

Informed Consent Document



Informed Consent and Agreement for the AcceleDent Patient

Notice to treating office: This form is to be signed by your AcceleDent patients prior to treatment and kept for your records. It should not be sent to OrthoAccel Technologies, Inc.

Patient's Informed Consent and Agreement Regarding AcceleDent Orthodontic Treatment

Your doctor has recommended the AcceleDent System as an accessory to your orthodontic treatment. Although orthodontic treatment can lead to healthy teeth and provide important benefits, such as an attractive smile, you should also be aware that orthodontic treatment (including orthodontic treatment enhanced with AcceleDent) has limitations and potential risks that you should consider before undergoing treatment.

Device Description

AcceleDent, developed by OrthoAccel Technologies, Inc. ("OrthoAccel"), consists of a Mouthpiece and Activator assembly that provides a light vibration to the teeth, as well as a Travel Shell (for ease of carrying the Mouthpiece and Activator) and Charging Port (for charging the Activator's battery). AcceleDent products combine your doctor's diagnosis and prescription for orthodontic treatment with a sophisticated device to help accelerate your treatment. The device is used on a daily basis after your orthodontic care is started by your orthodontist.

Procedure

You will undergo a routine orthodontic pre-treatment examination including x-rays and photographs. Your doctor will take impressions of your teeth and then decide on your treatment plan. Once your treatment plan has been decided by your doctor your orthodontic care will begin and the OrthoAccel AcceleDent System will be provided to you by your orthodontist.

The total number of orthodontic visits will vary depending on the schedule determined by your orthodontist. Unless otherwise instructed by your doctor, you should use your AcceleDent once daily for the full 20 minutes. Treatment may vary depending on your orthodontist's prescription.

Your orthodontist will provide you with a schedule for follow-up visits and treatments. Some patients may require additional treatments during standard orthodontic care in order to facilitate specific dental movements. Patients may require additional refinement later in treatment.

Benefits

- AcceleDent offers an enhancement to conventional braces that accelerates your orthodontic treatment.
- AcceleDent does not affect normal brushing and flossing tasks.
- AcceleDent can be added to whatever standard orthodontic treatment your orthodontist prescribes – it does not have to be used with any particular treatment.
- The use of AcceleDent may improve oral hygiene habits during treatment, since it is used daily and can therefore serve as a reminder for oral hygiene habits.
- The use of AcceleDent may reduce discomfort associated with orthodontic care.

Risks and Inconveniences

Like other orthodontic treatments, the use of AcceleDent may involve some of the risks outlined below:

- i. Failure to use the device as prescribed (typically once per day for 20 minutes) and directed by your orthodontist may not reduce the treatment time to achieve the desired results;
- ii. Overuse of the device (using for more than 20 minutes per day) has not been evaluated and therefore may not be safe;
- iii. Although not reported during the studies, AcceleDent could theoretically cause slight discomfort of the teeth or a headache;
- iv. Although not reported during studies, AcceleDent could theoretically damage your orthodontics, especially if used incorrectly;
- v. You will not be able to talk, sleep, or eat for the 20 minutes that the AcceleDent is in use;
- vi. As with any orthodontic treatment, a tooth that has been previously traumatized, or significantly restored, may be aggravated. In rare instances the useful life of the tooth may be reduced, the tooth may require additional dental treatment such as endodontic and/or additional restorative work and the tooth may be lost;
- vii. Although not reported during the studies, existing dental restorations (e.g. crowns) may become dislodged and require re-cementation or in some instances, replacement;
- viii. Although study data indicate AcceleDent does not affect the length of the roots of teeth, the length of the roots of the teeth may be shortened during standard orthodontic treatment and may become a threat to the useful life of teeth;
- ix. General medical conditions and use of medications can affect orthodontic treatment;
- x. Care should be taken with the AcceleDent - product breakage can occur if not properly handled;
- xi. Although not reported with AcceleDent, allergic reactions may occur with any product – talk to your orthodontist if you have allergy concerns.

Informed Consent

I have been given adequate time to read and have read the preceding information describing orthodontic treatment and use of the AcceleDent accessory device. I understand the benefits, risks, and inconveniences associated with treatment. I have been sufficiently informed and have had the opportunity to ask questions and discuss concerns about orthodontic treatment with the AcceleDent System with my doctor from whom I intend to receive treatment. I understand that I should only use AcceleDent after consultation and prescription from an orthodontist and I hereby consent to orthodontic treatment with AcceleDent products that have been prescribed by my doctor. Due to the fact that orthodontics is not an exact clinical science, I acknowledge that my doctor and OrthoAccel Technologies, Inc. ("OrthoAccel") have not and cannot make any guarantees or assurances concerning the outcome of my treatment. I understand that OrthoAccel is not a provider of medical, dental, or health care services and does not and cannot practice medicine, dentistry, or give medical advice. No assurances or guarantees of any kind have been made to me by my doctor or OrthoAccel, its representatives, successors, assigns, and agents concerning any specific outcome of my treatment.

I authorize my doctor to release my medical records, including, but not limited to, radiographs (x-rays), reports, charts, medical history, photographs, findings, plaster models or impressions of teeth, prescriptions, diagnosis, medical testing, test results, billing, and other treatment records in my doctor's possession ("Medical Records") (i) to other licensed dentists or orthodontists and organizations employing licensed dentists and orthodontists and to OrthoAccel, its representatives, employees, successors, assigns, and agents for the purposes of investigating and reviewing my medical history and also possibly for inclusion in an orthodontic journal (for publication purposes and distribution of information) or inclusion in other such marketing materials.

I understand that 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 such disclosure. I acknowledge that 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. A photostatic copy of this Consent shall be considered as effective and valid as an original. I have read, understand, and agree to the terms set forth in this Consent as indicated by my signature below.

Signature

Print Name

Address

City/State/Postal Code/ Country

Date

Witness

Print Name

Signature of Parent/Guardian

If signatory is under 21, the parent or Legal Guardian must also sign to signify agreement.

Use of my Personal Data

By signing this form, I release Dr. _____ from his/her obligation to treat medical records confidentially for the purpose of the treatment. The above named orthodontist may (for the purpose of the treatment) forward my pertinent medical and dental data (in particular dental x-rays, impressions, intra- and extra-oral photos and bite registration) and the treatment plan, which includes my personal data, to OrthoAccel Technologies, Inc., 8275 El Rio Street, Suite 100, Houston, Texas, 77054 (USA). (www.orthoaccel.com, www.acceledent.com, www.acceledent.co.uk).

OrthoAccel Technologies, Inc. undertakes to protect the data in compliance with the mandatory regulations for medical data and only to use the data for the treatment and related purposes. The data may only be disclosed to third parties in the course of the treatment if that third party is obliged to treat medical records confidentially like a medical doctor or if I have explicitly consented to such disclosure.

I am aware that OrthoAccel Technologies, Inc. has its place of business in the United States ("US") and is therefore not subject to the data protection regulations of other countries and therefore, different regulations apply with regard to the protection of personal data compared to other countries.

OrthoAccel Technologies, Inc. and its employees are, however, subject to the same obligations of secrecy that doctors in the US have to comply with.

I finally consent to the use of my orthodontic records for purposes of orthodontic consultations, educational, marketing and research purposes, and publication in professional journals. This consent is valid only, however, if neither my name, nor my address, are disclosed which would identify me as an individual.

I have consented voluntarily and can revoke my consent by notice to the above named companies and the above named doctor at any time - partially or completely - with effect for the future. If this right of revocation is exercised, however, the continuation or the beginning of the treatment may become impossible.

Patient Signature

Date

Print Name