clear Aligners

Your clear aligners will be individually numbered starting with aligner #1, #2, #3 and so forth. The wear time for each aligner is a minimum of 2 weeks and a maximum of 4 weeks. If the new aligner hurts, you have the option of wearing your old aligner for an additional week before trying again. If you still can't wear the new aligner after 4 weeks, go see your dentist to have them examine your aligner.

Standard Wear Instructions for Clear Aligners

The standard wear time for clear aligners is continuous wear for 2 weeks before switching to the next aligner. Of course, sometimes your treating doctor recommends that you wear each aligner for an extra one or two weeks. For instance, they may recommend daytime wear only for 3 weeks or night time wear only for 4 weeks. You should wear your aligner as instructed by your dentist. Only remove your aligners when you're eating, brushing or flossing your teeth. Remove your aligners when drinking hot and cold liquids, except water which is okay with aligners inside your mouth.

Follow-up Appointments

There are no follow-up visits required for Even28 at-home. You do not need to see your doctor until your treatment is complete. However, you should contact your doctor if you run into any problems during the course of your treatment. These include issues wearing your aligners, unusual pain, broken aligners or any other situation that concerns you. It's highly recommended that you see your dentist after completing treatment for a post-operative examination. This visit is used to make sure that you are pleased with the outcome of treatment. There is always the possibility that you may require additional orthodontic work or other restorative treatment after finishing your Even28 at-home program. These additional treatments are not a part of your Even28 at-home aligner therapy and have a separate cost. Your dentist will discuss these additional treatments with you if they are necessary.

Benefits of Wearing Clear Aligners

Clear aligner therapy is an alternative to wearing traditional braces with metal brackets and wires. Here are some benefits of clear aligner therapy for orthodontic treatment over braces:

- Clear aligners are less visible in your mouth as compared to braces.
- Clear aligners can easily be removed from your mouth whereas you can't remove braces by yourself.

- Clear aligners are more comfortable to wear than braces since there are no metal brackets or wires.
- Clear aligners cause less irritation, such as sore lesions in the mouth, as compared to braces.
- Wearing clear aligners is generally less painful than wearing braces because clear aligners place less force onto your teeth.
- It is much easier to maintain adequate oral hygiene throughout the course of aligner therapy as compared to braces since clear aligners can be removed to clean your teeth.
- There is no metal in clear aligners which is beneficial to those who suffer from metal allergies.

Improving your teeth alignment with clear aligners makes it easier to clean your teeth upon completion of orthodontic treatment. This could help reduce plaque accumulation in between your teeth to reduce your chance of developing dental cavities and gum disease.

Risks of Wearing Clear Aligners

Clear aligner therapy is an alternative to wearing braces for certain orthodontic conditions which qualify for aligner treatment. Here are some common risks and complications associated with wearing clear aligners which you should be aware of before starting your treatment:

- Just like with any other orthodontic treatment, your teeth will hurt when they start to move. Typically, the pain subsides within a few days as you get accustomed to your new clear aligners.
- You may find it more difficult to speak during the course of your aligner treatment, especially during the first few weeks as you are getting used to wearing your clear aligners.
- Wearing clear aligners can affect your taste, salivary flow and tactile oral sensation. These effects are typically temporary in nature and are reversed upon completion of aligner treatment.
- You must continue to maintain proper oral hygiene and routine dental cleaning throughout aligner therapy. Otherwise, you risk developing dental problems such as cavities, infection or gum disease.
- There is the possibility of some minor bone loss or gum recession during the course of aligner therapy. Fixing such gum problems is not part of your aligner therapy. You will have to address them separately with your dentist or a specialist.
- There is a chance that your teeth or fillings may break, fall off, develop recurrent decay or become infected during the course of aligner therapy. Typically, these teeth were already damaged and the aligner therapy simply expedites the end result. Fixing damaged teeth is not part of your aligner therapy. You will have to address these teeth separately with your dentist or a specialist. Occasionally, you may have to postpone or discontinue treatment until such conditions have been resolved.
- There is the possibility that your bite may slightly altered after completion of clear aligner treatment. This could result in some level of discomfort, especially when biting or chewing. Occasionally, you may require bite correction at the end of your treatment. This involves calibrating your bite by removing a small amount of tooth structure to eliminate interferences with your bite. Sometimes, correcting your bite may not be possible with clear aligner therapy or bite calibration. Fixing these bite problems is not part of Even28 at-home aligner therapy. You will have to address these teeth separately with your dentist or a specialist. Occasionally, you may have to postpone or discontinue treatment until such conditions have been resolved.
- Occasionally, your tooth roots become shorter during orthodontic treatment, which is known as *root burnout*. Root burnout is more common with braces but it can also occur with clear aligner therapy. Root burnout could cause dental problems in the future, especially if combined with gum disease. Consider slowing down your treatment and wearing your aligners for an additional 1 to 2 weeks if root burn out is suspected. Fixing root burnout is not part of aligner therapy. You will have to address this condition separately with your dentist or a specialist.
- Upon completion of your aligner therapy. You may end up with gaps in between your teeth which resemble a black triangle. Fixing these black triangles is not part Even28 at-home clear aligner treatment. Your doctor will present different treatment options to address this problem should it occur.
- Although rare, clear aligner therapy may lead to jaw joint (TMJ) discomfort, headaches, earaches or other head and neck related pain and discomfort. Fixing these conditions is not part of your clear aligner treatment and may require additional treatment, medication or referral to a specialist.
- You may require additional dental work to address minor imperfections upon completion of your clear aligner treatment. This could include the need for additional dental fillings, bonding, crowns, veneers or other dental restorations used to

correct tooth positioning, gaps or bite problems. These treatments are not included in your clear aligner treatment and need to be addressed separately with your treating doctor or a specialist.

- Clear aligners can not, and should not, move dental implants. Whenever possible, it is recommended to place dental implants after completion of clear aligner therapy. If you already have dental implants in your mouth, let your doctor know *before starting treatment*. It is recommended that you consider Even28 at-dentist if you already have dental implants in your mouth. This allows your dentist to continuously monitor your teeth movement to prevent damage to your dental implant(s). Occasionally, you may end up having to replace your *dental implant crown* (not the whole dental implant) upon completion of aligner treatment. This is not part of your clear aligner treatment and needs to be addressed separately with your dentist or a specialist.

- Not every tooth may be included in your clear aligner therapy. Occasionally, a tooth may be excluded due to reasons such as its position or existing condition. Fixing these teeth will not be a part of your aligner therapy. Your dentist will address these teeth separately upon completion of your clear aligner therapy.

- There is always the chance that your clear aligners may crack, break or otherwise become damaged. You may even accidentally swallow a fragment or piece of your clear aligner. Should this occur, stop wearing your aligners immediately and contact your doctor right away for further instructions.

- You may be allergic to the clear aligner plastic material. However, allergic reactions to clear aligner material are extremely rare. Most complications are sore lesions, cuts and bruises, not actual allergic reaction. If you believe you are allergic to your aligners, stop wearing them and contact your doctor right away. Your doctor will help you determine if you're experiencing an allergic reaction to your aligners or normal pain and discomfort. You may have to discontinue your clear aligner treatment in the most extreme allergic cases.

- Certain medical conditions and medications may adversely affect your clear aligner therapy. Be sure to disclose any medical conditions or medications you take with your doctor before starting aligner treatment.

- There are certain orthodontic conditions which can not be treated with Even28 at-home clear aligner therapy. These cases may be treatable with *Even28 at-dentist* instead. There are still those cases which can not be treated with any type of clear aligners. Most underbite, crossbites and skeletal abnormalities are not treatable with clear aligners. These cases require braces instead of clear aligner.

- *Orthodontic relapse* is a condition where your teeth start moving back to their original position after completion of orthodontic treatment. It is your responsibility to wear your retainers and make sure they are in good condition to avoid orthodontic relapse. Occasionally the relapse is so bad that you have to redo your aligner therapy a few years later to compensate for these unwanted movements. This is not considered part of your clear aligner treatment and you will have to redo your entire treatment.

- Dentistry and clear aligner therapy is not an exact science. Your final outcome may or may not resemble the *EvenCheck* computer animation presented to you. There is always the possibility that you may require additional clear aligners upon completion of your program. In some rare instances, you may have to be referred out to a specialist for additional orthodontic treatment. These treatments are not part of your Even28 at-home clear aligner treatment and require additional treatment and extra cost. Your doctor will review these treatments with you.

- As with any other aligner program, compliance is crucial with Even28 at-home. It is your sole responsibility to wear your clear aligners properly, in the correct sequence, and for the recommended amount of time. Failure to follow instructions could lengthen treatment time, adversely affect the final outcome or cause other unexpected problems during the course of your clear aligner treatment.

- Referrals to other specialists, such as an oral surgeon, periodontist, orthodontist, etc. may be required to achieve the final desired outcome. Your dentist will discuss any such referrals if they are necessary.

Consent to Even28 At-Home Clear Aligner Treatment

I have been given adequate time to read and understand the preceding information regarding *Even28 at-home* clear aligner therapy. I understand that Even28 at-home is a clear aligner program designed to move my teeth without the need for any adjustment or modification to my existing teeth. I understand that there are certain limitations to Even28 at-home due to the fact that my teeth are not modified. I accept any such risks and forgo Even28 at-dentist treatment in favor of Even28 at-home treatment. I understand that I will receive all of my clear aligners upfront as part of Even28 at-home program. I understand that it is my sole responsibility to wear and use the aligners as instructed by my dentist. I understand the benefits, risks, complications and alternative treatments to clear aligner therapy which are available to me. Furthermore, I understand that there is the option of not receiving any orthodontic treatment at all. I have had the

opportunity to ask questions and discuss my concerns with my doctor, from whom I intend to receive my Even28 at-home clear aligner therapy. I have received satisfactory answers to all of my questions.

Having understood all of my treatment and non-treatment options, I have decided to proceed with Even28 at-home clear aligner therapy. I understand that I am only allowed to use Even28 clear aligners after consulting with an Even28 trained dentist or orthodontist. I hereby consent to receiving orthodontic treatment with Even28 clear aligners as prescribed and supplied by my dentist or orthodontist. Due to the fact that dentistry and orthodontics is not an exact science, I acknowledge that my doctor and Even28 have not, and cannot make any guarantees or assurances regarding the final outcome of my treatment. I also understand that Even28 is not a provider of medical, dental or healthcare services and does not and cannot practice medicine, dentistry or give any medical advice. No assurances or guarantees of any kind have been made to me by my treating doctor or Even28, its representatives, successors, assigns or agents concerning any specific outcome regarding my treatment.

I authorize my doctor to release any necessary medical records, including but not be limited to, radiographs (X-rays), charts, reports, medical background, intraoral or extraoral photographs, plaster modeling, teeth impressions, or intraoral or extraoral scans, prescriptions, diagnosis, medical tests, test results, billing, and other treatment records in my doctor's possession ("Medical Records") to other licensed dentists or orthodontists and organizations employing licensed dentists and orthodontists and to Even28, its representatives, employees, successors, assigns, and agents for the purposes of investigating and reviewing my medical history as it pertains to orthodontic treatment with product(s) from Even28 as well as for educational and research purposes. I understand that the use of my Medical Records may result in disclosure of my *individually identifiable health information* as defined by the Health Insurance Portability and Accountability Act (HIPAA). I hereby consent to the disclosure(s) as set forth above. I will not, nor shall anyone on my behalf seek legal, equitable or monetary damages or remedies for any such disclosures. I acknowledge that the use of my Medical Records is without compensation and that I will not, nor shall anyone on my behalf have any right of approval, claim of compensation, or seek or obtain legal, equitable or monetary damages or remedies arising out of any use such that comply with the terms of this Consent to Treatment. I have read, understand and agree to the terms set forth in this Consent to Treatment as indicated by my signature below.

Patient Name

Guardian or Responsible Party Name (if applicable)

Patient or Guardian Signature

Date

Witness Name

Witness Signature

Date

Dentist Name

Dentist Signature

Date