

## **PATIENT'S INFORMED CONSENT AND AGREEMENT REGARDING TREATMENT WITH THE NUBRACE® SYSTEM**

*The NuBrace® System is a revolutionary orthodontic treatment that can straighten your teeth while avoiding the compromised appearance associated with wearing conventional braces. Developed specifically for patients with fully erupted dentition who are no longer experiencing significant jaw growth, the NuBrace System is removable and virtually invisible.*

*The following **information**, with the exception of the "Device Description" and "Procedure" sections, is routinely supplied to anyone considering orthodontic treatment. Although orthodontic treatment can provide the benefits of healthy teeth and an attractive smile, you should also be aware that orthodontic treatment has limitations and potential risks that should be considered before undergoing treatment.*

### **DEVICE DESCRIPTION**

The NuBrace System, developed by Beverly Hills Dental Corp, consists of a series of clear polymer, removable appliances (aligners) that move your teeth in small increments from their original state to a more ideal treated state. Some patients may also require bonded aesthetic attachments (small, tooth-colored dental composites) and/or elastics on their teeth to facilitate specific dental movements. The NuBrace System combines your doctor's diagnosis and treatment plan with sophisticated computer graphics technology to develop your series of customized aligners. You typically wear the aligners in pairs, one on your upper dental arch and one on your lower dental arch. Each aligner fully covers your teeth and is virtually invisible when in place; You wear each pair of aligners as instructed by your doctor.

### **PROCEDURE**

You will undergo a routine orthodontic pre-treatment examination (including x-rays, photographs and study models). Your doctor will take impressions of your teeth and send them, along with a prescription, to the Beverly Hills Dental Corp laboratory. Beverly Hills Dental Corp technicians will follow your doctor's prescription to create a series of customized aligners. The Beverly Hills Dental Corp laboratory will then mail the series of aligners back to your doctor. The total number of aligners varies depending on the complexity of your orthodontic case. The aligners are individually numbered and will be dispensed to you by your doctor with specific instructions for use. You will wear your aligners for approximately 20 to 22 hours per day, removing them only to eat and to brush and floss. Each aligner will be designed to guide your teeth to a more ideal position. Approximately every two weeks, you will switch to the next aligner in the series. Treatment duration typically lasts 6 to 24 months. Over the course of treatment, your doctor will monitor your progress through a series of follow-up appointments.

### **BENEFITS**

- The NuBrace System offers you an attractive alternative to braces. The anticipated patient benefits of the NuBrace System are:
- Improved aesthetics. Aligners are nearly invisible when worn.
- Ease of use. Aligners require little maintenance and are generally discarded after two weeks of wear.
- Improved oral hygiene. Aligners allow for normal brushing and flossing — tasks that are impaired by conventional braces.
- Comfortable. Aligners have no metal wires or brackets to cause the intraoral abrasive discomfort associated with conventional braces.

### **RISKS AND INCONVENIENCES**

The use of the NuBrace System in your treatment may involve the kinds of complications or problems that can occur with conventional orthodontic treatment. Many of these problems and inconveniences can occur without orthodontic treatment, but the risk is greater to an individual wearing an orthodontic appliance. The risks associated with conventional or NuBrace System orthodontic treatment may include the following:

1. Dental tenderness experienced after switching to the next aligner in the series should be expected. The period of tenderness varies with each patient and the procedure performed. The gums, cheeks and lips may be scratched or irritated. Orthodontic appliances may be accidentally swallowed or aspirated. However, there is no greater risk with the aligners than with other appliances, such as dentures or orthodontic retainers.
2. Tooth decay, periodontal disease or permanent markings (e.g. decalcification) on teeth can occur if orthodontic patients eat foods with sugar and/or do not brush their teeth properly before placing aligners on teeth.
3. For optimal results, small tooth-colored attachments may be bonded to one or more teeth during the course of treatment. Your doctor will remove these attachments at the appropriate time, usually at the end of treatment.
4. In some instances, teeth may require slenderizing in order to create space to allow tooth movement to occur. Any risks associated with this procedure should be discussed with your doctor.
5. Poor cooperation in wearing the appliances the required number of hours per day as directed by your doctor, not using the aligners as indicated, lost or broken appliances, missed appointments and atypically shaped teeth can lengthen the treatment time and affect the quality of the end results or the ability to achieve the desired results.
6. Teeth may shift their position after treatment. Faithful wearing of retainers at the end of orthodontic treatment should reduce this tendency. Throughout life, the bite can change adversely from various causes, including growth changes, playing of musical instruments and other oral habits. All of these causes may be out of the control of the doctor. In rare instances, problems may also occur in your temporomandibular joint (jaw joint), causing joint pain, headaches and/or ear problems.
7. For many patients, orthodontic treatment temporarily affects their speech, and they may experience a lisp, although any speech impediment caused by aligners usually disappears within one or two weeks.
8. The health of the bone and gums which support the teeth may be affected by orthodontic treatment, particularly if a condition already exists and in some rare cases where a condition does not appear to exist. Inflammation of the gums and loss of supporting bone can occur if plaque is not removed with daily brushing and flossing.
9. Oral surgery (e.g. tooth extraction) may be necessary in conjunction with orthodontic treatment, especially to correct crowding or severe jaw imbalances. If such surgeries are necessary, risks associated with treatment and anesthesia should be discussed with the oral surgeon.

A tooth that has been previously traumatized or significantly restored may be aggravated by orthodontics. In rare instances this may require additional dental treatment such as endodontic and/or additional restorative work. There is also the possibility that existing dental restorations (e.g. crowns) may become dislodged and require re-cementation or in some instances, replacement. In addition, you may incur additional fees if you undergo significant dental work or trauma during the course of treatment that results in creation of new aligners.

10. In some patients, the length of the roots of the teeth may be shortened during orthodontic treatment. Usually this does not have significant consequences, but on occasion it may become a threat to the longevity of the teeth. Some patients are more prone to this happening than others.
11. General medical conditions can affect orthodontic treatment. You should advise your treating doctor of any medical conditions you may have.

**NO ASSURANCE / GUARANTEES**

No assurance or guarantees can has or will be made to you regarding the outcome of the treatment. Orthodontics is not an exact science, and therefore neither Beverly Hills Dental Corp nor any doctor can guarantee any specific outcome. Once treatment has been initiated, there are no refunds. ( ).

**ALTERNATIVE TREATMENTS**

For most patients, orthodontic treatment is an elective procedure. Alternatives to the NuBrace System might include conventional orthodontics with braces or prosthetic solutions (bonding, veneers, and crowns). Alternative is no treatment at all. You could choose to live without orthodontic correction or improvement. The specific alternative to the orthodontic treatment of any particular patient depends on the nature of the patient's teeth and supporting structures.

**CONSENT**

I have been given time to read and have read the preceding information describing the NuBrace® System. I understand the benefits and the risks and inconveniences associated with the use of the NuBrace System as outlined in the previous pages. I acknowledge that no assurances or guarantees have been made to me by Beverly Hills Dental Corp or any other person or company concerning any specific outcome of my treatment. I have been sufficiently informed about the NuBrace System and have had the opportunity to ask questions and discuss concerns. I have discussed use of the NuBrace System with Dr. Tom Kalili, from whom I intend to receive treatment. With my signature below, I consent to treatment using the NuBrace System in conjunction with Dr. Tom Kalili or another doctor certified to use the NuBrace System by Beverly Hills Dental Corp , in accordance with the foregoing information and the conditions set forth below.

I further consent to the making of orthodontic records, including x-rays, photographs, prescriptions and other information which may include personal identification information before, during and after treatment, and to the above doctor providing orthodontic treatment prescribed by him/her. I also consent to my doctor and/or Beverly Hills Dental Corp forwarding any of my orthodontic records to other licensed dentists and organizations employing licensed dentists for the purpose of consulting regarding my treatment.

Finally, I consent to the use of my orthodontic records (e.g. dental x-rays, photographs, and plaster models) for purposes of orthodontic consultations, educational and research purposes, publication in professional journals, or use in professional collateral materials, but not to the use or disclosure of my specific name, address, full face photograph, or other personal identification information which would have the effect of specifically identifying me as an individual.

\_\_\_\_\_/ \_\_\_\_\_  
Patient Name                  Patient or Guardian Signature                  Date

\_\_\_\_\_/ \_\_\_\_\_  
Witness Name                  Witness Signature                  Date

## **Informed Consent for NuBrace Orthodontic Treatment**

As in the case with all treatments of the body, much of its success depends on the understanding and cooperation of the patient. While recognizing the benefits of a pleasing smile and healthy functional teeth, you should also be aware that orthodontic treatment, like any other treatment of the body, has some limitations, inconveniences and potential hazards. However, these are seldom enough reason to avoid treatment and the benefits generally outweigh any potential complications, but all risks should be considered before making the decision to wear NuBrace aligners. The following information is routinely provided to all patients considering orthodontic treatment with NuBrace. Please read this information carefully and ask your orthodontic provider to explain anything you do not understand. Be sure you understand and clarify what is expected of you as a patient, or as the parent of a young patient to achieve the desired results with NuBrace.

The goal of NuBrace treatment is always to improve the bite function and/or esthetics of your smile. Dr. Tom Kalili will use his knowledge, training and skill, and experience to achieve the desired results discussed with you at your examination. No guarantee has or will be given to the success of treatment and the final results may relapse if proper retainer wear is not followed as directed by your orthodontic provider after active aligner wear is complete. Treatment results can be compromised by each individual patient's growth patterns, genetics, oral health, and cooperation with NuBrace aligner wear. Orthodontics is not an exact science, and therefore neither NuBrace nor any orthodontic provider can guarantee any specific outcome. It is imperative that the patient, or the parent of a young patient, understand the following potential risks to treatment:

- Dental Decay, Decalcification (permanent markings on the teeth), or Gum Disease does not occur as a result of Orthodontic treatment: NuBrace aligners do not cause tooth decay, gum disease or decalcification. However, patients who do not maintain good oral hygiene habits and visit their dentist for regular dental exams and cleanings may experience these dental problems during treatment or otherwise. None of these dental issues are increased during aligner wear; as a matter of fact, NuBrace aligners are removable so that teeth may be brushed and flossed normally during treatment to help maintain a normal dental health environment during treatment.
- Cold sores, canker sores, oral irritations and/or injury to the mouth are possible during treatment but are rarely a symptom of aligner wear. If an aligner wear causes oral irritations, your orthodontic provider will prescribe therapy/medications to resolve these minor irritations.
- Root resorption (shortening) can occur during any type of orthodontic treatment, including NuBrace therapy. Under healthy circumstances, the shortened roots are of no disadvantage. In rare cases, root resorption can result in loss of teeth. There is no way to foresee if this will occur during your treatment and nothing can be done to prevent it.
- Tooth sensitivity or minor mobility are possible during treatment and could result in unexpected tooth loss.
- Jaw and Joint problems: Occasionally problems may occur in the jaw joints (TMJ) causing joint pain or discomfort, headaches or ear problems. These problems can occur without orthodontic treatment. Any of the above-mentioned problems should be reported to your orthodontic provider promptly.
- Tooth extraction: May be recommended for proper alignment during orthodontic treatment to improve treatment.
- Dental restorations: Fillings, crowns, root canals, or bridges, etc. can be completed during NuBrace treatment. However, please be sure and consult with your orthodontic provider before completing any needed treatments to insure proper NuBrace aligner fit after treatments are completed.
- Allergic reactions to NuBrace aligner materials or dental materials: It is uncommon that allergic reactions are experienced to these materials. However, if the patient suspects an allergic reaction please report it to your orthodontic provider immediately for advice.
- Aligner fit/wear: Aligners will fit very snugly. This is essential for proper tooth movement. Initially, patients will have a period of time necessary to adapt to speaking and wearing the aligners. Like any "new" appliance in the mouth, patients general!) Adapt quickly and it is rare that speech or normal function is impaired for an extended period of time.
- Aligner removal: Difficulty removing the aligners may occur if the patient has multiple buttons in place during treatment, and/or excessive crowding, and/or some particular bite patterns. Special instructions will be given to assist the patient with removal. If for any reason the patient finds removing aligners excessively difficult for an extended period of time, they should immediately inform their care provider for further instruction.
- Once treatment has been initiated, there are no refunds. ( )

Before beginning and in some cases during NuBrace treatment it will be necessary to take impressions, orthodontic x-rays, and photographs for diagnosis, professional review and education, and case submission to NuBrace for manufacturing of your custom aligner fabrication. NuBrace aligner treatment can only be successful if aligners are worn as recommended by your orthodontic provider and should not be worn longer than 20 hours at one time. If you notice that your bite is changing or uneven, decrease the use to less than 20 hours of daily wear and inform your dentist. All parties must be willing and able to cooperate with aligner wear as instructed. Otherwise, NuBrace results can be unsatisfactory and/or treatment time can be increased or compromised. In some instances, patients being treated with NuBrace appliances may require conventional braces or other conventional treatments to complete the treatment and associated risks and fees should be discussed prior to giving consent. Please be aware that this consent is to ensure that you fully understand all the risks and limitations of NuBrace. I have read and understand this letter or information and with this knowledge, consent to NuBrace treatment for:

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Patient Name                      Patient or Guardian Signature                      Date

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Witness Name                      Witness Signature                      Date