

Ortho Guide

Canada



AcceleDent[™]

THE **FAST** TRACK
TO STRAIGHT TEETH



Intended Use/Indications for Use

AcceleDent is an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps facilitate anterior tooth movement, its affect on overall treatment time has not been established. This is due to the many individual factors that may impact orthodontic treatment. You are encouraged to speak with your orthodontist to determine the impact this device may have on your specific treatment plan.

Contraindications for Use

- Use of osteoporosis drugs
- Poor oral hygiene
- Periodontal disease that is not under full control for at least 3-4 months prior to the start of treatment

Precautions

Consult your orthodontist prior to use of this product if you have had any recent craniofacial surgery (above the neck).

Contact your orthodontist if any bleeding, discomfort, or pain occurs after the initial use of AcceleDent.

AcceleDent meets the required electrical safety and emissions standards, however the appliance has not been tested for effects on any other specific medical devices (such as pacemakers, cochlear implants, nerve stimulators). Please contact the other device manufacturers with any questions or concerns about effects on their devices.

AcceleDent has been tested and is in compliance with safety standards for electromechanical devices.

OrthoAccel® is a registered trademark of OrthoAccel Technologies, Inc.®

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AcceleDent is covered by one or more of the following US patents: 6648639, 6832912, 7029276, and others pending.



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Warnings

To reduce the risk of burns, electrocution, fire, or injury:

Discontinue use if this product appears damaged in any way (Activator, Mouthpiece, or Charging Port). This product contains no serviceable parts. Refer to the section in the *Directions for Use* manual titled "Customer Service" if your AcceleDent or any of its components no longer works properly or needs repair.

Never use the Charging Port if it has a damaged cord or plug. Keep away from heated surfaces. Do not use the Charging Port outdoors.

Avoid using a Mouthpiece that is damaged, particularly if it is crushed or bent. Torn edges may break off while in use. Inappropriate cleaning may also cause damage to the Mouthpiece (see "Care" section in the *Directions for Use* manual).

This appliance is not intended for use by persons (including children) with reduced physical, sensory, or mental capabilities unless they have been given supervision or instruction concerning use by a person responsible for their safety, or unless otherwise indicated by an orthodontist.

Do not use the appliance while performing tasks that require full attention, such as driving or operating heavy machinery.

Do not play with the appliance or use it for any purpose aside from its intended use as described in the *Directions for Use* manual.

AcceleDent is a treatment-specific appliance and none of its components or accessories, alone or in combination, is intended for use by more than a single patient in any setting.

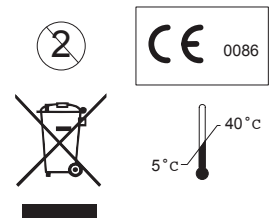
Do not use components, accessories, or attachments other than those recommended by the manufacturer.

Never incinerate the Activator, as its battery may explode.

DO NOT clean any component or accessory of AcceleDent in the dishwasher.

Rx only

For orthodontic applications



Congratulations on making the decision to implement AcceleDent™ as a part of your patients' care. OrthoAccel Technologies, Inc. is committed to improving orthodontic treatment through the development and commercialization of innovative science and technologies.

AcceleDent Overview

AcceleDent should be used by patients for twenty minutes per day. The Activator and Mouthpiece assembly is light (2.5 oz or 71 g), comfortable, hands-free, and can be used while multi-tasking or while engaged in a variety of other daily activities. Patients have reported use while reading, watching television, listening to music and doing school work. Refer to the *Directions for Use* manual for additional information on the operation of AcceleDent.

Components

1 Activator - Small extraoral component that generates the vibrational force of approximately .25N (25 g) at 30 Hz

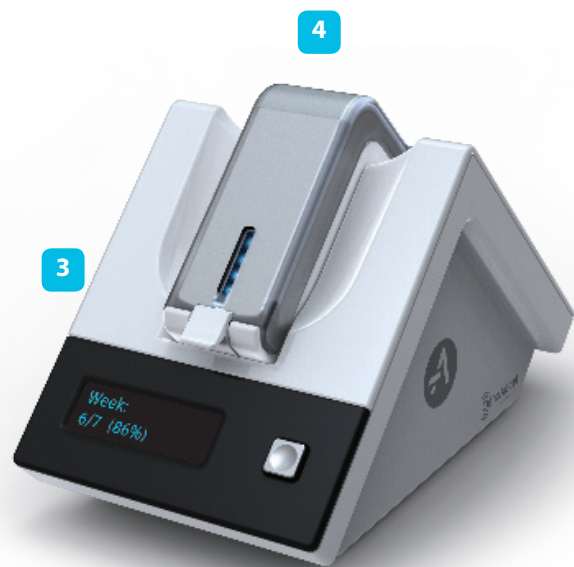
2 Mouthpiece - connects to Activator; patient occludes on the Mouthpiece to transfer vibrational force from the Activator to the dentition

3 Charging Port - for recharging the appliance and providing usage compliance information via the SmartDisplay LCD Screen

4 Travel Shell - allows the appliance to be easily and safely carried while "on the go"

Packaging

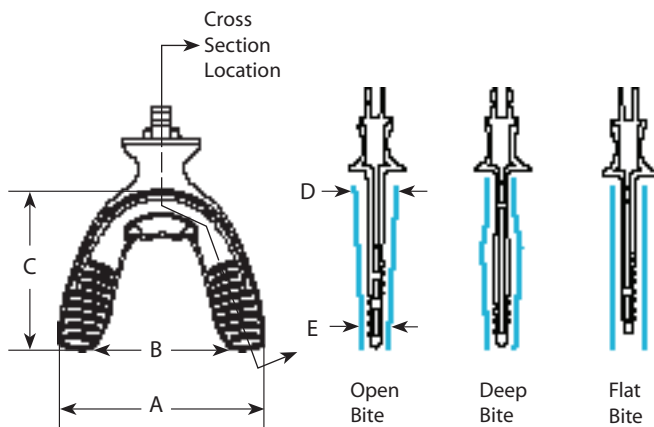
The Activator, Travel Shell, and Charging Port are packaged together in the AcceleDent Base Set. The Mouthpiece is packaged separately and, at the office, is added into the Base Set once the optimal size and profile have been determined for the patient by the orthodontist. Additionally, each Base Set comes with a complete Directions for Use booklet for easy reference plus a Quick Reference Guide for convenient initial use.



Overview of Mouthpieces

AcceleDent Mouthpieces are available in two sizes (small and large) based primarily on the anatomical dimensions of the patient's dental arches. Each size is available in three profiles based primarily on the type of malocclusion (anterior open bite, anterior deep bite and normal flat plane occlusion).

The sizes and profiles have been developed based on a statistical analysis of a sample population and are intended to allow for a maximum contact of teeth with the Mouthpiece in a high percentage of patients and case types.



	Small			Large		
	Open Bite	Deep Bite	Flat Bite	Open Bite	Deep Bite	Flat Bite
A	62.6	62.6	62.7	69.9	69.9	70.0
B	31.9	31.9	31.8	37.8	37.8v	37.8
C	52.1	52.4	52.1	51.9	51.9	51.5
D	5.3	3.5	4.4	5.3	3.5	4.3
E	3.1	3.1	3.1	3.1	3.1	3.0

All Dimensions in mm

Fitting Your Patients with the Mouthpiece

A sterilization tray with Trial Mouthpieces is provided in the AcceleDent System Starter Kit.

Select the size of Trial Mouthpiece that best fits the patient's upper arch in terms of width and anterior-posterior dimension. Optimize occlusal contact by evaluating the three profile options for the selected size.

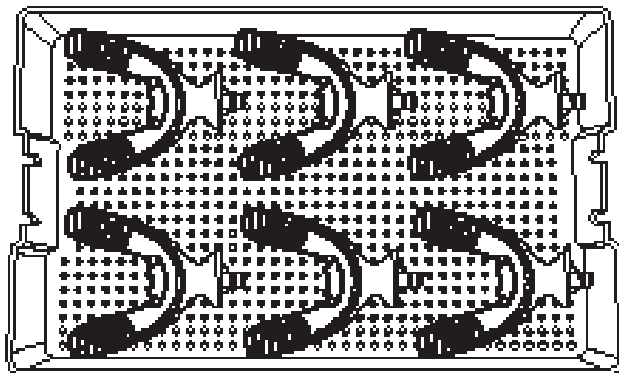
The Trial Mouthpiece must be sterilized prior to use as follows:

- Steam Sterilization with pre-vacuum: 3 - 4 minutes at 270°F (132°C) and 28-30 psi (193 - 207 kpa), double wrapped, 30 minute dry time
- Steam Sterilization with gravity displacement: 15 minutes at 270°F (132°C) and 15 -17 psi (104 - 117 kpa), double wrapped, 30 minute dry time

The sterilization instructions have been validated to a Sterility Assurance Level (SAL) of 10^{-6} in accordance with USFDA (21 CFR Part 58) Regulations and ISO 17664 and ISO 17665-1 using the biologics indicator overkill method.

In general, the Mouthpiece selected should be the smallest size possible for patient comfort without impinging on the cheeks and tongue.

During the course of orthodontic care the patient may require additional Mouthpieces due to wear, change in overbite, or continued growth. Therefore, the fit of the Mouthpiece should be reevaluated at adjustment visits, particularly if the patient complains of poor fit or discomfort.

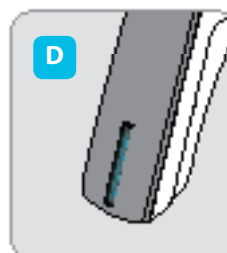
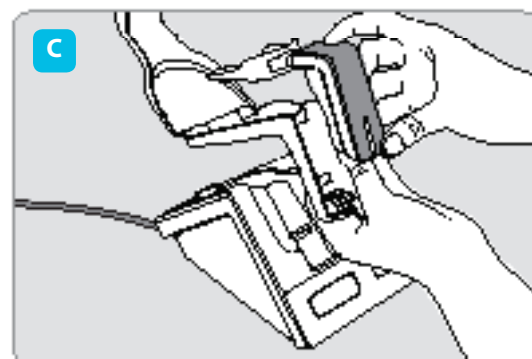
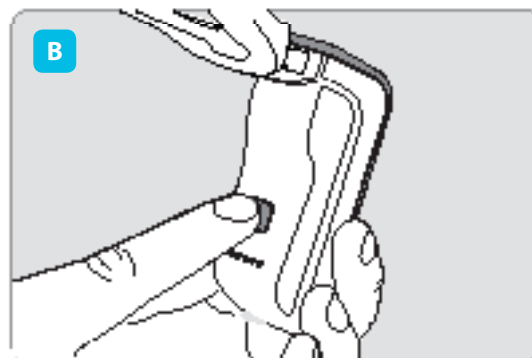


First Use

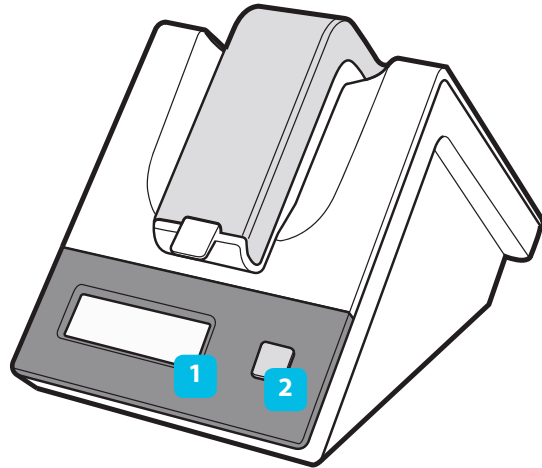
It is highly recommended that the patient quickly tests the appliance in the “on” position while in the office. For size selection purposes the sensation of the vibratory force may allow patients to better report the feeling of fit and comfort.

Ask the patient to attach the selected Mouthpiece to the Activator (A). It is advised to either observe the patient attaching these components or to demonstrate the process to ensure correct usage. Turn the Activator on by pressing and holding the power button until it begins gentle pulsing and place the Mouthpiece inside the mouth (B). Biting down lightly, with just enough force to hold the appliance in place, is ideal. It is not necessary to bite with excessive pressure. The appliance does not need to be held by hand once placed inside the mouth and held by biting, although the hands can be used to adjust its position throughout the session as needed. Educate the patient that relaxing the jaw and facial muscles, while maintaining enough force to stabilize the Mouthpiece, will improve comfort. Once the patient has experienced the appliance in use for a short period of time (approximately one minute) it should be turned off by depressing the power button so that an evaluation for fit and comfort of the Mouthpiece can be made. Although some people experience drooling due to the mouthpiece, people typically accommodate and have less drooling over time.

At home, and prior to the first use, the patient should charge the system overnight by plugging the Charging Port into an electrical outlet, placing the Activator into the Travel Shell and docking on the Charging Port (C). To properly dock the Travel Shell, first engage the Mouthpiece end into the Charging Port followed by a gentle push until the handle clicks into place. The Activator is properly docked to the Charging Port if the LED lights on the Activator cycle from dark to light and the SmartDisplay LCD viewing screen on the Charging Port can be advanced to the various information windows. To check the Battery Gauge, quickly push and release the power button. The battery is fully charged when all four lights are visible on the Battery Gauge (D) and will allow three to five complete treatments. The battery life is approximately 2.5 years. To maximize the time between charges the Activator should be recharged every three to five days or when no lights are visible on the Battery Gauge. Encourage your patients to review the Directions for Use, which can be found in the Base Set.



SmartDisplay Data Overview



The Charging Port has the capability to “read” data stored within the Activator and provide both the patient and office staff with information about compliance and appliance usage patterns. Therefore, the patient should be instructed to bring his or her Activator to each follow-up visit. It is not necessary to attach the Mouthpiece in order to dock the Activator, but the Activator must be enclosed within the Travel Shell to properly dock. Any Activator, Travel Shell, and Charging Port are interchangeable with one another. All information is shown on the SmartDisplay LCD Screen (1) on the Charging Port. The SmartDisplay Screen is located on the lower left side of the Docking Station. The Display Button is located to the right of the viewing screen (2).

There are five separate information windows available on the SmartDisplay screen allowing you to scroll through each screen by depressing the Display Button. Once the Display Button is depressed and released the viewing screen toggles to the next information window.

Visit
www.accedent.com

The first information window, the “Welcome Screen”, is displayed when the Charging Port is turned “ON”. You will see “Visit www.accedent.com”.

Week:
6/7 (86%)

The second window is the “Last Week” data area. This area indicates the number of days that AcceleDent was used during the last 7 days.

Month:
25/30 (83%)

The third window is the “Last Month” data area. This area indicates the number of days that AcceleDent was used during the last 30 days.

Total:
145 uses

The fourth window is the “Total” data area. This area indicates the total number of uses for the AcceleDent.

The fifth window shows the software version.
















Note: A standard treatment session involves using AcceleDent for the full twenty minutes. Therefore, when counting daily use sessions, if the appliance is used for less than ten minutes no treatment usage is registered and counted. If AcceleDent is used for at least ten minutes but less than twenty minutes, a half treatment usage is registered, and if used for a full twenty minutes, a full treatment usage is registered. For example, if AcceleDent is used for a full twenty minutes for six of the last seven days, but is used for only five minutes on the final seventh day, six usage sessions are registered. If used for a full twenty minutes for six of the last seven days, but used for eleven minutes on the final seventh day, six and a half usage sessions are registered.

Customer Service Information

For assistance, contact the OrthoAccel Technologies, Inc Customer Service Center at +1 832.631.1660 (North America) or + 44 (0) 203.318.1915 (outside North America) or customerservice@accele-dent.com or on the internet at www.aceledent.com.

For further information including troubleshooting, frequently asked questions, cleaning, warnings and hazards, and warranty, please also refer to the Patient Directions for Use booklet included in the AcceleDent System Base Set packaging, or visit www.aceledent.com.

Symbols

	Do not reuse		Use by YYYY-MM-DD or YYYY-MM
	Batch code		Serial number
	Date of manufacture		Authorized representative in the European Community
	Caution, consult accompanying documents		Upper limit of temperature
	Manufacturer		Temperature limitation
	Lower limit of temperature		Negative control
	Consult instructions for use		Separated collection for electrical and electronic equipment
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician or dentist		

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