

# Consent & History Form



## HOW DOES THE SMILEDIRECTCLUB ALIGNER SYSTEM WORK?

SmileDirectClub's aligner system is a series of invisible, BPA- free plastic aligners which apply subtle pressure to gradually shift your teeth. The invisible aligners are made to be worn in a specific sequence. Each new aligner will gradually shift teeth. While every case is unique to each patient, the process typically takes approximately 4 to 8 months to complete. During treatment an optional teeth whitening system may be used. You should be aware of the benefits, inconveniences and risks related to using aligners and teeth whitening products. Feel free to contact the SmileDirectClub patient care team to discuss any concerns you may have.

### ALIGNER BENEFITS

**DISCREET** – The aligners are made of clear, BPA- free plastic. The trays are thin, light weight and nearly invisible when worn; many people won't know you're wearing them.

**HYGIENE** – Aligners allow you to eat, brush and floss normally, and the process of using aligners may improve your oral hygiene habits.

### WHITENING BENEFITS

**WHITE TEETH** – The whitening system may lighten the color of your teeth by removing stains.

### ALIGNER RISKS

**DISCOMFORT** – Your mouth is sensitive so you can expect an adjustment period and some minor discomfort from moving your teeth. You may also experience gum, cheek or lip irritation when you initially use an aligner while these tissues adjust to contact with the aligner trays.

**ALLERGIC REACTION** – It is possible for some patients to become allergic to the materials used to create your aligners. If you experience a reaction, please discontinue use and inform us and your primary care provider immediately.

**TEMPORARY SIDE EFFECTS** – You may experience temporary changes in your speech or salivary flow while using aligners because of the presence of the aligner tray in your mouth.

**CAVITIES, GUM OR PERIODONTAL DISEASE** – Cavities, tooth decay, periodontal disease, inflammation of the gums or permanent markings (e.g. decalcification) may occur or accelerate during use of aligners. These reactions are more likely to occur if you eat or drink lots of sugary foods or beverages, or do not brush and floss your teeth before inserting the aligners, or do not see a dentist for preventative check – ups at least every six months. In addition, in some circumstances discoloration or white spots may occur; small cavities may increase in size, causing sensitivity and in some cases pain or tooth breakage; gingival inflammation may increase causing soreness and or bleeding. If underlying periodontal conditions persists unchecked, they may become more prevalent leading to tooth loss. You may have to discontinue aligner treatment. All of these

### Complete and Return Immediately

*symptoms will require you to seek care from a dentist of your choice.*

**SHORTENING OR THE ROOTS/RESORPTION** – The roots of some patients' teeth become shorter (resorption) during use of aligners. It is not possible to predict which patients will experience it, but patients who have had braces in the past are at higher risk. Resorption can impact the long – term health of teeth. If resorption is detected by your family dentist during orthodontic treatment, treatment may need to be discontinued or eventual tooth loss could occur. If a primary (or "baby") tooth is present, any orthodontic movement would accelerate the resorption process leading to its loss.

**DAMAGE NERVES IN TEETH** – Tooth movement may accelerate nerve damage or nerve death resulting in a root canal, other dental treatment, or loss of the tooth. It is not possible to predict which patients may experience nerve damage, but patients who have experienced tooth injury or had restoration work on a tooth are at higher risk. If your family dentist detects nerve damage prior or during your aligner treatment, treatment may need to be discontinued or eventual tooth loss could occur.

**TEMPOROMANDIBULAR JOINT DYSFUNCTION (TMJ)** – Problems may occur in the jaw joints during aligner therapy causing pain, headaches or ear problems. The following factors can contribute to this outcome: past trauma or injury, arthritis, hereditary history, tooth grinding or clenching and some medical conditions.

**IMPACTED AND SUPERNUMERARY TEETH** – Teeth may become impacted or trapped below the bone or gums. Sometimes some patients are born with "extra" or supplementary teeth. If you have impacted, un – erupted or supplementary teeth, aligners are not an ideal option.

**SUPRAERUPTION** – If a tooth is not properly covered by an aligner, it may migrate outwards (supraeruption) leading to difficulty cleaning, gum disease, tooth decay and loss of tooth.

**PREVIOUS DENTAL TREATMENT** – Aligners will not move implants and may not be effective on some dental restorations, such as bridges. Additionally, dental restorations, such as crowns, veneers, or bridges, may require replacement due to tooth movement.

**ORAL PIERCINGS** – Piercings are contraindicated during aligner therapy and therefore should be removed during treatment. In some circumstances, failure to do so could result in fractures aligners or broken teeth leading to termination of aligner treatment.

**OTHER RISKS** – Orthodontic treatment and the movement of teeth bring inherit and potential risks and side effects. In the case of aligner therapy such risks include, but are not limited to, discomfort, swelling, sensitivity, numbness, sore jaw muscles, allergic reaction to dental materials, and unforeseen conditions that may be revealed during treatment which may necessitate extension of the original procedures or the recommendation of other patient – specific procedures. Additionally, the tissue attachment between the front teeth may become inflamed which is a common result of aligner therapy. The procedure required to treat this, known as a frenectomy, is not a part of my SmileDirectClub treatment, but is a

recommended adjunctive treatment for the best outcome and long-term stability of my smile.

**SAFETY** – Aligners may break, be swallowed or inhaled. You may also have an allergic reaction to the materials used in the aligners.

**GENERAL HEALTH PROBLEMS** – Overall medical conditions such as bone, blood or hormonal disorders, and many prescription and non – prescription drugs (including bisphosphonates) can affect the movement of the teeth and the outcome.

**DURATION AND RESULT** – The length of time you wear the aligners and the results depend on many factors, including, but not limited to: the severity of your case, the shape of your teeth, or the amount of time you wear the aligners per day. The average person generally wears the aligners for 4 – 8 months, but your particular rate of tooth movement is impossible to predict and could take longer. If the duration is extended beyond the original estimate, additional fees may be assessed. Difficult cases may require IPR and/or extractions with traditional braces for ideal results.

**RETAINERS** – Teeth may move again after you stop wearing the aligners. Retainers will be required to keep your teeth in their new positions for a lifetime. Your retainer should be worn full – time for 2 weeks and then nightly from then on. You can expect a retainer to last about one year, but this can vary greatly from patient to patient.

**BITE ADJUSTMENT** – Your bite may change during treatment and may result in temporary discomfort. Your bite may require adjustment after use of the aligners.

**AGREEMENT TO ARBITRATE** – I hereby agree that any dispute regarding the products and services offered my SmileDirectClub and/or affiliated dental professionals, including but not limited to medical malpractice disputes, will be determined by submission to arbitration and not my lawsuit filed in any court, except claims within the jurisdiction of Small Claims Court, I understand that to initiate the arbitration, I must send a Demand for Arbitration via U.S. Mail, postage prepaid to Alex Fenkell, SmileDirectClub, LLC, Bank of America Plaza, 414 Union Str., 8th Floor, Nashville, TN 37219, Nashville, Tennessee 37203. The Demand for Arbitration must be in writing to all parties, identify each defendant, describe the claim against each party, and the amount of damages sought, and the names of the Patient and his/her attorney. I agree that the arbitration shall be conducted by a single, neutral arbitrator selected by the parties and shall be resolved using the rules of the American Arbitration Association.

**BLACK TRIANGLES** – Teeth which have been overlapped for long periods of time may be missing the gum tissue and when these teeth are aligned, a “black triangle” appears below the inter-proximal contact.

#### **WHITENING RISKS**

**TYPE OF DISCOLORATION** – The whitening system will not lighten all teeth or restorations in teeth. Blue, gray, multi – colored, or striped discoloration may not respond to whitening. If you have gum recession or periodontal disease, the area of the tooth near the gum line may not respond to the whitening. Similarly, fillings, cavities or other damage will not lighten. Use of cigarettes, wine, coffee, tea, and similar stain producing agents will also slow whitening process.

**WHITE/TOOTH COLORED FILLINGS** – White or tooth colored fillings will not lighten or may become softer after using the whitening system. These fillings may need to be replaced after whitening to match lighter teeth or if they become soft.

**SENSITIVITY AND IRRITATION** – Gum irritation may arise from excessive

use of whitening system, as throat irritation if whitening agent is swallowed. Tooth sensitivity may occur during initial use. In addition, discomfort and possible permanent nerve damage can arise if whitening agent leaks into damaged or cracked teeth fillings.

**REVERSIBLE** – Whitened teeth can darken again over time. Reduction of certain types of foods and beverages will reduce staining of teeth.

#### **INFORMED CONSENT (FORM 1 OF 3)**

**TELEHEALTH** – I hereby consent to engaging in telehealth with SmileDirectClub, as part of my aligner treatment. I understand that “telehealth” includes the practice of health or dental care delivery, diagnosis, consultation, treatment, transfer of medical/dental information, both orally and visually, to an affiliated SmileDirectClub licensed dental professional within my state. I further consent to SmileDirectClub sharing my personal and medical information with third parties, business associates, or affiliates for the purposes of treatment planning and/or manufacturing purposes. I certify that I can read and understand English. I acknowledge that SmileDirectClub has not made any guarantees or assurances to me. I have read this form and fully understand the benefits and risks listed in this form related to my use of SmileDirectClub aligners and whitening system. I have had an opportunity to discuss and ask any questions to a SmileDirectClub provider about the use of SmileDirectClub aligners. I understand that SmileDirectClub cannot guarantee any specific results or outcomes. I further understand that my SmileDirectClub invisible aligner treatment will only address the alignment of my teeth and will not correct my existing bite condition. In order to correct the current condition of my bite, I will need to seek more comprehensive treatment via local dental professional. Because I am choosing not to engage the in – patient services of a local dental professional, I understand and accept that my bite or occlusion will be improved and that my teeth will be straighter than they currently are but will still be compromised. I hereby grant SmileDirectClub the right to use photographs taken of my dental treatment and my first name for educational and/or marketing purposes. I acknowledge that since my participation is voluntary, I will receive no financial compensation and agree that my participation is voluntary, I will receive no financial compensation and agree that my participation confers upon me no right of ownership. I release SmileDirectClub from liability for any claims by me or any third party in connection with my participation or use of the invisible aligner treatment. In the event that SmileDirectClub (“SDC”) determines that I am not an appropriate candidate for SDC treatment, but that I am a candidate for more – advanced clear aligner treatment, I hereby consent to having all of my records in SDC’s possession (including without limitation dental impressions, digital scans, photographs, and medical history documentation) sent to Align Technology, Inc. for further review and treatment planning, including, but not limited to, contacting me to refer my case to an Invisalign – certified provider of my choosing or to market and sell me Invisalign products or services.

Signature of Patient  
(Or Parent/Guardian If Minor)

Printed Name of Patient

Date:

# Patient Dental & Medical History

## WHY DO I NEED TO SHARE MY MEDICAL HISTORY AND DENTAL HISTORY WITH SMILEDIRECTCLUB?

Many diseases, medications and medical and dental conditions can have an effect not only on your overall healthy but also on how your teeth will respond to aligner therapy and tooth whitening. A SmileDirectClub dental professional has all four years of doctoral and post-doctoral graduate education and is trained to utilize the information you provide in your health history to ensure you are a viable candidate for SmileDirectClub and that your teeth and body are currently in optimal health to maintain your aligner therapy and whitening. Please keep our team updated if you have any changes to your medical or dental history during your treatment. Your medical and dental history by law is confidential and will not be released to any other entity or doctor without your written request.

### DENTAL HISTORY

- |     |    |  |
|-----|----|--|
| YES | NO | Do you feel pain in any of your teeth  |
| YES | NO | Do you have any sores or lumps in or near your mouth   |
| YES | NO | Do you currently have any head, neck, or jaw injuries  |
| YES | NO | Do you currently experience: jaw clicking, pain, difficulty opening and/or closing or difficulty chewing |
| YES | NO | Have you noticed any loosening of your teeth   |
| YES | NO | Do you have untreated periodontal disease  |
| YES | NO | Do you have any know allergies to any dental materials   |

### MEDICAL HISTORY

- |     |    |  |
|-----|----|--|
| YES | NO | I am currently taking one of the following medications (oral biphosphonates); Fosamax, Actonel, Didronel, Boniva, Aredia, Zometa |
| YES | NO | I have current acute corticosteroid or immuno supressants  |
| YES | NO | I have had a bone marrow transplant or treatment of hemotol within the past 2 years  |

### AUTHORIZATION AND RELEASE (FORM 2 OF 3)

*I certify that I have read and understand the above information to the best of my knowledge. The above questions have been accurately answered. I understand that providing incorrect information can be dangerous to my health. I authorize the dentist to release any information including the diagnosis and the records of any treatment or examination rendered to me or my child during the period of such dental care to third party pay-ors and/or health practitioners. I authorize and request my insurance company to pay directly to the dentist or dental group insurance benefits otherwise payable to me. I understand that my dental insurance carrier may pay less than the actual bill for services. I agree to be responsible for payment of all services rendered on my behalf or my dependents.*

Signature of Patient  
(Or Parent/Guardian If Minor)

Date:

Printed Name of Patient

# Healthy Teeth & Gums Acknowledgement

SmileDirectClub aligners are most effective if your teeth and gums are healthy. It is your responsibility to see a dentist to verify that your teeth and gums healthy prior to using SmileDirectClub aligners. **Complete the form by providing your signature.**

- My dentist cleaned my teeth.
- My dentist took x-rays of my teeth.
- My dentist checked for and repaired cavities, loose or defective fillings, crowns or bridges.
- My dentist checked my x-rays and I have no shortened or resorbed roots.
- My dentist checked my x-rays I have no impacted teeth.
- My dentist has probed or measured my gum pockets and says I do not have periodontal or gum disease.
- My dentist preformed a full oral-cancer screening in the last 6 months and I do not have oral cancer.
- I have no pain in any of my teeth.
- I have no pain in my jaws.
- I have no loose teeth.
- I have no "baby teeth" and all of my permanent teeth are present.

*In the event that dental work is required after I purchase the SmileDirectClub aligners, I understand that my SmileDirectClub aligners may have to be remade and that I will have to pay a replacement fee.*

Signature of Patient  
(Or Parent/Guardian If Minor)

Date:

Printed Name of Patient